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Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Synthon BV

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Enter any general comments you may have:

We would like to know if this also applies to generic pharmaceutical companies? If yes, should we follow the originator (and where can these be found)? What if there is an MA, but we are not marketing the product. Should we still comply?

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- ( ) Other

Name of your organisation:

Italian Medicine Agency - AIFA

Indicate the key principle you would like to comment on (select all that apply):

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- [x] 2.1 Expanding access to information
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- [ ] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

General Comments
Additional risk minimisation measures should be included. In some cases, videos are part of additional risk minimisation measures (e.g. Obizur with an on-line video to further elaborate on the required calculation and administration of the drug for HCPs).

Healthcare Communication Letter and EMA press releases should also be considered.

Additional information approved by CHMP/NCAs (e.g. videos, etc) as well as Blue-Box information should also be considered.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

General Comments
With the ePI also the Reporting of suspected adverse reactions could be possible.
Provision of the latest information on a medicine's safety, benefits and its conditions of use, cross-reference to other medicinal products information (e.g. those taken in combination as per indication or with known interactions) and to diseases could also be possible.

Updated text should be highlighted respect to the previous versions.

An ePI updated in real time, with further navigation and search functions, audio contributions, images, videos, dosage calculation help and phone numbers to be contacted with a simple click in case of need, would be helpful for benefit of patient safety.

Following line 159, we propose to add the following text:
They can also select the medicines of their interest, having thus available all the information on the drugs, automatically updated. The update of new information should be reported to the user through a notification system and/or pop up.

Following row 169 we propose to add the following text:
The electronic PI could be extended with a menu of new options and additional features such as an advanced search function or a browsing feature which allows to visualize, without limitations of format or size, authorized videos (e.g. an explanatory tape on the method of administration of a medicinal product), audio formats of texts (useful in case of dyslexia, blind or visually impaired and, although rare cases, of illiteracy), links to the competent authorities's website in order to facilitate the reporting of suspected adverse reactions by an authomated upload of the reports in the Pharmacovigilance database.

Row 179 - 182, the following wording should be clarified:
"Correct ePI depends on the medicine batch: some parts of the ePI may be applicable to all batches and some only to specific batches (e.g. when excipients change). Therefore the need for the correct ePI to be supplied for the medicine batch should be taken into consideration."
AIFA comment:
It is not clear which are the cases where the ePI is batch-specific (i.e., only applies to specific batches). Referring to the example provided on excipients, actually, all batches with one MARKETING AUTHORISATION NUMBER, must have the same composition.

Following row 179, we propose to add the following text:
As indicated in the Key Principles, the ePI should be available even through an App, in order to be able to use the application without internet connection, and to consult the documentation previously downloaded by the same user.

Footnote 5:
The link to the EMA guidance should be to the single EMA document "Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products"

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Row 186: we propose to integrate the text in brackets (e.g. use of large font size,) with the following: " translation in different EU Braille codes".
Text should read:
(e.g. use of large font size, translation in different EU Braille codes)

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Row 217, add the text in inverted comas:
The paper PL "and outer labeling" should include a statement directing to the ePI as the most up-to-date version of the PL.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

Please take into consideration the following opinion given by the QRDWG regarding the cookies in video:

"There is no legal basis for the EMA to provide any opinion/recommendation on cookies & privacy as to the appropriateness of their presence, as this would be out of EMA institutional remit and potentially interfere with the compliance obligations of the company with national Internet legislation and/or data protection legislation. Given that the MAH is the sole responsible for maintaining and managing the website, they are, therefore, responsible also for the processing of personal data connected to the operation of such website in accordance with the applicable national data protection legislation.
However, the MAH should ensure that these elements of the website are consistent with what they committed to by signing the declaration form for the QR code and do not have any promotional aspect."

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Row 271 Figure 1:
As pointed out (row 271) the burden to convert final PI to ePI is on charge to MAH. In order to preserve a certain homogeneity in the file conversion, we deem more appropriate that it is up to the NCA to perform directly the transformation to ePI at the end of regulatory evaluation (otherwise in case of initial submission of ePI will it be included in the actual eCTD version or is it expected any evolution of the eCTD format?) instead of the MAH.

Row 295 “Submission of ePI”
Considering that the use of the ePI format is not mandatory, although strongly recommended, and that the Product Information proposed by the Applicant in the dossier submitted for an application for marketing authorization is in word format, the most appropriate approach should be that the competent authority could continue revising the texts in the word format, because the last one allows to revise the proposed PI in tracked changes, insert comments and compare texts. Only after the approval of the PI, the competent authority’s workflow should be able to automatically transform the texts into an ePI format and make them available directly on the competent authority’s website. In this way the electronic standard ePI would represent the last step of the authorization process through the workflow.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Rows 325-326: ePI could be helpful also for MAH requests for translation exemption under art. 63.1 and 63.3 of directive 2001/83/CE.

Statement (Row 328-330)
As pointed out in the text, ePI could support different languages. We propose to specify in the key principle that the burden to translate the final PI into different languages (accompanied by a declaration from the MAH confirming that the converted version is identical in content to the one approved) should be on charge to MAH.

Rationale (Row 331-340)
The usefulness of the proposed functionality is agreed. Translations of texts into the various languages of the European Community would ensure that all EU citizens have access to information on medicinal products marketed outside their country. The translations should be entered by the MAH into the system, only after the approval of the national PI by the competent Authority. In addition, in order to ensure a textual correspondence between PI issued in the different languages and the national PI approved by the competent authority, the MAH should provide a declaration in order to confirm that the translated version is identically in content to the one approved.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ Other

Name of your organisation:

European Forum for Primary Care

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
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- ☐ 2.2 Accessibility
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- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Enter any general comments you may have:

We endorse this document. It is excellent.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

European Patients' Forum

Indicate the key principle you would like to comment on (select all that apply):

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- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

EPF agrees with the definition.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

EPF supports the definition of a common EU electronic standard for ePI. As stated in the key principles (line 130-131), a common technical standard is necessary to avoid multiple different standards being developed and used in different parts of the EU.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

EPF supports the ePI initiative as part of a comprehensive strategy to ensure all patients across the EU have access to comprehensive, high-quality, up-to-date, understandable information on medicines. Information is a cornerstone of patient empowerment that enables health literacy, shared decision-making and effective self-management. (EMPATHIE, 2014) More and more people look for health information online, with medicines information a top search topic. According to the 2014 Eurobarometer, 6 in 10 Europeans look for health information online and whilst most people think they can distinguish high from low-quality information online, 17% think they cannot.
Statutory product information – particularly the package leaflet – is a key and sometimes only source of information available to patients on the medicines they take. It is particularly important to improve the availability of up-to-date information on any changes, whether regarding safety, benefit/risk, dosing or other factors that patients need to know and, possibly, act upon.
Information on medicines must be unbiased and available through an authoritative, public source, such as the EMA and the national competent authorities. We agree that the development of ePI by public authorities is an urgent task, as lack of action will simply result in industry and other, possibly unreliable, actors filling this need. Action led by EMA and national authorities should ensure that ePI will be developed with public health and patient safety as the primary goals, and is critical to ensure patients' and public trust.
Please also see below, under "other comments".

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Accessibility of ePI to everyone, including people with various impairments, is critical to ensure equity and inclusivity. EPF agrees that ePI offers different possibilities to address the needs of those who have, for example, visual impairments by using large fonts or audible formats. We agree on the principle of accessibility by design.
We stress, however, that in order to be accessible for people with limited or low health literacy, the easy understandability of the product information needs to be ensured, and this will require further work on content (see previous question). People from the target populations should be involved in testing the content and user interfaces, to ensure these are fit for purpose and truly accessible to all.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

EPF agrees with this principle. ePI should not be a substitute for the paper leaflet, but instead seen as an opportunity to expand the formats available. Paper information will remain necessary for people who do not have online access or have limited digital literacy.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

EPF agrees with this principle. ePI should only include the regulator-approved information. Furthermore, it should not include links to information provided by third parties, which could be promotional in nature, such as industry websites accessed through barcodes on medicines packaging.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

EPF agrees with the principle that ePI does not include personal data, and its processing must be in accordance with the EU data protection legislation.
We would add that any mobile applications developed for the use of patients to access ePI should ensure that personal data, e.g. on what information a given patient has accessed, or information the patient has submitted (e.g. reporting a possible side effect), will not be collected inappropriately or passed to third parties without consent. Any informed consent provisions must be explicit, clear, and understandable. Application by third parties of the EU data protection legislation must be monitored and enforced.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

EPF believes that the European-level medicines portal, maintained by the EMA, should be developed as an urgent priority. The EMA information portal is critical to pull together all existing resources and ensure unbiased, up-to-date medicines information is truly accessible to patients across the EU in a coherent way. National competent bodies should ensure their own medicines portals link to the EMA portal. The information portal should also be comprehensively linked, in an understandable way, with other relevant information resources, such as the EU clinical trials portal and the EU database on adverse reactions. The interfaces need to be designed with users' needs as priority, and with user involvement, to ensure they are user-friendly, understandable and intuitively easy to navigate.
We also call for a role for patients and patient organisations in the governance of ePI, to ensure that the actions and steps foreseen meet patients' needs and address any concerns.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

EPF agrees that some countries may be able to progress faster than others. However, to avoid too much divergence leading to a "multi-speed" implementation that is detrimental to the patients' right to information wherever in the EU they live, we believe sufficient resources should be allocated to the implementation of ePI by all countries. EU funding possibilities could be explored to support those countries that need it.
The roadmap mentioned on lines 302 and 311 should include the involvement of patients in implementation, describing concrete elements and specific activities where patients' involvement is needed. The Patient and Consumer Working Party should be a natural discussion partner in elaborating the roadmap and should have opportunity for meaningful input at development stage.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

EPF agrees that the ePI must support all official EU languages, plus Norwegian and Icelandic. This applies only to product information for centrally-authorised products. For national authorised products, we would highly recommend that Member States also make PI available in English in addition to the country's official languages, as well as linking to all other available language versions. This is because people are increasingly mobile, living and working in different EU countries, and they need information on medicines in their own language. Access to information in one's own language is an important support to patients' medication safety and self-management. Electronic systems should make it easy to include additional languages.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

EPF agrees with the principle that ePI should be integrated with other eHealth initiatives, including cross-border prescriptions and electronic health records. We would add to this: tools for patients reporting of suspected adverse events. We repeat our call to prioritise the development of the European medicines portal, mentioned on line 348, and the allocation of appropriate resources to the EMA for this. When considering interoperability of information, a person-centred approach implies the meaningful involvement of patients in designing systems and processes to ensure they really are well-coordinated and connected from the user perspective. Relevant information mentioned on line 362-3 should include also safety notifications, DHCP communications and other updates.

Enter any general comments you may have:

EPF believes electronic product information needs to be seen as one part of a more comprehensive strategy on information on medicines, which should also include a focus on health literacy and actions to address the critical areas identified in the studies commissioned by the European Commission studies, “PIL-S” and “PILS-BOX” (2014): enhancing readability and understanding, i.e. improving the content of product information to ensure it is really “fit for purpose” for health literacy and informed decision-making; and improving patient involvement both in the development and the testing of product information – not currently prioritised in the EMA strategy.

The shortcomings of the package leaflet have been known for a long time. According to the European health literacy survey (HLS-EU, 2012) almost a third of respondents found understanding package leaflets “fairly” or “very” difficult, whilst there was significant variance per country. Side effects listings and the causal relation between the listed side effects and the medicine often confuse both patients and health professionals (Mühlbauer et al. (2018); Herber et al. (2014); Mühlbauer and Mühlhauser (2015). Patient review of package leaflets comes too late in the process, is limited to one or two reviewers, and constrained by the legal requirements; patients’ comments can often not be considered because of the constrained format. There is no systematic approach to user-testing by the EMA.

EPF calls for the EMA and national medicines agencies to prioritise the above issues and to allocate the appropriate resources to the EMA from the EU budget in order for it to take action in this long-overdue area.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ( ) Other

Name of your organisation:

AGE Platform Europe

Enter any general comments you may have:

Indicate the key principle you would like to comment on (select all that apply):

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- [ ] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

335 -336 National authorities decide in which official and other language (s) PI will be provided in their countries for nationally authorised Products.

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- (•) Other

If other, please specify:

Management / Technology Consulting Firm

Name of your organisation:

BearingPoint

Indicate the key principle you would like to comment on (select all that apply):

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- [x] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Line 92 : The definition of semi structured should include a reference to data driven elements that could be provided through the implementation of IDMP or other standards. The current processes and data structures at both regulators and MAHS, can have multiple locations for the same data element that can lead to a duplication of effort e.g. Product name in Both databases and PDF/word-based documentation.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Line 102 : This comment is incorrect as on line 313 states that early adopter regulators may require a conversion of PI information at the end of the assessment process by the MAH, also on line 217 where ePI data is available , MAHs will be required to print the location of the ePI data on the paper insert.

Line 118 : A common standard would also facilitate the assessment process for ePI information and a reference to this use case should be included.

Line 127: As the regulatory network and MAH's are transitioning from XEVPMD to the ISO IDMP standard and FHIR standards are using ISO IDMP is this not the common standard for product information that we should be aligning with going forward.

Line 128 : The current and future system does not capture the level of data in a data driven structured format to provide the level of information required e.g. indications are currently text based not codified or stored in IDMP.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 156: To deliver this benefit will require process changes at both the regulatory agency and the MAH.

Line 167 : FHIR standard has been adopted to deliver this level of interoperability.

Line 179: To deliver batch level ePI data will require changes in the production of PI data.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Line 187: text should include “web or mobile applications”

Line 217: location of the ePI will be at the regulatory authority? if so then there will need to be a consistent approach to how the information is presented on the regulatory agency’s website.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

No Comment

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

No Comment

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

No Comment

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Line 259 : for those agencies that decide to implement ePI in a stepwise approach it would be helpful for those agencies to publish their timeline to covert to full ePI as part of the assessment process as maintaining both ePI and the current paper process will add a level of complexity to the process, increase the possibility of data corruption and add cost to the overall assessment process.

Line 270: Conversion of PDF and word into an ePI format is possible but will require significant effort to ensure that both the PDF / word are exact content matches. If the evaluation was based on data stored in a defined standard, then the approach would be extraction and confirmation which would lead to more accurate and timely data.

Line 284: In the event that the regulator is managing pdf /word and ePI data it should be clearly defined in the document what is the single source of truth for the PI data.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Line 306 : it is likely that even if a member state decides to implement ePI using one of the two defined approaches , MAH's may not be in a position to provide ePI data. Will there be an agreed road map for the full adoption across all member states for ePI to enable MAH's to plan accordingly?

Line 313: Early adopter member states should publish their plan and road map for implementation to allow MAH's and other regulators to plan accordingly.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

No Comments

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Line 346 : to ensure interoperability with other healthcare systems ePI data should conform to the FHIR standard which is becoming the standard for interoperability within healthcare systems.

Line 349 : The European common data model review in 2017 focused on the regulatory and decision making in support of pharmacovigilance activities and post market surveillance not the presentation of medicinal product information contained within ePI.

Enter any general comments you may have:

The concept of ePI information to provide more accurate and up to date information on medicinal products is something that all stakeholders have tried to achieve for a number of years. The document is an excellent start to formulating a plan to define and implement a standard but this work should be time limited along with any recommendations that are produced as this will provide all stakeholders with a clear roadmap of activities.

Although the document calls out in a number of areas that the current process and approach to the assessment will be unchanged it is difficult to see how it will not require changes in the submission and assessment processes of both regulators and MAH's for it to be achieved.

Unlike previous projects that have attempted to implement ePI within the network I would stress that the group should (1) define the standard for ePI, (2) provide guidance on best practice and (3) avoid engaging in developing ICT solutions to meet the requirements that will be created as these software solutions can be developed independently once the standards are created and agreed.

Even with a stepwise approach there will be a requirement to commit human resources and cost to the business process and ICT changes that will be required to implement ePI, a roadmap with commitment from all stakeholders will be required to enable a successful launch of the ePI initiative.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- Academic
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- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (●) Other

If other, please specify:

Not-for-profit organisation – medical journal – made up mainly of health professionals, committed to providing independent information on drugs, therapeutic and diagnostic strategies

Name of your organisation:

PRESCRIRE

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Statement
Lines 87 and 88 state that ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print. Currently PI is available via EU or national databases or in print form. Regulators should promote the dissemination of ePI through national competent authorities and/or on the European Commission and EMA websites. These websites should be user-friendly.
In respect to the current legislation and to prevent any misuse (for promotional purposes for instance), it should be required that the dissemination by a third party of one or several components of ePI (SmPC, labelling and/or package leaflet) via the world wide web, e-platforms or in print form, should concern the full file(s) (comprehensiveness) while dissemination/publication of parts or extracts be prohibited.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Statement
Lines 110-112 state that the common standard for ePI in the EU refers to the technical features agreed by regulators and stakeholders. It is unclear what is precisely understood by “regulators” and “stakeholders”. Those entities participating in the process should be listed beforehand and competent member state authorities should be consulted for agreement on this process. Regulators and authorities should have the final word on the common standard to be put in place.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Lines 143 – 144: EMA, HMA and the European Commission acknowledge that many future applications of ePI cannot currently be predicted. It should however be made sure that the outreach to electronic ePI will always be fully under the Regulators' control. EMA and other competent authorities should assess the proper use of the electronic handling and dissemination of ePI (conformity and comprehensiveness). EMA and other competent authorities have a duty to guarantee the quality of the dissemination of ePI and to avoid any deregulation.

Lines 160 – 164: as outlined, ePI will enable wider availability on a range of platforms. To guarantee the public health imperative, the source of information and of publication plays a key role. In respect of current EU legislation, ePI should be hosted on national competent authorities and/or on the European Commission and EMA websites. Competent Member state authorities should decide if and on which other officially controlled plateforms ePI might be made available.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Statement
Lines 185-188: facilitated access to ePI, especially in adapted formats for consumer/patients with specific needs is welcome. Enhancing the ePI readability and patient input in the development and testing by lay persons should be considered as well as a priority.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

We welcome and fully support the statement that the generation of ePI does not remove or replace the currently available paper format included in the medicines package. We also welcome the suggestion that the paper PL should include a statement directing to the ePI as the most up-to-date version of the PL (line 217). This should be done by including a QR code and/or the link to the ePI. All leaflets (paper and electronic versions), should clearly mention its date of validation.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Line 223 states that "ePI should always be published as open data, freely accessible for use and reuse". As we mentioned under heading 1.1 on ePI, the reuse and the dissemination of one or several components of ePI - the SmPC, labelling and/or package leaflet – might be possible provided the file is published in full while the dissemination of selected extracts or parts should be prohibited.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Lines 263 – 264: we fully support the dissemination of ePI through regulator and public websites at EMA and Member State levels.
Lines 284- 287: we also support the suggestion to put in place a pan-European medicines web portal providing a central point for access of ePI for all centrally and nationally authorised medicines. It is important to make it user-friendly and to promote its use among the public.

Lines 263-264: we see the utility to use ePI for electronic health records and e-prescribing systems. However, this use should take place under the control of competent authorities.
Lines 267 – 268: it is stated that ePI will be made available for use by third parties who can reproduce them and make them available to patients and healthcare professionnals. As mentioned previously, third parties intending to disseminate ePI should be required to reproduce them in their integrality while disseminating parts or extracts should be forebidden. To be considered as official approved document/file, ePIs have to be considered in their integrality. As ePI are anyway disseminated through public websites, third parties who would like to use them for dissemination should include the direct link to the public website(s).

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Lines 371 and 372 mention that ePI will be interoperable by design with eHealth initiatives and EU Telematics projects, and will consider national infrastructures and global health standards. We consider that national competent authorities have to be consulted on interoperability aspects. This should not be dealt alone by EU initiatives and projects.

Enter any general comments you may have:

Access to reliable and updated official approved product information is essential for healthcare professionals and patients. In order to protect public health, Prescrire invites EMA, the HMA and the European Commission also to strive for improvement of the product information and to make sure, as highlighted several times in the consultation paper, that any initiative resulting from the current consultation process is fully in line with the current legislation and respects the EU agreement to uphold the ban on DTCA in Europe. The provision of public access to officially approved product information falls under the role of competent authorities, notably by their publication on national competent authorities and/or on the European Commission and EMA websites. As outlined in the consultation paper, access to the ePI should always be considered as an additional option to the printed version of the patient leaflet provided within the product package.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Pharmaceutical Group of the European Union (PGEU)

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

PGEU agrees with the definition.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

PGEU supports the definition of a common standard for ePI in the EU.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

PGEU welcomes the use of ePI as a tool to increase citizens' access to objective and neutral information on pharmaceuticals at home, improving confidence and patient empowerment. In addition, due to its semi-structured and accessible format and design, ePI has indeed opportunities to improve readability and engagement of citizens to important information on pharmaceuticals. The ePI offers also additional opportunities for better linkage to and visualisation of risk-minimisation information.

Today, the package leaflet is a widely used by patients/public as a complement to information received from healthcare professionals. In order to ensure that ePI remains a source of trusted and non-promotional information, it will be crucial that citizens, using the various technologies and applications to access ePI as an intermediate, will be directed to independent sources such as the official websites of EMA and/or national competent authorities. It should also be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

PGEU shares the EMA views that ePI can facilitate the creation of product information accessible to everyone, and that it offers opportunities to meet specific patients' needs such as those with impaired sight and low literacy levels. However, it should always be considered that some of these vulnerable patients have limited access to digital tools or lack digital skills. It should therefore be ensured that the ePI strategy is part of a wider strategy on improving universal accessibility to product information for patients with diverse abilities.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

PGEU strongly supports the principle that ePI complements the use of paper package leaflets, and that it does not intend to remove or substitute the currently available paper format. As pharmacists we see that the paper package leaflets are today widely used by a very diverse group of citizens, including parts of the population with limited access to digital tools such as certain elderly and people with limited financial resources. In addition, the digital literacy levels vary still strongly across the population of all EU countries. Due to its importance, it is crucial to ensure at all time that product information is made universally accessible.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

PGEU welcomes that ePI is intended for the delivery of regulator-approved medicine product information only, that it will not be used to deliver promotional information and that is should always be published as open data, freely accessible for use and reuse.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

It should be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities. At the same time, it has to be clarified how software, apps or websites will process and store citizens' data when searching for a medicine's ePI – be it a search query or by scanning a medicine's barcode linking to the ePI.

The appropriate application of European data protection legislation should at all times be closely enforced and monitored in these third-party applications.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

PGEU supports that ePI will be made available to users through websites at EMA and NCA level. We also welcome the integration, where applicable, in eHealth systems such as electronic health records and eprescribing systems. Today, Summary of Products Characteristics (SmPC) information is in several EU countries already directly electronically available in software programmes and/or applied in scientific databases of healthcare providers. This improves the user-friendliness and accessibility of product information for healthcare providers.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

PGEU welcomes the acknowledgement of a necessary flexible approach towards the implementation of ePI across European countries. European community pharmacists are committed to contribute to an appropriate and timely implementation of ePI in their practice.

When implementing ePI, EMA and national competent authorities should also ensure that pragmatic solutions will be in place to address the potential issue of outdated paper PLs compared to updated ePI's. PGEU wishes to remind that the printing of paper PLs is a legal obligation for marketing authorization holders, and strongly believes that this should be conserved. Community pharmacists are concerned that, as last point of contact with patients in the medicines supply chain, the implementation of ePI might introduce both a direct financial cost for pharmacies as well as time loss in practice that could be better spent on caring for patients, when potentially having to print an updated paper PL for many of the medicines dispensed. Also when it comes to liability, the introduction of ePI opens new questions that need to be clarified.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

The ePI offers a unique opportunity to meet special patients' needs, including multi-lingual choice options. We encourage national competent authorities to consider linkage to all available EU language versions (as well as Norwegian and Icelandic) of the ePI on their websites, so that European citizens can at all time access the ePI in their language of choice in the community and country of presence.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

PGEU welcomes the focus on interoperability with existing EU and global initiatives in the implementation of ePI in Europe as a measure to ensure a pragmatic implementation process and harmonised access for patients and healthcare providers across EU.

In the implementation process of any digital technology in healthcare, we would like to stress the need for early involvement of experienced end-users such as community pharmacists to ensure endorsement, support and commitment of all users involved.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Standing Committee of European Doctors (CPME)

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

CPME welcomes the goal to expand access to information on medicines using different media. Nevertheless, when it comes to make ePI available through various technologies and applications incl. mobile scanning technology on the medicine package (lines 178-179), a link to official websites of EMA and /or national competent authorities on the medicine package should be preferred.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Ensuring the accessibility of product information to everyone (line 185), and in particular to patients /consumers with diverse abilities is essential. However, addressing the provision of information through internet might prove contrary to the goal of equal access to all citizens if digital health literacy is not widespread.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

CPME strongly support this statement which emphasizes that ePI will not remove or substitute the current available paper format (lines 208-209). Indeed, ePI should never replace the paper version which is included in the medicine package.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

In line with the statement on the fact that ePI will not be used for delivery of promotional information (lines 221-222), CPME reiterates the importance of product information that fulfils standards of objectivity, be transparent, independent and without any advertisement or commercial interests.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

CPME strongly supports the opportunity to make ePI available to users through EMA or national competent authorities' websites (lines 263-264).
However, the statement also refers to the possibility to make ePI available for use by third parties who can reproduce ePI and make it available to patients and HCPs (lines 267-268). It would be useful to clarify what are the implications behind this statement and which entities are considered.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

TATA CONSULTANCY SERVICES

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

It will be good if we are sharing images of drugs on ePI platform to avoid potential medication error

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

It will be good if we are sharing 3 dimension images of drugs on ePI platform to avoid potential medication error. Further, it would be a good sign if agency taking a control on similar shape, size, colour, alpha numeric coding, Embossing & Debossing of drug. Perticularly drug drug interaction drugs. That will avoid a medication error.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Regeneron Pharmaceuticals, Inc.

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Section 2.1: Implication. It is noted on Line 179 that ePI will be made available using mobile scanning technology on the medicine package. This will present a major issue for manufacturers in managing supply chain, especially for low volume medicinal products used to treat rare diseases. It these scenarios it may be extremely difficult to ensure ePI captured on a 2D barcode is current. We would ask that the Agency reconsider this proposal.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Section 3.1: Complementing paper package leaflet. The consult explains (Line 206) that because current legislation does not require the use of an electronic version of PI, the use of ePI will not constitute a new legal obligation. We request the Agency provide clarification on whether legislation will be updated in the future to make the use of ePI a regulatory requirement. If such plans are in progress or anticipated, an estimated or targeted timeframe for this change. Clarification of any proposal or planned strategy would enable MAHs time to plan for and implement new processes and/or revise existing processes to ensure compliance with any new requirements.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Section 4.1: Governance. It is noted that ePI will be made available to users through websites (Line 264). For this promise of ePI to be realized, it will be important that such sites (and therefore the ePI held) are maintained current. It is noted that even the existing EMA website can operate with a significant lag time in the update of product information following label changes. Therefore, Regeneron requests that timely updates to both sources should be the goal such that misaligned information is not encountered when working with ePI versus the EPAR product information posted on the EMA website.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Section 4.2: Flexibility in implementation. Regeneron appreciates the Agency's understanding of the significant time and resources that will be required for the ePI implementation effort as noted in Line 302, and looks forward to the release of the Agency's proposed roadmap for implementation. To allow MAHs sufficient preparation time for ePI implementation, we ask that the Agency include a transition period as part of the implementation roadmap.

Additionally, it should be recognized that ePI implementation may present unforeseen technological or logistical challenges for both the Agency and Applicants. Given this potential challenge, we request that the Agency consider facilitating a pilot program prior to or as part of implementation. Such a pilot program will allow Applicants to familiarize themselves with the ePI system, provide feedback prior to formal implementation, and ensure alignment with Agency's expectations.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Section 5.2: Interoperability with EU and global initiatives. As part of ePI implementation efforts, MAHs may need to update their regulatory submissions/operations systems accordingly. We request that the Agency outline guidance on considerations to be taken when designing the EU ePI system. This information will allow MAHs to adequately prepare for submissions/operations changes that come with ePI, thereby ensuring compatibility when the EU's ePI system is live.

Enter any general comments you may have:

Regeneron is a fully-integrated, biopharmaceutical company that produces and develops biological drugs, including recombinant fusion proteins and monoclonal antibodies, for the treatment of a broad array of diseases and conditions, particularly for the treatment of serious medical conditions.

Our research is conducted on a global level and includes clinical development in EU Member States. Our approved medicines and those in our pipeline are designed to help patients with eye disease, heart disease, muscle disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

General comments.
Regeneron commends the work of the Commission and Agencies on enabling electronic product information (ePI). As PI is one of the key means of providing health care professionals and patients/consumers with regulated, scientifically validated information on prescribed medicines, enabling such a PI structure as ePI will facilitate access to the current Summary of Product Characteristics (SmPC) and package leaflet (PL) for any medicine, ultimately providing a significant benefit in the interest of public health in the EU.

We submit these comments in an effort to aid the Commission and Agencies in finalizing a future detailed guidance on the implementation of an innovative ePI system in the EU that provides Sponsors with key information to help them prepare for the transition.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- ○ Other

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Patients stand to benefit from moves to replace conventional paper-based drug product information with an electronic system compatible with smartphones and computers, a conference heard.
There is no need to complementing paper package , the benefit is also ecological and to reduce paper.
Visually impaired, the system could allow them to hear the information using text to speech software.
Health care professional could help the patient to access the e-version (printing option, mobile phone, computer link...

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

The system could also allow patient information to be translated into different languages and allow medicine packs to be used across Europe.
At the moment, some smaller markets are poorly served because of the need to produce patient information in their national language. The proposals therefore help to encourage free flow of medicines across the EU, removing a major barrier that prevents drugs manufactured and approved in one country being sold in another.

Enter any general comments you may have:

Having the electronic system would also allow continuous updates, such as new uses for medicines, updates on safety, or changes to manufacturing arrangements.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

independent consultant

Name of your organisation:

Regsolutions consulting

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

line 93: ePI refers to a semistructured content-however unstructured formats (pdf/word) are not considered ePI. The reason for ePI is to expand the dissemination of PI information (line 149) however line 96 states that ePI refers to the structure not the content-what is correct?

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

line 186: blind people will not benefit from a larger font size -please adapt
linw 187: peole with low literacy levels will most likely not benefit from an audible format whereas blind people would do so-please adapt. Will this lead to an amendment of the readability guideline?

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

line 228: will it be possible to include the QR code in the ePI? What about videos on the IFU (explaining handling steps of the device) that are part of the PIL? Will these be included?

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

line 267: third parties will include the MAH? If so it should be stated explicetly.
line 278: third party is only an app? What about company websites?
line 281: the responsibility for creating the finale PI files lies with the MAH-how will the MAH be able to check the correctness as it will also be a reliable source of information for the regulator according to line 284?

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

line 313: Why not start with an EN version first that is accessable via the EMA website for all CPs?

Enter any general comments you may have:

Overall a very good initiative and hopefully it will be successful.
Please define ePI more clearly: at present it seems that it refers only to the structure however the benefits stated refer to the PI content and the accessibility. I trust the ePI development will also include professionals from user design/readability companies in order to ensure a smart and convenient IT interface.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

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- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

[redacted]

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

149 and next - only is valid when there is a mandatory regular updating process; legacy text should be critically apprised.

Enter any general comments you may have:

SmPC limited to scientific data, less marketing oriented

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

Italian National Printing House

Name of your organisation:

Poligrafico e Zecca dello Stato Italiano S.p.A.

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [ ] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
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- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

According to the key principles introduced through the public consultation, Poligrafico proposes to establish a technical committee with the aim to define a set of standards, that may include an XML grammar, controlled vocabularies and interoperability specifications, to be agreed by regulators and stakeholders and used at EU level. The main topic to be addressed about this standard is the structuring of the ePI, as it should provide authorized contents in such a way that it can be easily interpreted and used in a non-ambiguous way. Poligrafico's proposal expects the use of the XML markup language in order to support the structuring of the data. The so structured information could be accompanied by metadata that could describe and represent additional information from a semantic point of view. To reach this goal, an appropriate ontology could be developed and used through the RDF modeling language to represent, for example, consolidated versions of an ePI at given point in time, as provided for the consolidation of legal acts. Also, common web identifiers (URIs) standards for pharmaceutical resources addressing across the network could be developed.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Common standards are necessary to ensure consistent usage of ePI at EU level. The most used format, as PDF or other unstructured formats, are not to be considered suitable for ePI because they don't ensure optimal representation and reuse of the information especially when accessed by online services and systems that constitute added value services for patients.
Similar approaches are carried out at EU level for what concerns the representation of the legislation published by Member States: standards for the XML structuring of the legislation when published on online official journals are available as well as ontologies for the representation of the semantic information related to legal resources and for their addressing across the network. Italy implements the AKOMA NTOSO standard and the ELI specification for the legislation that publishes on its Official Gazette and participate to e-law working groups at EU level to give its contribution to the definition and the implementation of these standards. Based on these skills Poligrafico would like to address the ePI issues with the mentioned above information models and technologies.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Being standard used on a large scale and shared at an EU level, proposed models and technologies for ePI allow wide sharing of contents as stated by the applicable EU legislation with all the stakeholders across Member States and open access to anyone who need to consult PI in an affordable way. For instance, it could support the access to information for researchers studying features related to medicines and their product information, e.g. widening aspects regarding pharmacovigilance.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

One of the main advantages ePI should bring is the assurance of compliance with the requirements of pharmaceutical legislation, simplifying the regulatory activity in the updating process. Based on the experience gathered thanks to the work conducted on legislative standards, Poligrafico proposes the consolidation management for ePI (as for the publication of consolidated normative acts); a very important aspect of the digitalization of the PI could be represented by the possibility of providing patients and all stakeholders with an easy access to information in force at a given time, as approved by the regulators, also making available previous versions of ePI with related validity dates and medicine's production lots.
The digital format should also simplify the approval process for official texts, creating an effective tool for exchanging proposals between regulators and pharmaceutical industry. In addition to simplifying the approval process for contents or their updates shared in a unique standard format, the use of ePI can also streamline the subsequent sharing process as any new content or update is approved in the official format and ready for publication.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

UCB Pharma GmbH

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

In the description of figure 1 is stated that a "declaration from the MAH confirming that the converted version is identical in content to the one approved" is necessary. What is missing from my point of view is a clear statement if the ePI should only contain the information from the regulatory approved textfiles or all information included in the printed version of the package leaflet or SPC. For centrally approved medicines information for example about the "Date of revision" or the contact details of the "national reporting system" for adverse reactions are only included in the printed version and would be missing in the ePI if the basis is the regulatory approved file alone.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ Non-EU regulatory authority

Other

Name of your organisation:

BPI e.V.- German Pharmaceutical Industry Association e.V.

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Line 86 ff, Footnote 3 to Annex II:
According to the footnote of the document regarding “labeling” the definition of ePI encompasses Annex II information. Details on manufacturer are already covered by SPOR initiative and
Proposal: We propose to refrain from discussing a second passway for identical information in the context of ePI,

As different groups of stakeholders (patients, industry, healthcare professionals, NCA, EMA) will take part in the ePI project all conceptualities should be clarified by clear definitions, even what is exactly understood by semi-structured formats, organised format, re-usable elements, connection to SPOR.
Proposal: Please add clear definitions on the electronic formats

Line 102ff
It is stated that the development of ePI will not create new requirements with regard to content of the PI or a new legal obligation to use ePI. In addition, this initiative should not be understood to change the interpretation of European legislation. This means that ePI should be an additional requirement and paper PI will still exist in parallel. For industry, this approach creates a double work and this should be incentivised (see chapter general). The time for all stakeholders to create and use information in ePI format should be long enough, but at the end it will be appreciated to replace the paper-format by ePL in a step-wise approach taking particular products into account and having all stakeholders involved to ensure a smooth implementation under consideration of all relevant aspects for all stakeholders regarding the information for patients on medicinal products.
The implementation should also reflect the current practice administering medicinal products. For infusions, injections and vaccines which are administered by healthcare professionals, patients rarely gets paper-PL, so ePI could be the only source of information for patients and it could be referred to ePL instead of paper-PL.
There should also be a phased approach with regard to delivering ePL and eSmPC and further risk minimising documents. Especially for patients or consumers this much improved format is of great advantage delivering possibilities like e.g. increasing font sizes, using search functions, availability of formats

for patient`s reading tools. The focus should be on ePL in structured xml-based format. Availability of SmPC in structured (xml-based format) should be foreseen but rather as next step. Lesson`s learned from ePL can be used for eSmPC and further PI relevant for patients and healthcare professionals.

It has to be taken into account that pharmaceutical companies have to consider the requirements of liability law, and that`s why some companies are rather reserved to ePI strategy for the time being. Even a system on data security of the ePI system has to be established which should build trust in using the system. As the information officer is responsible for the information on medicinal product and personally liable, it has to be guaranteed that every patient/user gets the correct information. This can be fulfilled by validated systems. To find a good solution here and to consider this uniformly in a process that is set up, is also in our sense.

For patients without internet access or in the case of power outage, there should be the possibility to still have access on PI (dispensed by pharmacies). Otherwise there will be a safety risk for patients. Access of PI have to be guaranteed any time.

With regard to liability law for companies, it is important to consider these issues when implementing the roadmap for ePI.

Furthermore, patients have to get familiar with the new way of communication for medicinal products.

Proposal: The use of ePL should be tested in a pilot project in order to reflect the current practice and the acceptance to all stakeholders. In order to avoid a lot of confusions it would be grateful to test the ePI in the first step with the scanning technology which is used for serialization (Data matrix code with the unique identifier required by the Falsified Medicines Directive). Therefore in the first step only prescription medicine should be involved in the project ePI. Such products are often subject to numerous changes in side effects and so it is important to inform people early. The new in the EU implementing scanning technology for products only available on prescription can be tested in more detail. Other products should follow step-wise.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

The common EU electronic standard for ePI should be agreed with all stakeholders. Especially industry has to work with these standard as they will mainly provide PI in electronic formats. The standard has to fulfil as well a cross boarder-function between NCA, EMA, patients and healthcare professionals and has to be compatible to all available EU telematic projects in the regulatory field as well as healthcare systems. So, the common electronic standard has to fulfil high requirements.

Line 107 ff
BPI agrees on the general principle on a common approach and standard for ePI in a structured/semi-structured format. QRD-Templates should be made available as eQRD templates including precise requirements/recommendations also for free text (style guide as prerequisite for easy conversion of unstructured documents (like word) into structured xml format). For the lifecycle of the document, it is important to keep a defined standard which should be in alignment with the telematics tools already in place or in development (eCTD, CESP, CESP data module set, SPOR, approaches to simplify variations of the Regulatory Operation Group). So, the common standard has to fit with all other applications on the regulatory procedures concerning PI. This is a provision to streamline, simplify and speed-up the corresponding regulatory procedures affecting PI which represents an advantage (see line 127-129). However, it would be in the interest of both pharmaceutical companies and patients to have EU-wide uniform

requirements with regard to both the format and the type of publications under the consideration of already existing national portals.

ePI should interface as well with many ongoing and foreseen eHealth initiatives in the Member States. That`s why this interoperable system needs to be GxP-validated to be sure that the information of electronic product information is distributed unchanged to the single portals or applications. The interfaces between the systems need to be validated and there should be a tracking system in order to see where the information of ePI is implemented in different eHealth initiatives. As the information officer is responsible for product information, a comprehensibility of the distributed information is necessary.
ePI should be interoperable with SPOR data management service. It should be considered that the information should be legible and good understandable for patients.
So, not only the creation of ePI has to follow a common standard, it is also the submission, review, authorization and dissemination of PI which has to follow a common electronic standard in a validated area of the interoperable tools.

Proposal: ePI in the EU for all human medicines, including both centrally and nationally authorised medicines, should be created, submitted, reviewed, approved and integrated to other eHealth Portals and application in a validated, trackable system. It would be in the interest of both pharmaceutical companies and patients to have EU-wide uniform requirements with regard to both the format and the type of publications.

Line 124
It is stated that the aim of the common standard is to create the technical foundation for the dissemination of trusted information in the world, which will allow patients/consumers and healthcare professionals an additional and tailored approach on information for medicines according to his/her need and/or wish by using suitable (electronic) output forms and platforms. It is not clear what the “tailored information” would be. As all information on PL might be important for patients.

Proposal: It should be pointed out what possibilities should be provided by tailoring the information of product information for patients.

Line 127-129
ePI should offer a possibility to streamline and speed-up regulatory procedure in creation and updating PI by using data of the SPOR-system. These SPOR data can be regarded as validated and approved e.g. Manufacturer data (OMS), so that there is no need to assess these information by a separate variation procedure.

Proposal: Changes to data that are included in SPOR (e.g. OMS data), do not need to be assessed by a variation procedure

Line 139
It is stated that interoperability specifications yet to be developed may be added at later releases. From our point of view, these interoperability standards should be fixed from the beginning, otherwise ePI does not correspond with these systems and the electronic formats have to be converted again.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 151ff
It is obvious that ePI can be maintained in the current versions very easily as changes can be implemented immediately in the electronic versions. Due to the reason that a PI in paper-format is still mandatory, there will be differences between an ePL and the paper PL associated with the medicinal product in the box. This can cause confusions to patients and has to be explained. Hopefully, planning will also take into account the organizational challenges that the pU faces in maintaining the texts to be published, for example when two PL (electronic format and paper format) are in circulation.
The PL in paper-format should include a sentence to inform on the availability of the current version of PL in electronic format with a link to the source (portal/website) or to 2D barcode. The location of the correct PI is of importance as PI can differ from country to country for products authorised nationally. Mix-ups should be avoided.
In Spain the paper version of PI (available on prescription) already includes such a sentence. But as ePI is not legally mandatory, this sentence should only be implementend in PL, if an ePL is available.
Proposal: As soon as ePL is available, paper PL should implement a sentence on the defined source of the ePL as a current version of the particular medicinal product. The sentence should be included in QRD template. Inclusions of such a statement will lead to a significant number of updates to the PL which should not require a regulatory procedure (review/assessment).

Line 178-179
ePI should be made available by mobile scanning technology such as 2D barcode. By using the 2D barcode, which is also used for serialization (Data matrix code with the unique identifier required by the Falsified Medicines Directive), no additional data should be encoded within this code but the included product code should be used for linking to the ePI.

Line 179-182
Batch-related product information is of special importance, especially if there is a change of excipients. Therefore, it should be guaranteed that the patient/consumer has access not only to the most up-to-date version of PI but also to the information which is of relevance for the specific batch (e.g. when excipients change). Industry controls the batch specific implementation of product information very carefully to ensure that the correct PL in paper-format is associated with the appropriate box of the batch of the medicinal product. There is a clear need to think on technical features in order to inform patients about such batch-specific changes in an ePI system.

Proposal: There should be a technical solution to reflect batch specific changes in the ePI project. This solution should be agreed with stakeholders, especially industry and patients and should be of less workload and costs for industry.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

We welcome the creation of PI that is accessible to everyone but would like to get the ability to take more profit of today's technologies. For now the changes evoked in this public consultation are limited to allow a bigger font and audible content. But for blind or partially sighted people, formats prepared for patient´s reading tools supported by smartphones are the means of choice. Patient health could really benefit from today's technologies. Indeed the use of interactive and educative videos could help patients, even with poor literacy skills, to get the information on their medicine and to really better understand their disease and how to take their treatment. Many companies have already these non-commercial information videos on the company webpages

Proposal: ePI should include interactive and educative videos as well or should at least contain hyperlinks to these videos.

Line 185
Please correct typo: …..including patients/consumers with print impairments such as blind and partially sighted people. It should be visual impairments.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

It is understandable that the implementation of the ePI must currently occur within the framework of the current European legislation in order to be able to offer the ePI to the EU patients as soon as possible. However, it is strongly recommended that an opening clause in the EU directive should be considered with regard to leaflet-free boxes. There should be a stepwise approach for abolishing the requirements for paper leaflets. For a transition period, industry has to maintain two systems (paper and electronic) regarding the creation and maintenance of product information, which takes great efforts, resources and costs to adapt to new business procedures. For industry, ePI will result in an additional workload.

A transition period or a pilot is justified, because stakeholders, especially patients, have to get used to ePI portals and applications.
For a pilot for leaflet-free boxes, we would suggest to start with medicines only dispensed in hospitals or in other settings where the medicine package is not directly distributed to the patients. These include vaccines which would additionally benefit since you might prevent shortages by avoiding repackaging. Infusions and injections administered by healthcare professionals offer another possibility as well. Based on the experience from national projects (like GI4.0) the use and acceptance of ePI should be evaluated.

Acknowledging the importance not to lose sight of patients with low digital literacy or limited internet access, we recommend to add the statement that for patients with low digital literacy or limited internet access the PL should be available as print-out, e.g. in pharmacies at the point of sale. The willingness of pharmacists has to be evaluated.

In order to support a rapid dissemination of ePI the pharmaceutical industry should be highly encouraged to start or push their activities. Therefore, incentives for the pharmaceutical industry would be helpful, e.g. extension of timelines requested by NCA for updated paper leaflet in the box if an electronic version is available; an option of leaflet-free boxes for certain medicines (e.g. hospital-only medicines). Additionally, there should be an incentive for the companies with regard to cost compensation (reduction of fees) taking into account the costs for the companies for conversion of unstructured documents into xml-format.

Proposal: Although ePI should be established in the current setting of the EU legislation, it would be appreciated to get an evaluation on ePI in a pilot to take considerations of leaflet-free boxes where it is feasible. The additional work industry has to cope with in establishing procedures for ePI, should be incentivised.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

BPI agrees that any element of promotional nature should be excluded. But, there should be the possibility to deliver additional information connected with the product information like risk minimization material or educational material (e.g. via link). Such materials are also approved by the authorities. Also inclusion of videos with e.g. instructions for proper-use of medicines would be of benefit for the patients.
ePI should leave the freedom to complement or list national peculiarities e.g. like plasma source countries that are listed in the package leaflet or SmPC in Germany or on the outer box in Slovenia. If these possibility does not exisit in the ePI concept, these national peculiarities have to be deleted or changed.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Line 265-268 + Line 271
ePI will also be available for use by third-parties and for other e-health systems, such as electronic health records and e-prescribing systems. This can be regarded as an advantage, but it bears the risk that the information will not be transferred correctly.
The conversion tool and ePI system needs to be GxP-validated to be sure that the information of electronic product information is distributed unchanged to the single portals/systems. The interfaces between the systems need to be validated and there should be a tracking system in order to see where the information of ePI is implemented in different eHealth initiatives. As the information officer is responsible for product information, a comprehensibility of the distributed information is necessary. It has to be clarified who will transfer the data into the different system and if the information officer should approve the release electronically.

Proposal: As companies are responsible for PI, a validated system has to be established to assure that the correct information of ePI is transferred to different systems. Companies should have the right to give an approval on information used for the different system.

Line 285 + 286
It is envisaged that a pan-European Medicines web Portal could provide a central point for ePI for all centrally and nationally authorised medicinal products. Please bear in mind that purely nationally authorised products (NAPs) might have differences in PI (e.g. indications). The danger of mix-ups will be greater, if patients look for their medicine in a pan European Portal.

National portals, like Rote Liste Compendium in Germany benefit from trust patients gain during the long-term use for medicinal product information. They should not fall behind the pan-European Portal

Proposal: National portals should be adapted to ePI, pan European Portal should not replace national portals.

Line 288 ff
Flexibility in generating ePI is important. Establishing ePI by using eQRD-templates at time of application allows to have profits for faster regulatory procedures. A conversion to ePI after assessment is also possible, but should then not delay the national phase of a regulatory procedure.
The demand for having ePI should be coordinated amongst NCA in a roadmap. As NCA can chose to accept or demand ePI from the beginning or by conversion later on, MAHs have to prepare all necessary business procedures to fulfil the demands of ePI for each NCA.
The companies have to cope with different processes (with ePI and no ePI) for the same submission in different countries in MRP and DCP. This would be a burden for industry.
A realistic and reliable roadmap for all stakeholders with defined milestones, especially for NCA and industry is therefore important. Further national specific requirements regarding creation of ePI or submitting ePI should be avoided by NCA as the process should not be diversified with the result of a high workload for industry.

A process should be considered for existing PI documents to transfer/convert these into ePI. This should be done very smoothly in order to avoid a complex and resource-consuming burden for industry, even if a sentence in the paper PL should be included to refer on eP- availability.

Proposal: Implementation of ePI should not delay regulatory procedures, national particulars regarding implementation of ePI should be avoided. The proposed roadmap should include a harmonised implementation in the Member States taking into account a smooth process for converting the existing PI.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

To realise the concept of ePI a clear roadmap with defined, reliable and realistic timelines for all stakeholders should be established, introducing the workflows and evaluation testing. Lessons learned from eCTD should be included in setting the milestones. The needs of small and medium sized companies (SME) have to be taken into account.

In addition to what is proposed in the draft key principles, platforms for ePLs already in use (e.g. Rote Liste, German Compendium) in some Member States should be allowed to continue and adapted to ePI.

It has to be considered to perform user acceptance tests (UAT) in which patients, industry, NCA, EMA and healthcare professionals take place as focus groups. These tests can be regarded as a proof of concept and an evaluation of the workflow for establishing ePI. As information for medicine is very important for the safe use of medicinal products and very different stakeholders are affected by ePI, acceptance tests seem to be important for a successful implementation.

Proposal: The concept of the roadmap, the workflow for ePI, milestones and user acceptance testing should be agreed with the stakeholders concerned taking account the needs of small and medium size companies. The ePI project will only have success, if all companies can take part and PI are nearly complete.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

If there is no common text basis of the PI (i.e. nationally approved medicines – in contrast to medicines approved via MRP/DCP or centrally approved) it should be taken into account that the content of the nationally approved product information may vary in the respective countries. However, even if a medicinal product was approved after a MRP/DCP different wordings can occur, e.g. because of national deviations from excipients guideline or different naming of ingredients. If you offer PI in different languages or translations of nationally approved PI it should be clearly stated that the PI approved for its respective country is valid/legally binding.

Proposal: According to the above explanations it would be grateful, if you could offer only approved PIs (in the official language of the appropriate country) from the competent authority.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

With regard to the interoperability, we would like to draw attention once again to the different health systems.

ePI should interface with many ongoing and foreseen eHealth initiatives. That`s why the system needs to be GxP-validated to be sure that the information of electronic product information is distributed unchanged to the single portals. The interfaces between the systems need to be validated and there should be a tracking system in order to see where the information of ePI is implemented in different eHealth initiatives. As the information officer is responsible for product information, a comprehensibility of the distributed information is necessary.

ePI should be interoperable with SPOR data management service. It should be considered that the information should be legible and good understandable for patients. Terms laid down in the ISO Standards to reflect the product or substance or referentials might be too complicated to understand.

Enter any general comments you may have:

BPI realises the advantages of an electronic format of product information (PI). By using digital technologies, PI are widely-available in real-time. Patients as well as health care professionals have access to up-to-date product information. The electronic format allows a user-friendly presentation of the information and patients as well as health care professionals can navigate the information which allows an improvement in retrievability and legibility. Blind and partially sighted people have the opportunity to use the formats for patient´s reading tools. Changes to ePI can be implemented much more easier in an electronic format.

Nevertheless, industry has to take efforts regarding costs and resources to implement all necessary electronic systems and to adapt internal business processes to fulfill all requirements for generating and maintaining ePI. That`s why we fully agree on a step-wise phased approach regarding delivering ePI laid down in a roadmap with realistic and reliable timelines. But BPI sees the opportunity to have further improvements on regulatory procedures that should be integrated within the roadmap:

- Processing variations for particular changes impacting PI can be facilitated by changing directly the electronic version of PI. This also leads to an easier review process for EMA/NCA, in many cases without performing a separate variation (e.g. when referring to SPOR data). Reduction of fees will be possible.
- Especially safety variations occurring from referral procedures can be implemented easily and published earlier in an electronic format. Extension of timelines requested by EMA/NCA for updated paper leaflet in the box should be possible, if an electronic version is available.
- Implementation of ePI (conversion from PI to ePI) should not be done by an additional regulatory procedure
- Delivery bottlenecks can be countered by providing ePI if a product of another country can be delivered. Time for repackaging can be extended.
- User Testing should be adapted to ePI and can be reduced taking technical possibilities into account.
- Option of leaflet-free boxes for medicinal products administered by healthcare professionals only (e.g. infusions, injections, vaccines)

In general, there should be incentives for the companies with regard to cost compensation (reduction of fees) taking into account the costs for the companies to follow ePI strategy (e.g. for conversion of unstructured documents into xml-format or creation of ePI by eQRD).

ePI should not lead to an increase of workload on maintenance of PI. The opportunity to decrease workload should be exploited. This should be reflected in corresponding future guidance documents.

Even if electronic tools can support a better retrievability and legibility of information on a medicinal product which can even be supported by instruction videos, there is a strong need to improve and shorten the content of PI to make information more precise and purposeful.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission and identity will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Your name

[redacted]

Your email

[redacted]

You are a:

- ○ Member of the public
- ○ Patient/consumer
- ◉ Patient/consumer organisation
- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ○ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ( ) Other

Name of your organisation:

BEUC, The European Consumer Organisation

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [x] 3.3 Data protection
- [x] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

BEUC supports the proposed definition of ePI.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

BEUC agrees that use of common EU electronic standard for ePI is crucial to ensure functionality and uptake of the tool. The chosen standard must also be compatible with the standards used for the EU cross-border exchange of e-prescriptions and electronic health records.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

BEUC strongly supports consumers' right to access high quality information about medicines and treatments. We, therefore, welcome EMA-HMA's intention to improve information on medicines through electronic means. Electronic leaflets as complement to the paper leaflet holds a potential to improve readability and layout of leaflets, as well as provide an opportunity to ensure patients' access to the most updated version. Implementation of electronic leaflets must however not come at the expense of efforts to improve the readability of the existing paper leaflet. We therefore insist that the EMA in parallel continue improving the paper leaflet.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

BEUC agrees that ePI can serve as a good tool to improve access to information for vulnerable patient and consumer groups, including visually impaired users and those with low literacy level. However, we underline that there is a strong need to improve digital literacy both among vulnerable groups and the general population. Several studies (1) have shown that individuals with limited (digital) health literacy skills not only consume less online information sources, but also gain less positive outcomes from such sources.

To diminish the risk of a digital divide and increase the usefulness and uptake of ePI, it is important to consider the following aspects throughout the development of ePI (2):
- Specific needs of the vulnerable groups;
- Access to the tool;
- Literacy level;
- Potential incapacities;
- Cultural sensitivities, habits and beliefs.

To make ePI useful, accessible and addressing users' needs, it is of key importance to involve future users with diverse perspectives, circumstances, capacities and experiences in the designing and assessing the tool.

(1) Bol, N., Helberger, N., & Weert, J. C. M.. Differences in mobile health app use: A source of new digital inequalities? The Information Society, 2018, 34(3), 183-193.https://pure.uva.nl/ws/files/25256057/Differences_in_mobile_health_app_use.pdf

(2) Latulippe K, Hamel C, Giroux D. Social Health Inequalities and eHealth: A Literature Review With Qualitative Synthesis of Theoretical and Empirical Studies. Eysenbach G, ed. Journal of Medical Internet Research. 2017;19(4): e136. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5427250

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

While we welcome ePI, it is nonetheless of key importance to make sure that both paper leaflet and e-leaflet are well-integrated, and provide safe, comprehensive and unbiased information to patients and consumers. Furthermore, we recommend that a single portal for ePI is managed by the medicines agencies to guarantee the transparency of information provided, as well as any apps developed to facilitate ePI provision (for example, as the apps on patient reporting of adverse drug reactions, developed under WEB-RADR).

BEUC insists that it is crucial to ensure strong compliance with the GDPR, and the portal/app must be thoroughly tested and constantly assessed on the subject of user privacy. Careful attention is in particular needed to ensure the compliance of potential private operators developing a future portal/app.

The raise of public-private partnerships in the healthcare sector are highly concerning from a patient safety and data protection perspective. One of the recent controversial examples is the UK's NHS partnership with Amazon's voice-assisted application Alexa enabling health advice search through the NHS website.

Amazon is a company with a worrying track record when it comes to the way they handle their users' data. Recently there was a scandal that revealed how they had contracted thousands of employees to listen in on users' interactions with their Alexa device.(1) (2)

Based on this example, we call on the EMA to choose a service provider with a particular attention to their compliance with the EU's data protection framework.

(1) https://en.softonic.com/articles/amazon-alexa-privacy-concerns
(2) https://www.coons.senate.gov/imo/media/doc/Amazon%20Senator%20Coons__Response%20Letter__6.28.19%5B3%5D.pdf

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

BEUC strongly supports the notion that ePI must be free of any element of promotional nature and the information must be approved by the regulatory authorities.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

All parties involved into ePI development must be compliant with the EU's data protection framework. It must be done not only by checking contract terms, but also by consistently monitoring practical application of ePI. BEUC further insists that any personal data which may occur in relation to the implementation or use of ePI must be handled in accordance with the EU Regulation 2016/679 and EU Regulation 2018/1725. Moreover, we would like to highlight, beyond data protection, that the security of ePI software and stored personal and non-personal data is crucial. This is especially relevant in the context of ePI integration into a European cross-border exchange of electronic health records. Weak cybersecurity of ePI might offer a backdoor to the massive storage of personal sensitive data.

Therefore, for ePI it is essential to ensure security of health data and preventing access to the system both in case of system failure (e.g. virus causes loss of data) or damages caused by an external force (e.g. hacker attack). Even though it cannot be fully avoided, implementation of security by design and security by default principles in ePI's development could significantly minimise the risks. To ensure security by design, all connected digital health products and services should incorporate state of the art cybersecurity functionalities at an early stage of their design process and before ePI software is used. To guarantee security by default, the settings of ePI software must be configured to the most secure setting by default. (1)

BEUC also recommends EMA to closely collaborate with the European Data Protection Board and with the EU’s Cybersecurity Agency to ensure that ePI is aligned with the EU’s law on data protection and cybersecurity.

(1) BEUC-ANEC Position Paper, Cybersecurity for Connected Products, 2018 http://www.beuc.eu /publications/beuc-x-2018-017_cybersecurity_for_connected_products.pdf

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

BEUC is highly concerned about the intention stated in lines 267-268 to make ePI available for use by third parties, who “can reproduce ePI and make it available to patients and healthcare professionals.” We insist that key principles must further clarify to whom ePI will be available. In particular, it must be ensured that third parties do not have access to any personal information to avoid potential misuse of data and targeted promotional information dissemination.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

BEUC strongly supports the statement that ePI should support all official EU languages, and Icelandic and Norwegian.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

BEUC agrees that ensuring ePI's interoperability with other EU initiatives. When implementing common technologies and standards to interconnect databases, it is crucial to make the ePI format user-centred and to ensure continuity of care.

Enter any general comments you may have:

While BEUC welcomes the ePI initiative, we insist that work on ePI should not come at the expense of EMA's work to improve the package information leaflets (PILs), which are still not user-friendly enough. Problems have been identified with the content and lay-out of PILs, which still include language that is too complex. While the elderly and those with low literate skills are the most disadvantaged, other groups report similar problems. As mentioned above, while the development of electronic product information is welcome, it must not come at the expense of efforts to improve PILs. One of the ePis advantages is that information on medicines can be updated faster, however, EMA should make sure that PILs update is quick enough too. PILs remain crucial for consumers. In case of any connectivity issues – or for consumers with low digital literacy – PILs are the only accessible point of information on how the medicine should be taken. Providing better and timely information on approved medicines to end users must therefore be an EMA priority in the years to come.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ◉ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Sanofi

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Line 86-88:
‘ePI is authorised, statutory product information for medicines (i.e. SmPC, PL and labelling) in an organised format created using the common EU electronic standard. ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print.’

Comment:
As stated in line 86-88, the definition of ePI is not restricted to PILs but also includes SmPCs and labeling. We agree on this broader definition especially with regard to availability of SmPC and PIL from a trusted source of information.
Clarification is necessary concerning the persons (i.e. HCPs, patients) who have access to the PIL and SmPC (i.e. SmPCs not only for HCPs).

According to the footnote of the document regarding ‘labeling’ the definition of ePI encompasses Annex II information. Details on manufacturer are already covered by the SPOR initiative and we propose to refrain from discussing a second transmission pathway for identical information in the context of ePI.

Line 91-95:
‘There are many different interpretations of ‘electronic product information.’ Therefore, it is important to clarify that for the purposes of this collaboration, ePI refers to a semi-structured format suitable for electronic handling. Semi-structured means that ePI contains some structured elements (e.g. fixed headings and vocabularies), and some unstructured elements (i.e. free text). Unstructured formats such as PDF, Word or other unstructured text are not considered to be ePI because these do not deliver the benefits to stakeholders outlined in these principles.’

Comment:
We agree on the general principle of a common approach and standard for ePI – in a structured or semi-structured format. A structured format (i.e. xml-based) delivers new opportunities to better tailor product information to the needs of the stakeholders. Especially for patients/consumers this much improved format is of great advantage delivering possibilities like e.g. increasing font sizes, using search functions, availability of audible formats. Therefore, first of all the focus should be on ePI for patients in structured xml-based format. Availability of SmPC (and labeling) in structured (xml-based) format should be foreseen but rather as next step.

Establishment of a ‘Glossary of terms’ delivering precise definitions of the respective terms (e.g. ‘structured elements’, ‘unstructured elements’) would be very helpful to ensure a common understanding.

Line 100-104:
‘Implementation of the use of ePI, as described in the definition, will allow delivery of the benefits to stakeholders as explained in the key principles 2.1 and 2.2. Such implementation will be carried out in accordance with applicable European legislation. The development of ePI will not create new requirements with regard to the content of the PI or a new legal obligation to use ePI. In addition, this initiative should not be understood to change the interpretation of European legislation.’

Comment:
Concerning the statement that implementation should be carried out in accordance with current European legislation see comment under 3.1- Complementing paper package leaflet, line 201-212. So, this statement should be adopted accordingly.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Comment:
We agree on the general principle of a common approach and standard for ePI in a structured or semi-structured format (e.g. xml).
QRD templates should be made available as eQRD template including precise requirements /recommendations also for free text (style guide as prerequisite for easy conversion of unstructured documents (like word) into structured xml format).

Line 107-108:
'ePI in the EU for all human medicines, including both centrally and nationally authorised medicines, will be created using a common electronic standard.'

Comment:
In this section 1.2., there seems to be no explicit statement about the objective of an alignment of this common data model to the one EMA will be enforcing as part of the EU IDMP implementation.

Rationale: There is a statement on line 128 related to the SPOR data; an explicit statement about this common electronic standard being aligned with the ISO IDMP standards would be very much welcome. Use this format would offer possibilities to streamline, simplify and speed up the regulatory process in the creation and updating process (variation) of PI by using existing data of the SPOR (substance, product, organization and referential) process, both for regulators and the pharmaceutical industry. The possibility to update the PI by using existing data of the SPOR would also allow a uniform way of working across systems (e.g. IRIS platform, Eudravigilance, e-application form).

Proposed change:

Consider adding a statement, possibly on row 111 'This common standard will be consistent with the EU IDMP implementation', with a footnote referencing to the EMA document 'A common data model for Europe ? why ? which ? how ? Workshop report', EMA/614680/2018, https://www.ema.europa.eu/documents/report/common-data-model-europe-why-which-how-workshop-report_en.pdf

Excerpt : Recognising this, the regulatory network is implementing the ISO IDMP standards for the identification of medicinal products in regulatory submissions will allow regulatory questions to be addressed in the same language in which they are phrased.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp&mid=WC0b01ac058078fbe2

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 170-172:
As stated in line 170-172 availability of ePI from a trusted source of information will counterbalance unreliable and spurious claims about medicines often spread through internet. Besides establishment of a tool delivering ePI the broad public should be made aware of this new source of trusted information. Therefore, informative and educational campaign for patients/consumers and HCPs should be planned.

Line 178-179:
'To achieve this principle, ePI should be made available through various technologies and applications, including mobile scanning technology (such as a 2D barcode) on the medicine package.'

Comment:
As stated in line 178-179 the ePI should be made available by mobile scanning technology such as 2D barcode. By using the 2D barcode which is also used for serialization (Datamatrix code with the unique identifier required by the Falsified Medicines Directive) no additional data should be encoded within this code but the included product code should be used for linking to the ePI.

Line 179-182:
'Correct ePI depends on the medicine batch: some parts of the ePI may be applicable to all batches and some only to specific batches (e.g. when excipients change). Therefore the need for the correct ePI to be supplied for the medicine batch should be taken into consideration.'

Comment:
As stated in line 179-182, batch-related product information might be of special importance especially if there is a change of excipients. Therefore, it has to be emphasized that the patient/consumer has access not only to the most up-to-date version but also to the information which is of relevance for the specific batch (e.g. when excipients change). There is a clear need to think on how to best inform the patients aboutthese changes.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Line 185-188:
‘ePI will facilitate creation of PI that is accessible to everyone, including patients/consumers with print impairments such as blind and partially sighted people (e.g. use of large font size) and those with low literacy levels (e.g. audible formats). ePI on the web will accessible to screen readers, convertible to large font and amenable to other accessible format.’

Comment:
Sanofi welcomes the creation of PI that is accessible to everyone but would like to get the ability to take more profit of today’s technologies. For now the changes evoked in this public consultation are limited to allow a bigger font and audible content. Today’s technologies could really benefit to patient health. Indeed the use of interactive and educative video could help patients to really better understand their disease and how to take their treatment.

Line 192-194:
‘Current PDF and print copy formats of PI do not well serve all citizens equally, given the wide range of abilities throughout society.
In contrast with current PDF and print copy formats of the PI, the availability of ePI will allow third-parties, such as companies, not-for-profit organisations or patient/consumer groups, to convert the PI into accessible formats.’

Comment :
First of all, the focus should be on ePI for patients in structured xml-based format because patients are the ones who will benefit most of this improvement from a public health perspective. While Sanofi supports the availability of SmPC (and labeling) in structured (xml-based) format but we would rather see it as next step.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Line 201-212:
‘Statement: ePI will not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of 202 Directive 2001/83/EC1) to include a PL in the packaging of all medicines or directly convey all information required (by Articles 59 and 62 of the Directive) on the outer or immediate packaging.
Since the current legislation does not require the use of an electronic version of PI, the use of ePI will not constitute a new legal obligation.

Rationale: The ePI is intended to expand the formats in which PL is available and not to remove or substitute the currently available paper format. PLs are a valuable tool presented directly in the medicines package and therefore provided to all patients/consumers when they open their medicine. The paper PL is particularly important for patients/consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access.’

Comment:
It is understandable that the implementation of the ePI must currently occur within the framework of the current European legislation, in order to be able to offer the ePI to the EU patients as soon as possible. However, it is strongly recommended that a revision of the European legislation should be considered, i.e. an opening clause in the EU directive should be envisaged with regard to leaflet-free boxes. Considering the fact that a lot of discussions have already been done on the advantages digital development offers we won’t list them here again. That being said, Sanofi would encourage health authorities to undertake a stepwise

approach for abolishing the requirement of the paper leaflets. We would suggest to start with products only dispensed in hospitals or in other settings where the product is not directly distributed to the patients. These include vaccines which additionally would benefit sinceshortages might be prevented by avoiding repackaging.

The concomitant activities across the entire Union to grant internet access to the whole territory and to support citizens with low digital literacy should render redundant the use of the paper PI for the time for which the European legislation will be modified. Acknowledging the importance not to lose sight of patients with low digital literacy or limited internet access, the PL should be available as print-out, e.g. in pharmacies at the point of sale.

It should be noted that while accessing EMA/agency website may require some digital literacy, scanning a 2D code with the mobile phone would ease the access to citizens with low digital literacy.
We would like to stress out that New Zealand also has no requirement for leaflets in packs and the agency website is the prime source of medicines information.

Line 215-216:
'The use of ePI will be a recommended innovation; however it is not mandatory.'

Comment:
In order to support rapid dissemination of ePI with all the benefits described the pharmaceutical companies should be highly encouraged to start using ePI. Maybe there should be further incentives for the pharmaceutical companies to start and push their activities (e.g. with regard to extension of implementation timelines requested by the HA for updated paper version in the box if ePI is available; option of leaflet-free boxes for certain medicines, e.g. hospital-only, in the near future due to an opening clause in the EU directive). Additionally, there should be an incentive for the companies with regard to cost compensation (reduction of fees) taking into account the costs for the companies for delivering xml-based documents (conversion into xml through third parties necessary).

Line 217:
'The paper PL should include a statement directing to the ePI as the most up-to-date version of the PL.'

Comment:
The paper leaflet should make reference to the ePI, but only if the respective ePI is available. Inclusions of such a statement will lead to a significant number of updates to the PL which should not require a regulatory procedure (review/assessment).

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Line 225-228:
‘The development and implementation of ePI will be carried out in accordance with applicable EU legislation; therefore the content of ePI will be approved as a result of regulatory procedures currently prescribed in the legislation (or as will be amended by any future legislation). Accordingly, no additional information — either for promotional or other purposes — can be included in the ePI.

Comment:
We agree that any element of a promotional nature should be excluded. But, there should be the possibility to deliver additional information connected with the product information, like risk minimization material or educational material approved by the authorities (e.g via link). Also inclusion of videos for e.g. proper-use of the medicine would deliver a real benefit to the patients.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3-Data protection:

Sanofi acknowledges the need to comply with the GDPR regulation and applicable European data protection legislation.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Line 284-285:
'The NCA in each country will store and handle ePI in their jurisdiction.'

Comment:
Interoperability and the same format must be ensured between the various countries. Some countries (e.g. Spain and Germany) are known to have already developed their electronic product information capabilities and use their own format.

Line 295-296:
'Submission of ePI: PI is submitted to the authorities in electronic format, evaluated in this format, and is therefore already in ePI format once the evaluation procedure is complete.'

Comment:
The evaluation of the ePI will have to be conducted in accordance with the IDMP dataset, as appropriate /applicable.

Rationale:
It would be beneficial to have a review of the PI and the IDMP data set happening at the same time

Proposed change:
Consider including this third scenario as a part of the foreseen discussions between the EMA and the stakeholders on the IDMP Target Operating Model (TOM) – process, in the context of the EU Consultation phase I.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Flexibility in implementation is important. In addition to what is proposed in the draft key principles, platforms for ePILs already in use in some member states should be allowed to continue to be in use - and develop - until the common European system is in place. It cannot be in the interest of patients or health care providers that the development of established and well-functioning digital solutions stops.

There are no timelines whatsoever. There should at least be an ambition to have system in place within a certain time frame and with a more precise defined stepwise approach of delivering ePI. Since ePI includes all documents (SmPC, PL and labelling) as mentioned in section 1.1 there should be a more precise plan how to proceed in a more harmonized approach (e.g. starting with ePI for patients).

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Comment:
If there is no common text basis of the PI (i.e. nationally approved medicines – in contrast to medicines approved via MRP/DCP or centrally approved) it should be taken into account that the content of the nationally approved product information may vary in the respective countries. If you offer PI in different languages or translations of nationally approved PI it should be clearly stated that the PI approved for its respective country is valid/legally binding.

Sanofi would welcome more clarification concerning the proposed translations of the information of nationally approved products. While we fully understand why the EMA let the national health authorities organize the translation of the ePI we would appreciate a more precise guidance on how it will be handled. Indeed, for the sake of interoperability we foresee that more governance would be of major interest.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Sanofi would encourage the EMA to focus on implementation and interoperability in the European Union as a first step keeping in mind that systems/standards should also be interoperable internationally. Global platforms such as HL7 and ICH could be of help.

Line 350 :
'Use of ePI in both an EU and global context should also be taken into account.'

Comment:
The use of 'global context' is rather vague.
Rationale: the implementation of global interoperable common electronic standards would be valuable.

Proposed change:
Use of ePI in both an EU and global context, including other regions than the EU, should also be taken into account. To that, the consistency of a common EU electronic standard with standards implemented for similar purposes in non-EU regions should be sought.

Enter any general comments you may have:

In general, too little consideration is given to existing national solutions and their development up to the transition to a common European platform. It should be noted that the described type of customized ePILs and platforms are already in use in some member states. It should be allowed to continue using and further developing these systems until the common European system is in place. It cannot be in the interest of patients or health care providers that the development of established and well-functioning digital solutions stops.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Abteilung fuer Transfusionsmedizin Klinkum Universitaet Muenchen

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it.

Enter any general comments you may have:

I support all eforts for EPI, if the result is: simplefy all the procedures for all participants in the process, if not don´t do it. Please think about simplefying not complicating the issues

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

F. Hoffmann-La Roche Ltd

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Line 128 Comment: Suggest the change below in order to allow flexibility for other parts of PI to be included and not limit to current SPOR. Proposed change: "…by using existing data of the eg. SPOR".

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 151, lines 156-159 Comment: In case the code is damaged, there is a need of thinking for alternative solutions or a back-up (human readable information with the web-site, such as an URL)
Line 161 Comment: Suggest adding a definition of "platform" in the glossary
Line 179 Comment: In regards to mobile scanning technology, we suggest to put a symbol next to the code (2d or linear) that should be scanned for information, in order to avoid confusion of users in case there are multiple codes on the package.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Lines 190-194 Comment: The 2D code on the outer carton, implemented for the purposes of the Falsified Medicines Directive, should be expanded with an extra data element containing a link to a landing site for ePI. The GTIN (also included in the 2D code) indicates the product, and the phone setting indicates the preferred language. Together, this can direct you to the correct ePI in your preferred language.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Lines 202 - 204, Line 217, Lines 220 - 222 Comment: In case the code is damaged, there is a need of thinking for alternative solutions or a back-up (human readable information with the web-site, such as an URL).
Lines 205-206 Comment: Whether to retain the paper PIL in the package or not should be a national decision. The countries most advanced in access to internet and e-health literacy, could then start implementing ‘ePI only’ before the others, and gather ‘electronic only’ experience as early adopters. Countries can then implement ‘electronic only’ when they are ready.
Lines 208-209 Comment: The reference included in the paper PIL should be directly to the ePI of the product, and should be at least in a human readable URL and preferably in a scannable code.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Lines 220-221 Comment: ePI would offer the opportunity to include additional information such as videos on the use of the medicine which currently seems to be ruled out. This is preventing maximal value generation. In electronic formats the content can be often better transported other than in a printed materials. Therefore exceptions, where the printed and the electronic information are different, should be allowed.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Line 260 Comment: Recommend clarifying use of ePI throughout the assessment process, if electronic structured data is submitted (eg. shall it change the submission process; would it allow for different ways of assessment to be performed, for instance use of algorithms).
Line 267 Comment: Recommend clarifying how will the third parties be validated and for what purposes specifically they can use ePI (to prevent misuse).
Line 285 Comment: Clarify whether for the storage of ePI, the NCAs/EMA are going to store ePI (be hosts).
Line 286 Comment: Clarify whether for the storage of ePI, it implies that there will be a platform/portal developed and by whom.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Line 335 Comment: Ideally we would have only one ePI for all of EEA. All language could be selected by the patients, and not restricted by the local HA. This would be particularly useful for patients using the freedom of movement implemented within the EU.

Enter any general comments you may have:

Roche appreciates the efforts that EMA/HMA/EC are putting in establishing the regulatory framework on the development of standardized solutions for electronic product information, and welcomes the opportunity to provide comments on this document.

As a member of Inter-Association Task Force (IATF) we have provided comments to and are aligned with comments provided by IATF, but we deem it is important to additionally outline key points for your consideration, given our experience, expertise, and current and upcoming engagement on the topic.

We believe that there are two key elements to be emphasized and further detailed and clarified during the next steps of roadmap for implementation development:

1) Establishment of the framework for harmonized solution*
- Strong need to have harmonized solutions; this is a unique opportunity for system to be built up as a global solution that is interoperable; one pathway to start that discussion globally could be through ICMRA
- Roche is already engaged in the activities in ISO, that are developing the use of data carrier to access authorized validated and trustworthy information

2) Establishment of solutions that will address both development of the label and its dissemination
- New technologies are expected to lead to more dynamic data submission process for (dynamic) regulatory assessment;
- New sources of information are providing insights into treatment outcomes (e.g. RWD);
- It would be important that any future ePI system will enable this evolution.

Background

Roche has been driving e-labeling projects across Europe and beyond, and gained specific insights relevant for shaping future policies and framework. Our aim is to strive for a harmonized solution.
Topic of e-labeling and digital labeling is advancing externally in different regions: in addition to the draft key principles for ePI that have been released in EU, discussions are ongoing in international countries (e.g. Singapore, Taiwan, Hong Kong, Brazil) that either drafted or are in process of drafting proposal for regulations, and Roche is participating in pilot projects either alone or with other companies to explore possibilities of advancing the opportunities of e-labeling.

Some of our engagement in European countries include:
- Participation in German “Gebrauchsinformation 4.0“ project
- Participation in GS1 Digital link pilot project in Belgium & Luxemburg
- Ongoing discussion on initiation of pilot project in Norway
- Ongoing discussion on initiation of pilot project in the Netherlands
- Participation in IMI ePIC Health project

In parallel, there are internal projects and initiatives addressing various aspects of the electronic and/or digital information providing to end-users (patients, HCPs etc.) being launched and executed.

As Roche is strategically focused on personalized healthcare (PHC), this topic is being recognized internally as one of the enablers for further roll out of PHC concept, and a step towards not only providing appropriate, adequate and timely information that could lead to improved treatment outcome and better personalized experience to patients, but eventually could support changes in our development programs and ways in how the regulatory submissions and approval processes have been executed.

We would also welcome any opportunity to engage in further discussion on the topic.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

Consultancy

Name of your organisation:

Qdossier

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Question to confirm that e-platforms include mobile health applications? As that will be a key vehicle for PI to actually reach the patient in a user-friendly manner we would like to make sure this is indeed captured.
Row 96: we believe the term structured format should stand out. So suggest to consistently use that throughout the document. In this row we suggest: ePI refers to the structured format of the PI...

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Row 110: suggest to add: ....technical features OF A SEMI-STRUCTURED FORMAT.
Row 123: we believe it should stand out in this description that its the electronic structured format that will allow re-purposing PI for multiple outputs. The latter will enable patients/consumers and healthcare professionals an additional and tailored approach.....
Row 128: instead of SPOR suggest to specifically call it SPOR data management services (as done in row 349). The latter reflects the multiple purposes that using existing SPOR data will have, including the potential of seamless updates of information in multiple document by just making the entry of the update once. If deemed helpful, this advantage of using SPOR data management services could be spelled out .

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Row 172: Suggest to consider a way in which for example mobile applications can add a disclaimer that the information presented comes from regulators approved ePI. Some certificate/stamp like that will allow patients (and other users of the info) to easily detect whether the info they read comes from a trusted source. Implementing something like this, will also require raising awareness of the use and existence of such a certificate/logo/stamp, so that people learn to recognize it.
Row 179: to be speficically mentioned that the intention is not to add an additional 2D barcode, but to integrate the info into the already existing 2D barcode which is included following the falsifiend medicines legislation.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

General comment: Besides accessibility we believe supporting user-friendly dissemination of information is another key principle which should be further explained in this (or a seperate) section.

Ideally patients have one (digital) go-to place to for example do their performance based tests (in support of RWD collection, where applicable), set reminders for when to take medication, track use of medication (for adherence purposes), find instructions for use, info one side effects AND to report ADRs or connect to a medical information service of the respective product. Ideally such apps would not be product specific, but focused on overall disease management (therefore making reference to relevant PI of all products the respective patients use).

ePI is not going to address all of the above, but it facilitates it by enabling mobile app providers to include the continously up to date PI in these applications which would enable personalized patient views of the latest approved info for all products relevant to them and to automatically send warnings in case of for example contra-indications. So it can be a push-and pull communication.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Row 217: in additional to the paper PL including a statement that the most up to date version can be found in the ePI, any other outputs should also include a statement that the full information about the product can be found in the ePI (e.g. when a patient is using an app which is already personalized and therefore missing certain pieces of information). Even though the missing information should not be directly applicable to that patient, he/she should be able to locate the full set of info available.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

No comment

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

348: under the future European medicines web portal we suggest to specifically mention 'including the EMA application form'. We believe there is a huge time-saving potential (which will also result in more consistency) if data fields to be entered in the application form are automatically generated and believe this ePI project relates to that. Furthermore, we suggest to also mention FMD, EMVS and consider EudraCT

Enter any general comments you may have:

We believe the word 'structured' should stand out more. For example in the background, row 64. The electronic STRUCTURED format is the most pressing priority.....
We believe the document could put some more emphasis on what is in it for industry and regulators (especially because it is not going to be mandatory). Reason being that we believe ePI offers a great potential for industry and regulators to improve and speed up internal business processes and decreases risks of errors and/or inconsistencies in product information (e.g. in the review process of updated PI, as already outlined in the document). a solution like this is a win win for all parties involved.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- European Institution
- EU agency
- Non-EU regulatory authority

◉ Other

If other, please specify:

European Industry Association representing medical gases producers and distributors

Name of your organisation:

European Industrial Gases Association

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

EIGA's members note the contents of Articles 58, 59 and 62 of Directive 2001/83/EC and support this joint EMA-HMA-EC collaboration document on electronic product information. EIGA proposes an exemption to the Article 58 due to the unique characteristics of medicinal gases.

EIGA would like to propose for the implementation of ePILs for medicinal gases instead of attaching paper leaflets to every medicinal gas package:

• For medicinal gases used by patients at home, the most effective way of providing the information contained within the PIL is when patients receive their training for the safe use of the medicinal gas packages.
Having trained patients and provided them with a paper version of the PIL for reference, there is no requirement to provide any further PILs with replacement packages.
• Where medicinal gases are used in hospitals and other healthcare facilities, the patient would not have access to the PIL if it were attached to the medicinal gas package. The most effective way of distributing the information in the PIL so that it is available to the patient is to provide the healthcare facility with an electronic version of the PIL so that it can be provided to the patient should it be requested. This method is particularly relevant where the medicinal gas is delivered via a medical gas pipeline system.
Having an electronic version of the PIL allows the healthcare facility to print a current version for the patient should it be required.

The conclusion of EIGA is that there are no benefits of providing a paper copy of the PIL attached to every medicinal gas package.

Enter any general comments you may have:

EIGA's members note the contents of Articles 58, 59 and 62 of Directive 2001/83/EC and support this joint EMA-HMA-EC collaboration document on electronic product information. EIGA proposes an exemption to the Article 58 due to the unique characteristics of medicinal gases.

EIGA would like to propose the implementation of ePILs for medicinal gases instead of attaching paper leaflets to every medicinal gas package:

A number of national authorities including Denmark, Ireland, Netherlands, Sweden, Switzerland and United Kingdom have already accepted the implementation of the basic principles of using an ePIL instead of attaching paper leaflets to every medicinal gas package.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- European Institution
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- (●) Other

If other, please specify:

Services Provider for Pharmaceutical Industry

Name of your organisation:

ProductLife Group

Indicate the key principle you would like to comment on (select all that apply):

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- [x] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

269-277 How EMA/NCAs would cross-check the information of the converted ePI against the source PI document(s)?

269-277 CAPs and NAPs approved via MRP/DCP have the same scientific content approved: it could be possible to get the translation in French of a product bought in Bulgaria, the system should be able to go back itself to the same product in France (if marketed also in France) thanks to the EU Presentation number for CP or the MRP/DCP number.

282 It could be more efficient and safe to get at least the Product Master Data from PMS directly as the submitted information through CESP would then be approved during the procedure providing the PMS Target Operating Model is implemented.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

349 SPOR, particularly PMS could be used as the basis for ePI as PMS will provide the link between Medicinal Products and PI documents, so ePI should take the opportunity to benefit from this foundation and be "anchored" to PMS using the same MPIDs.

Enter any general comments you may have:

This ePI initiative reinforces the needs to have PI documents written in Compliance to Standards from the initial version. If the PI documents in PDFs are already written in compliance to standards, the conversion to ePI would be even more quick and reliable.

PI document templates: templates should include, in addition to the name, RMS Term ID, ORG & LOC ID (for the MAH) and the future SMS ID to ensure a proper integration to SPOR. This would push Industry to have a closer look on local SmPCs of the same global product where sometimes the translation leads to a different Pharmacautical Form for example.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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[redacted]

Your email

[redacted]

You are a:

- Member of the public
- Patient/consumer
- Patient/consumer organisation
- Healthcare professional
- Healthcare professional organisation
- Academic
- Media
- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

drug database and drug therapy safety software vendor

Name of your organisation:

ifap Service-Institut für Ärzte und Apotheker GmbH

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [ ] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

We think it is a very good idea to harmonize and regulate format and content of ePI for human medical products.
Most important is the requirement of ePI to be in a structured form instead of unstructured formats such as PDF, as is the norm currently.

The data should (preferably) be in a structured format (e.g. JSON) or at least in form of a parse able text in addition to a plain text version. It must contain a versioning system (preferably strictly ascending numbers) and the date of its last change.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

We think it is inevitable to not only specify the ePI's structure and format, but to also require a minimum set of required content, as they are necessary for interoperability.

As a minimum, a structured (ePI) version of SmPCs must include the following information (as "controlled vocabularies"):

* structured data for divisibility and release properties
* standardized dictionary for pharmaceutical forms curated by EMA (instead of "invent your own pharmaceutical form" (Darreichungsform) where pharmaceutical companies can freely invent "new" pharmaceutical forms only needing to register them, as is currently the situation in Germany).
* qualitative and quantitative composition:
** along the lines of cosmetics and food products
** enforce usage of INN / INNM for "active ingredients" and "other active ingredients" (in addition to whatever local name the manufacturer wants to use)
(already suggested in guideline on SmPC (Guideline-EMEA/379462/2008))
** stop the confusion of pure substance vs. salt/ester vs. incl. crystal water and enforce the recommendations given in Guideline on SmPC (Guideline-EMEA/379462/2008), link https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf) without allowing exceptions (remove last sentence from page 4).
** the quantity of a salt or an ester may be given in addition to the quantity of the active moiety.
* a complete list of products described in a SmPC (each product name with its marketing authorisation number)

Preferably, the following information should be included in a structured form as well:

* reference quantity and unit stated clearly and separately from active substances and other active substances
* application path, location, form stated clearly and separately at the beginning of a section
* indications and contraindications should (additionally) be stated as ICD 10-codes
* a statement for dosage adjustment in renal failure should be mandatory; national kidney foundation CKD stages' cut-off values (1,2,3a,3b,4,5) should be used, NOT arbitrary cut-off-values like "GFR <50ml/min"
* a statement about dosage adjustment in reduced liver function based on Child-Pugh score

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Regarding the publication of ePIs, we think it is necessary to force pharmaceutical companies to publish them at Competent Authorities' systems (e.g. BfArM database (PharmBundNet) in Germany) and require these systems to be publicly and freely accessible.
The current situation in Germany is quite unsatisfactory: While there is a website, operated by the german NCA (BfArM) and german law gives BfArM the authority to enforce publication of SmPCs on their site, they chose not to do so, resulting in a very incomplete database.

If an ePI is updated, changes / updates should be highlighted in a consistent way.

Updates of ePIs / SmPCs should be distributed in a timely manner, and this requirement should be sanctioned by authorities.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

> We agree with the proposed statement, but we think it is necessary that some end date is defined, even if it is many years in the future (e.g. 10 years).

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

Brightpharma is a collaboration between key experts and companies with extensive global scientific and operational backgrounds in pharmacy (community as well as industry), knowledge modeling, project management, standardization, (digital) healthcare and innovation.
Closely connected to all global major pharmaceutical networks and federations and with standardization bodies such as the Object Management Group (OMG) and ISO.
Our mission is to facilitate pharmaceutical innovation to create sustainable and maximal medication impact.

Name of your organisation:

brightpharma

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [ ] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Lines
86-88
Comment
Not only should ePI be authorised and statutory, it should, for all stakeholders, be the de facto “single point of truth” for all information carriers on drug information (digital and non- digital). This means that information about the product should be directly derived from the ePI in order to be classified as valid and trusted information.
Rationale
If we want to reap the benefits of the digital revolution in healthcare and life sciences, it is a necessity that there is a single point of truth for medicinal product information that is structured, standardised and authorised. The ePI is an ideal output from a single point of truth drug information platform.
Proposed change
Add a sentence to the definition of ePI, identifying the ePI as the single point of truth for authorised information about a medicinal product.
Lines
91-93
Comment
We agree with the choice for a semi-structured format. However, the statement that “ePI refers to the structure of the PI and not its content” does not reflect our view that an ePI approach can and should facilitate standardisation of terminology of content as well.
Rationale
It would be over-ambitious to attempt to predefine a structure and a list of possible values for every single element of PI and therefore a semi-structured format seems very sensible. Some pieces of PI however, are very much subject to standardisation in terms of both structure and content and ePI should facilitate in providing this information in a standardised manner as well.
For example: in the EMA’s guidelines on SmPCs, in the part on ability to drive and use machines, it is clearly stated that PI should “specify whether the medicinal product has a) no or negligible influence b) minor influence, c) moderate influence or d) major influence on these abilities.” This means that the ePI in this case should have a ‘influence on ability to drive and use machines -field’ restricted to the possible values: ‘no or negligible influence’, ‘minor influence’, ‘moderate influence’ and ‘major influence’. An unstructured ‘free text’ field can then be used in order to provide additional information or a description of the studies and/or reported adverse reactions.
It would take relatively little effort and provide great advantages for automatically providing relevant information to the relevant audience if the ePI concept were to aim to structure the contents of at least these kinds of ‘low hanging fruits’. If ePI would merely structure the PI into sections and would not standardise any content itself, it would not fully optimise the application of structured data.
Proposed change
Further specify which information is structured in which way in the key principle text while providing some examples for this as well.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Lines
110-112
Comment
Just making ePI a technical standard, does not add sufficient value to stakeholders.
Rationale
What is needed by the stakeholders is a common conceptual and semantic framework to receive or publish PI in any format required. Standardisation into one technical standard (or even multiple inter-operable technical standards) is needed, but first and foremost a common structure for PI is required, which carries the same semantic value to every stakeholder. The way that this structured information can technically be transferred from one stakeholder to another should follow from the model of the necessary information, not the other way around. One cannot have consistent and structured ePI without consistent and structured PI.
Proposed change
Extend the definition to cover not just technical aspects, but also a formal standardised semantic model for the content of PI.
Lines
135-137
Comment
Involvement of all types of stakeholders is desirable, not just competent authorities.
Rationale
Of course it is of great importance that the standard “fulfils the requirements outlined in the key principles and is compatible with use at centralised and 136 national (through national competent authorities [NCA]) levels.” However, it should also fit the needs of the pharmaceutical ecosystem and its primary stakeholders. The Marketing Authorisation holders (MAH) are responsible for providing input for ePI in the first place. But primary stakeholders like for example patients/consumers, healthcare professionals (HCP) and academia should be able to integrate their views into the new concept of ePI. Therefore, the system would benefit from all parties being involved in some way in the development of the standard.
Proposed change
Mention the involvement of all relevant stakeholders in the text.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Lines
152-153
Comment
ePI is a prerequisite for dissemination of the right information to the right patient/consumer, but not the only one.
Rationale
Although machine readable and structured data is a prerequisite for automated support systems bringing the right information to the right people at the right moment, it should be noted that the context in which this information is needed should also be formally modelled in order to do so. If the ePI has, for example, a machine readable indication of a patient group for which the medicinal product is contraindicated, then - in order to deliver this information to the right patient/consumer or healthcare professional - there should also be an inter-operable standard in the connected system (e.g. a treatment support system in a hospital) specifying which patients are linked to this category.
Proposed change
Specify at which points the ePI will be interoperable with other standards in order to support better delivery of information.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Lines
214-216
Comment
ePI is the electronically exchangeable version of PI and the PL is part of PI. It would therefore make sense to derive the PL directly from the ePI, instead of generating ePI in addition of the PL.
Rationale
ePI is the machine readable, structured version of PI. If this is the case then logically any information in the PL must also be present in the ePI, because PL is part of the PI. In other words: PL is a subset of PI, which is a subset of ePI.
Therefore, it would be most convenient and safe to generate a PL directly out of the ePI. In this way, there can never be an inconsistency between ePI and a PL. In the case that a certain party wishes to comply only to the mandatory PL, they can simply create a PL manually.
In other words: so far paper PLs are mandatory and providing ePI is optional, but when ePI is provided the PL should be directly derived from ePI.
Proposed change
Change the phrase “ePI generation will be performed in addition to the current inclusion of the PL in the medicine package” to “The use of ePI will be a recommended innovation; however it is not mandatory. When ePI is provided, the PL should be derived from ePI.”

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Lines
278
Comment
To maximize the diversification and usefulness of services for the patients/HCPs on the right hand side of this diagram, the trusted source in the centre should contain as much structured data as possible. To maximize the structured data in the trusted source, structuring the data should be shifted left as much as possible.
Rationale
If the data in the structured source is structured an standardised where possible, third-parties such as companies, not-for-profit organisations or patient/consumer groups are enabled and empowered to create reliable services for the end-users (patients/HCPs).
It also facilitates different stakeholders to develop innovations and setup connectivity with applications for hospital systems as well as applications for home virtual assistant systems like Alexa or Siri.
However, once the bulk of conversion to structured data is to be manually performed by the MAHs just before publishing the ePI, it is not likely that much data can be structured as this is a labor intensive, expensive and error sensitive process.
Therefore, in order to work with structured data as cleanly and easily as possible, the MAH should also be able to provide the EMA/NCA with as much structured data as possible without having to go through error sensitive conversions. In addition, the costs and errors in the approval process for both the EMA/NCA and the MAH can be minimized in this way.
Proposed change
Time spent developing the applicability or compatibility for inter-operability with other standards of ePI standard on the left side of the diagram, can yield great results in the success on the right hand side. It Is advised to look beyond (or rather, before) the publishing aspect of ePI in order to ensure its success.

Enter any general comments you may have:

> Please express some context with regards to the common standard. There is a huge variety of ecosystem partners to which ePI will have to connect. The bigger picture seems currently to be missing from the principles.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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Your email

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- Academic
- Media
- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (●) Other

If other, please specify:

Information design and user testing consultancy

Name of your organisation:

Consumation Ltd

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [ ] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Enter any general comments you may have:

We are supportive of the submission made by Prof Dr Karel van der Waarde, which he has shared with us and which we have commented on. In particular, we support the creation of a set of standards which address fundamental principles of medicines information: urgent issues such as prescribing errors, dispensing errors, medicines adherence, and sustainability. While digital standards are important, a broader and deeper review of the role of product information in promoting public health.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: 967c410a-4f08-4162-8c5b-4cf8fec839e7
Date: 03/04/2019 15:38:41

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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Your name

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- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Enter any general comments you may have:

I, as a patient and a member of the public, point blank refuse to download any apps that involve scanning data etc onto my phone. I believe the world has become too technology orientated and encouraged to stare at our phones too much (I may be in the minority here). Plus, having been a victim of fraud, it is just yet another thing waiting to be hacked

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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Your name

[redacted] (representing consolidated comments from NCAs: Finland, Iceland, Norway, Sweden)

Your email

[redacted]

You are a:

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- ○ Patient/consumer organisation
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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Finnish Medicines Agency, Icelandic Medicines Agency, Norwegian Medicines Agency, Swedish Medical Products Agency

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

- The same technical solution should be implemented for both HUM and VET ePI's, however the agreed ePI structure might be different.
- The scope of ePI should include patient- and HCP information that is a part of an RMP. This is information that is of special importance for patients and HCP and should therefore also be made more accessible as part of the ePI initiative (line 86).
- An important added value for structured electronic information is that it may easily be linked to other relevant information such as technical instruction videos that demonstrate correct handling of inhalers, injectors etc. and or disease related information to provide tailored information service to patients (line 88).
- An important added value for structured electronic information is that it may be used to provide relevant information to other systems/sources such as internal data bases for instructions to printing companies, internal core texts (line 88).
- To avoid ambiguity of information and duplication of work, implementation of controlled vocabularies into ePI should follow the successful implementation of controlled vocabularies into the regulatory process (lines 90-96, 110-111 and 138-140).
- To avoid duplication of work and decentralized copies of the same ePI, the EMA should be "first mover", ensuring uniform access to ePI and a "once over" process for industry for conversion to ePI for centrally authorized products (CP). The foreseen scenarios would then be some member states only having access to ePI for CP, while others may have access to all or some ePI for the other products authorized in that member state. NCAs may in such a scenario choose to prioritize the implementation of ePI for the most used medicinal products to ensure that these have available ePI. For ePI to be of use at the national level, the most commonly used products must have available ePI. The mostly used products in all member states are generic medicines. The ePI Roadmap must take into consideration that a high availability of ePI for generic medicines is needed if ePI is to be of real use for patients and HCP (lines 288-323).

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

- The aims of the common standard will not fully be achieved unless there is a high up-take in the use of the standard by EMA and NCAs. A ePI roadmap that facilitates a high and fast uptake of the standard across the network is essential to the success of the common standard (line 174-175).
- A common exchange format (API, FHIR-profiles) should be included in the standard in order to facilitate use of PI originating from different sources (eg. EMA, other NCAs). Therefore the implementation of a common exchange format should be addressed in ePI roadmap. (lines 174-177, 263-268 and 284-287).

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

•An added benefit of ePI may be easier access to the relevant ePIL when products in foreign packaging are being dispensed to remedy a supply shortages. (lines 152-153). ePI also facilitates that patients more easily may access the information in the PL before they have their prescriptions filled.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

•An added benefit of ePI may be easier access to the relevant ePIL when products in foreign packaging are being dispensed to remedy a supply shortages. (lines 152-153). ePI also facilitates that patients more easily may access the information in the PL before they have their prescriptions filled.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Allowing flexibility should not allow differences in accessing PI originating from different sources (eg. EMA, other NCAs):

- The aims of the common standard will not fully be achieved unless there is a high up-take in the use of the standard by EMA and NCAs. A ePI roadmap that facilitates a high and fast uptake of the standard across the network is essential to the success of the common standard (line 174-175).
- A common exchange format (API, FHIR-profiles) should be included in the standard in order to facilitate use of PI originating from different sources (eg. EMA, other NCAs). Therefore the implementation of a common exchange format should be addressed in ePI roadmap. (lines 174-177, 263-268 and 284-287).

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

•An added benefit of ePI may be easier access to the relevant ePIL when products in foreign packaging are being dispensed to remedy a supply shortages. (lines 152-153). ePI also facilitates that patients more easily may access the information in the PL before they have their prescriptions filled.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

•Strongly agreed that ePI will interface and interact with eHealth initiatives (SPOR, CESP, eAF etc).

Enter any general comments you may have:

- Our overall view is positive to a well written document describing the way to reach a common ePI model in EU. ePI will open possibilities to better accessibility of the product information.
- From the document it is not quite clear if the outcome is only an agreed data structure or common portal for ePI management.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Freelance regulatory consultant

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Comments concern lines 89 -96 of the draft key principles document.
The text mentions the following:
-semi structured format suitable for electronic handling
-unstructured formats e.g. pdfs
-structured elements e.g. fixed headings and vocabularies
-unstructured elements e.g free text

Having read the text several times, it is not very clear what all of this terminology actually means. Perhaps at the next draft, further clarification text could be added so that the reader is left in no doubt about what each of the terms mean. It seems that the sentence in line 96 is the most important sentence as it clarifies that ePI refers to structure and not content. Perhaps this needs to be clarified at the beginning of the document as the reader might easily understand ePI to mean content rather than structure.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

The comments here concern lines 202 - 206.

Clearly, the intention is still to maintain the paper version of a leaflet in the pack.
Is/are there a compelling argument(s) to maintain this paper version or is it time to think about moving away completely from the paper based version? Patients could easily access a leaflet via e.g. a QR code on the pack or other suitable means. For those patients that are unable to access a leaflet electronically, they could ask their pharmacist to print them a copy.

Some potential advantages of moving away from a paper based version are:
-An environmental benefit as it would avoid millions of leaflets being made available in packs, only to be read once or never and be thrown away. Enough basic research is available on how leaflets are used once patients receive them in medicine packs. Further research can be undertaken as necessary to anser very relevant and basic questions.
-A huge resource saving in terms of time and money (e.g. very expensive product recalls because there is an error in a leaflet) that could be allocated to much more important areas of health care where such resources are desperately required to resolve basic healthcare problems.

In the internet age, the status quo of maintaining patient copies of leaflets in packs must be challenged vigorously and other suitable equivalent alternatives sought.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: 3341f72b-689b-477c-a8d6-c5e42c6978a6
Date: 03/07/2019 12:06:08

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ Member of the public
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- ○ Patient/consumer organisation
- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ◉ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Graviti Pharmaceuticals Private Limited

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Enter any general comments you may have:

ePI is a good idea but how its going to be monitored in the member states as maximum member states having different languages.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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Name of your organisation:

DRA Consulting Oy

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
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- ☑ 2.2 Accessibility
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- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Comments to rows 178-182: Batch-specific ePI is a good idea but in practise extremely difficult to execute. Companies should set up additional communication models to ensure that information is distributed from production site to the department responsible for update of the ePI database. It is also unsure how patients are able to utilise this function. Quite often batch number details are printed in such small font that it is impossible to read for elderly. Separate 2D barcode for correct ePI might be solution, but difficult to execute due to space restrictions in the smaller packages.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Comment to rows 192-193: Does the rights for the original text still remain in the company of third-parties have access and rights to convert the ePI into different formats? Who is responsible that the information in third-party databases or mobile apps is correct if third-party modifies the ePI?

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Comment to rows 220-222: It is mentioned that the content of ePI should be identical to the latest version of the PI approved by regulatory authorities. This is contradictory to the batch specific ePI which is discssed in rows 179-182. In case there is a remarkable change in the medicinal product (for example change in container), it would be better not to release the updated ePI version until the applicable batches are released.

Comment to row 223: If ePI is published as open data which is freely accessible for use and reuse, is it allowed for third-parties to use it for their own commercial purposes?

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Comment to rows 259-262: The eventual goal to use the ePI format from the point of submission throughout the evaluation process in regulatory applications is fine, as it will facilitate version management of PI by applicants and authorities and there would be no delays in publishing new PI. However, there needs to be clear approach also in the short to medium term by regulatory authorities in each Member State level and the principles in implementation of ePI in each Member State should be similar. Regulatory authorities in all Member States should be stressed to implement ePI as a part of scientific evaluation. If authorities in Member States don't have similar models, the roles, e.g. responsibility for conversion from PI to ePI, may be unclear for each party.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Comment to rows 313-318: The use of ePI will not be mandatory since current legislation does not require the use of an electronic version of PI. For SME (micro, small or medium-sized enterprises) there should not be any unreasonable burden due to implementation and maintenance of ePI. On the other hand, there is a risk that ePI will not be implemented by majority of companies unless it is mandatory. Clear implementation timelines could ensure the effective progress of this useful initiative.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

It should be taken into account that assessment timelines for different national competent authorities vary a lot and therefore all language versions may not be identical for nationally authorised products at all times. Further, the PI for products with purely national MAs but having the same trade name might not be harmonised to begin with. If in these cases harmonisation of PI would be required, that would add the financial burden to MAHs.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

It would be very useful feature within the ePI database to publish also up-to-date information about availability of medicines in each member state. Open and on-line information about shortages of medicines would create benefit for all parties in healthcare; patients, healthcare professionals (physicians, nurses, pharmacies), pharmaceutical companies and authorities. According to ePI workshop materials, this feature is already in use in Fellesgatalogen (Norway) and Fass (Sweden).

It would be very useful add a possibility for patient to report adverse events via ePI database. There could be a link to the electronic reporting system in connection with ePI.

Also it would be useful to combine all authority approved materials, e.g. DHPC letters and risk minimisation materials to ePI.

Enter any general comments you may have:

General comment #1:

Although the implementation timelines for the printed package leaflet are purely national issue, we wish that national competent authorities would lighten the strict implementation timelines for the printed package leaflets. That could be executed by adding a reference to the printed package leaflet that electronic package leaflet version is available (example Denmark). Strict implementation timelines (next batch release) lead often to destruction of already printed packaging materials.

General comment #2:

It should be taken into account that financial burden from this initiative can be too much for smaller companies. That could lead to termination of the marketing authorisations. Therefore we wish that financial model would be fair also for smaller companies / marketing authorisation holders in case ePI would cause direct costs to companies.

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Introduction

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- ○ Other

Name of your organisation:

Ministry of Health

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

In general, common standard for ePI streamlines the process for the registration of medicines. By this many technical barriers are removed or lowered which should support broader public access to medicines. This is especially important for smaller markets as Iceland where even though medicine has marketing authorisation it is not marketed as it is seen too expensive to meet local language requirements and adaptations. Iceland has only 40% rate of availability of medicines in Europe according to EFPIA report 2019. The ePI should furthermore support lower barrier of trade and therefore more continuous supply of product to the market. ePI could also make it easier to carry out joint tenders and purchasing of medicines for two or more countries which also supports steady supply and more reasonable price for smaller markets.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Information about medicines are more and more integrated in computer prescribing systems and patients' records used on daily basis by health care professionals. These information's are now also integrated in patient's online platform where they communicate with health care professionals, order renewal of prescriptions or look at their medical history. Having access to always the newest information is without a doubt improved safety for public health. Orphan medicines - ePI especially ePIL makes access to orphan medicines easier, in particular smaller markets where it is too expensive to put paper leaflets in the national language into medicine packages for a small number of patients with rare diseases.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Being stuck with article 58 of Directive 2001/83/EC seem in many ways outdated situation. One could argue this for several reasons. 1. Electronic access is safer, up to date and environmentally friendly way of communicating medicine information. 2. Being obligated to put in paper leaflet is a marketing hinderance especially for smaller markets. 3. All medicines are packed with patient leaflet in one or more language. There is no need to remove it to put in local language and e-PIL for local use is in many cases enough. If one must choose of not having access to the medicine due to paper patient information leaflet requirements vs. having the medicine with e-PIL the choice become obvious.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Multilingual ePI is of great and increased importance. The flow of work force in Europe where people stay in countries for longer periods makes is necessary to have important information on their medication accessible in language of their preference.

Enter any general comments you may have:

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- ○ Other

Name of your organisation:

ADVANZ PHARMA

Indicate the key principle you would like to comment on (select all that apply):

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- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
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- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Lines 127-129 makes only a mention of the SPOR process as a means of simplifying the regulatory process. This is my opinion is misguided as an aim as there is a significant number of ways in which the labelling submission-review-approval process could be simplified without even bringing SPOR into the equation, for example:

1. Comparison of current and previous versions
2. Targeted review of only the updated sections of the PI
3. Using MD5 as a means of assuring there are no discrepancies between approved and published PI
4. Potential for collaborative review/approval of changes at the HA level

I firmly believe that the procedural benefits that ePI could bring should be one of the key principles as a means of focusing on the best possible solutions and encouraging more widespread adoption of an ePI standard.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Line 217: There would need to be ways to ensure that the correct ePI is accessed - which will not always be the latest version e.g. where the formulation has changed.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Lines 269-271: The expectation that the MAH should generate the ePI from the using a conversion tool introduces scope for inconsistency and error. In my opinion there should be no "Conversion to ePI" stage (Line 293) at all.

Figure 1 (Line 278): this process appears to propose parallel evaluation of the Word/PDF and ePI versions of the PI. This is not an ideal process since it will effectively double the workload of the EMA/NCA and introduce potential discrepancies between versions. A much better solution in my opinion would be to work towards the aim of creating the PDF PI from the approved ePI (in reverse to the proposed model as described).

Enter any general comments you may have:

This is in my opinion a great opportunity to simplify and improve the PI submission, review and approval processes, and it should definitely be treated as a priority for the project in order to increase engagement with industry at an early stage.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

Trade Association

Name of your organisation:

Associazione Farmaceutici Industria (AFI)

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Line 104: we suggest to better clarify that ePI will not replace the paper version of the PL in medicinal product packaging. The text reported at line 202 could be added also here [ePI will not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of Directive 2001/83/EC1) to include a PL in the packaging of all medicines or directly convey all information required (by Articles 59 and 62 of the Directive) on the outer or immediate packaging].

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Line 110: A simplification of the current QRD template should be considered in order to simplify the structure with the aim of guarantee a better understanding and compliance of HCPs and patients.

In addition, the QRD template should include a clear reference to standard vocabularies (such as MedDRA, etc.) and appendix with standard statements (such as statements on pregnancy, excipients etc.).
This will guarantee an overlapping of certain standard information across PI of different medicines and will allow HCPs and patients to seek specific information in PI of different medicines, for example to identify the correct medicine for a patient with specific needs (example Seeking lactose free medicine as outlined in the Electronic product information for medicines in the EU Report from an EMA–HMA–EC workshop held on 28 November 2018).

The QRD template should also contain a reference to the ePI including detailed link to the platform and an explanation to help patients to recognize the latest version.
ePI information might be included on the pack, for example in the data matrix for serialization if technically possible.

Also the update of other applicable guidelines should be considered.

Line 129: Proposed change, addition of “to enhance their digitisation” after “both for regulators and the pharmaceutical industry”.

Line 135: The system should be compatible not only through national competent authority levels but also with other national official systems already in place.
Proposal change to the text, addition of “and other national official systems” after “centralised and national (through national competent authorities [NCA]”.
The first step and pre-requisite for ePI implementation is the agreement of a common standard that fulfils the requirements outlined in the key principles and is compatible with use at centralised and national (through national competent authorities [NCA] and other national official systems) levels.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 149: In addition, ePI advantages listed from 149, the following can be considered:

- provision of alert in case of safety and/or quality issues that lead to product recalls
- ePI can beneficial to special patient categories like blind or partially sighted people
- availability of multilingual PL for foreign people
- availability of tools (such as regulatory-approved apps, videos etc) on different topics relevant for both HCP and patient (video on administration, management of adverse event etc.)
- availability of regulatory-approved educational materials for both HCP and patient

Line 160: It should be clarified that the main source of ePI should be unique, at centralized level.
The ePI could be available on different local platforms linked to the official source but no copies of ePI should be created by third parties and made available as standalone document on their own platforms. This aims to avoid the dissemination of superseded versions of ePI on different platforms.

Line 170: Efforts should be made to limit the availability of unofficial sources of product information and create public awareness on ePI project as unique source of trusted information.

Line 180: “Correct ePI depends on the medicine batch: some parts of the ePI may be applicable to all batches and some only to specific batches (e.g. when excipients change). Therefore the need for the correct ePI to be supplied for the medicine batch should be taken into consideration.”

This functionally should be better clarified with additional example of the applicability of batch-specific ePI and the system should be developed to address this need and a unique way of managing this particular aspect should be identified.
For example, in the future a link between ePI platform and the serialization/traceability systems could be considered to address this need.

Proposed change: addition of “in a user-friendly way in order to easily match the traditional (paper) PL and the corresponding electronic PL” after “medicine batch should be taken into consideration.”

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Line 185: in addition to audible formats, other interactive systems and artificial intelligence (example chat-box) should be considered to help patients and even HCPs to easily find specific information in ePI.

Proposed change: Addition of “ePI should be supported also by all software and mobile operating system (even the oldest ones) if it possible.” After “and those with low literacy levels (e.g. audible formats).”

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Line 202: Despite the current legislation requires paper PL to be mandatory, there could be situations where paper PL could be easily replaced by ePI, such as cases where patients don't have direct access to the medicinal pack (hospital or injectable medicine). In these cases, paper PL might be avoided but a reference to the electronic PL should be mentioned on the medicinal pack. For this kind of medicines, medicinal packs might contain only the instruction for use for healthcare professionals, if applicable.

Line 215: The project is considered as a recommended innovation and not mandatory.
However in order to have an harmonized situation in all EU countries, a specific timeline and a common implementation approach should be define to guarantee the roll out of ePI in all EU countries within a specific timeframe (definition of a roadmap like what was done for eCTD) and structure.
This will guarantee that across EU, all HCPs and patients have the same rights to access the same regulatory-approved and the latest version of product information.

Proposed change to the text:
The use of ePI will be a recommended innovation; however it is not mandatory at the moment. EU Commission, through HMA and EMA, will cascade a specific roadmap for the implementation in all EU countries.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

Line 227: promotional contents should be avoided however other kind of contents previously approved by regulatory HA should be made available if beneficial for patients and HCPs (example educational materials).

Proposed change to the text: Accordingly, no additional information containing promotional contents can be included in the ePI; other not promotional contents previously approved by regulatory HA could be made available if beneficial for patients and HCPs (example educational materials).

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Line 265: the availability of many different electronic systems and platforms for health records, prescribing and dispensing medicines should be take into consideration defining the functionalities and structure of ePI systems in order to guarantee the compatibility of ePI system with the majority of the existing electronic systems and platforms for health records, prescribing and dispensing medicines.

Line 267: The use of ePI by third parties should be limited to the link to official centralized ePI platform to ensure that the correct ePI is made available for a specific medicine.
Third parties should use ePI available in the centralized ePI platform as source; a direct link from third party platform to the ePI official platform should be created.
Third parties should not be allowed to create copies of ePI and make them available as standalone document on their own platforms. This aims to avoid the availability of no updated copies of ePI on different platforms.

In addition, in the third party platforms and also in the official centralized ePI platform, a warning should be included to inform patients and HCP that ePI should always been consulted online in the official ePI portal and it shouldn't be downloaded, in order to avoid the consultation of superseded versions.

The official centralized ePI platform and/or the third parties platforms should include the possibility for patients and HCP to decide to receive notifications on the availability of update versions of the ePI for specific medicinal products, like RSS feed.

Line 269: Figure 1 - a specific timeline to make the ePI available on the ePI platform should be defined.

Line 285: the creation of an European medicines web portal as a central point for access of ePI for all centrally and nationally authorised medicines would represent the best option to guarantee a common and unique way to implement the project also at local level. The creation of national websites for ePI should be avoided.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Linea 306: the creation of an European medicines web portal as a central point for access of ePI for all centrally and nationally authorised medicines would represent the best option to reduce financial and other kind of burden for MS and companies.

Line 313: the decision on how to implement the ePI should not be demanded to local HA in order to avoid inconsistent approaches through EU countries and creation of local specific requirements different among each EU countries.
In addition, to facilitate the management of changes to PI during regulatory procedures, PI should be converted to ePI format only once the evaluation process has been finalised.

Enter any general comments you may have:

The project is considered as a recommended innovation and not mandatory.
However in order to have an harmonized situation in all EU countries, a specific timeline and a common implementation approach should be defined to guarantee the roll out of ePI in all EU countries within a specific timeframe (definition of a roadmap like what was done for eCTD) and structure.
This will guarantee that across EU, all HCPs and patients have the same rights to access the same regulatory-approved and latest version of product information.

In addition, this new project should not represent a new workload and a financial burden for marketing authorization holders.
Moreover, similar systems already available in some countries should be withdrawn in order to avoid duplications.

Public awareness should be created on ePI project in order to spread the information of the availability of a new source of official information to HCPs and patients, for example through media advertisement commonly created at European level.

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Name of your organisation:

Hospital General Universitario Alicante

Indicate the key principle you would like to comment on (select all that apply):

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- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
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- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Enter any general comments you may have:

In the leaflets and technical sheets of the drugs references are made to clinical trials that almost never specify the bibliographic reference, which I consider should be included. Likewise, it should be specified which clinical trials are the ones that give rise to the approval of the use of the medication by the regulatory agencies. The way in which documents are currently produced without bibliographical references makes that physcicians and prescribers are left at the expense of the information conveniently sent to us by the pharma industry, if it comes to us.

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- Patient/consumer organisation
- Healthcare professional
- Healthcare professional organisation
- Academic
- Media
- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

We are a company that translates text into sign language to make it accessible for deaf people

Name of your organisation:

Sign Time GmbH

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

There are around 500,000 deaf people in Europe (Source: European Commission). Deaf people have poor text comprehension skills. Their mother “tongue” are sign languages, which are NOT a sign transcription of languages of the hearing, but a complete other way to communicate. To make information accessible for deaf people you have to translate it into sign language. We strongly recommend translating the package leaflets for medicines into sign language.
We know it's expensive. Our company has developed an avatar system for machine translation into sign language, with which these translations can be carried out much more cost-effectively.

Enter any general comments you may have:

Here are some examples of what an instruction leaflet in animated sign language might look like (German or Austrian sign language): https://vimeo.com/album/5906706
For any questions pleas contact me.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Ferring Pharmaceuticals

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

I am thinking that if an app exists gathering all PI in a digital manner like Google Primer (to ensure understanding) it will help adherence and increase

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

With smartpackaging, we can scan a box and ensure we could link a patient or a caregiver to an information online that is presented in a nice way

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

Because of the box being scanned, we can avoid having personal data but if needed (for extra services provided by the pharma company, we could put in an EMA regulated blockchain the patient data.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Because of the geolocalisation of the browser or device, we can ensure the PI is pushed in the right language

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Because it is digital, we can ensure the distribution of the PI to all devices (access by whatsapp, sms, email...)

Enter any general comments you may have:

> I am personally happy to support the EMA going that route. It truly believe that we should as an industry stop creating patient support program in silos but rather using a platform defined by the EMA or the EU for managing healthcare. It would give direction to the industry and startups. Happy to connect and shade some lights on this. I could build a startup incubated close to you and build the team to drive this.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ( ) Other

Name of your organisation:

AGE Platform Europe

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
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- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Enter any general comments you may have:

I just wanted to inform EMA that we had a careful look at the principles and we very much support them. We particularly appreciated the attention paid to accessibility of documents and information.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

pharma.be

Indicate the key principle you would like to comment on (select all that apply):

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- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
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- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

The format that will be used in the ePI must be clear and structured so all MAHs can easily provide the information to the Patients and Healthcare Providers and make sure that this doesn't create more work for the MAHs. It should not be the case that the MAH needs to submit and get approved both ePI and PI in parallel as this would double the work for the MAHs. Ideally companies that are willing to work with ePI should be able to transform the current PI into an ePI version without having this ePI version approved by the CA.
Some clarification is sought on the term "semi-structured" used on line 91 as the term "organized" is also used earlier on line 87; these terms do not have the same meaning but yet both are used to qualify the format of the ePI.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

To implement a common EU electronic standard we must consider the current infrastructures, interoperability and the technical requirements to make sure the implementation of the ePI can be successful.
Line 118-119: it is suggested to add "healthcare providers" to " a common standard enables the generation and dissemination of the electronic authorized information for patient and consumers of medicines in the EU /EEA".
Line 127-129: "to offer possibilities to streamline, simplify and speed up the regulatory process in the creation and updating process (variation) of PI by using existing data of the SPOR (substance, product, organization and referential) process, both for regulators and the pharmaceutical industry". Some clarification is sought for this statement as it suggests that sections of SmPC and PL will be managed separately. Ideally, a parallel management of common sections of PI of different strengths of the same product would be preferable as this could shorten of texts approval.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Line 161-162: In addition to the adherence to the treatment, better compliance could be expected. Proposed change: “[…] to comply and adhere to their medication regimes, ultimately contributing to optimal outcomes”.

Line 177: “The most up-to-date ePI version should be always easily available” Timelines and responsibilities should be defined, in order to ensure that a smooth and timely update of the electronic version of the PI is carried out.

line 178-179: “To achieve this principle, ePI should be made available through various technologies and applications, including mobile scanning technology (such as 2D barcode) on the medicine package”. Can 2D barcode be replaced by "FMD specific 2D barcode for prescription medicines or other barcode for OTCs". The inclusion of different barcodes in addition to the 2D barcode included for serialization could confuse patients.

Line 179-180: “Correct ePI depends on the medicine batch: some parts of the ePI may be applicable to all batches and some only to specific batches (e.g. when excipients changes)”. This statement could be confusing as an ePI should be related to an authorized product and the related approved PI. If the ePI is a conversion of the approved PI, this should not be linked to a batch. If the ePI needs to be linked to the relevant batch this will increase the complexity at the level of the manufacturing site and will also require to have 2 versions of ePI ‘active’ at the same time as batches with difference in ePI will be on the market simultaneously.
The benefit of having up to date information with ePI outweighs the risk of having an incorrect ePI and outdated leaflet in the package.
Education program is also needed to drive the future success of this. Most people do not typically scan a barcode currently or have potentially necessary apps to enable this on their mobile devices. Without continuous education and reinforcement this will fail.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Line 196: “ePI will be accessible by design”. We suggest that it is better elaborated as the meaning is unclear.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

The ePI should not be immediately a new legal obligation.
Is there however a timeframe known by when the ePI could replace the paper PL, especially when it comes to hospital products administered only by HCPs, and not handled by patients? The experience of national pilot projects such as the Belgium-Luxembourg pilot project in hospitals should be taken into account.

Line 213-216: “The use of ePI will be a recommended innovation; however it is not mandatory”. This statement seems in contradiction with that, lines 298-299: “All stakeholders, including pharmaceutical companies and regulators, will commit to implementation of the common electronic standard for creation of ePI for all EU medicines”. Proposed change: “The use of ePI will be a recommended innovation; however it is not legally mandatory”.

Adding a statement in the paper PL that directs to the ePI as most up-to date version of the PL should be

done as a reference to a central database were the product can be searched. It should only be done when the ePI is available. A statement should not only be mentioned on the paper PL but also ePI to clarify which is the latest updated one
Line 217: “The paper PL should include a statement directing to the ePI as the most up-to-date version of the PL”. When it will be applicable, will clarification be available on how this should be handled? (e.g. optional standard text as part of the QRD template?)

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

The ePI should be available as open data, however this needs to be available to a trusted single source like an agency website or via an EU database.
Line 221-222: Would it be possible to add that this is "notwithstanding the fact that promotional information could include ePI"

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Preferably the PI is converted into ePI once the regulatory procedure is complete without any additional approval step by the MSs, in the step-wise approach.
A common single trusted source of ePI (at EMA level or MS level) is a must.
Lines 255-262: with respect to the proposed implementation date, it would be welcome if the regulator can give more clarity on the timelines e.g. how long would the step-wise implementation approach last? Or would it be an ongoing option for member states?

Lines 263-264: “ePI will be made available to users (patients/consumers and healthcare professionals) through websites at EMA level and if available , Member State level”. As stated above, at one point of time, there should be a unique website to access all ePIs. Link redirecting to sources at national level should be possible. It would also be useful for the ePI at the EMA level to include the SmPC/PIL date of revision.

Line 269-271: (Figure1) it is reported that “following regulatory evaluation, if final PI is not already in ePI format, it is converted to ePI by the MAH using a conversion tool”. Who will set the standards/support the "standardized" conversion tool? EMA/NCA/MAH? We believe that it would be important to define which tools must be used for the conversion and how it is ensured that these tools are validated to guarantee their correct functioning.

Line 281-282: It is stated that responsibility for creating the final ePI lies with the MAH. Will the companies upload the ePI on the single trusted database (at EMA or MS level), and be the final responsible? It would be important to define how/when the MAH should perform the conversion of PI to ePI and then the step of transmission of the ePI to the Competent Authorities (MA/NCAs).

Line 286: How will the EU portal handle nationally authorized medicines, per country (as content of PI may be different per country, for instance for approved indications) or per language (in the spirit of the centrally approved products)
How will be the process to add country-specific information to PL centrally approved? (e.g. addition of AE reporting details)
In addition, the fact that they could be available at the same virtual site raises concerns regarding misuse/off-label use of some medicinal products.

Line 295-96: An electronic format is already being submitted: to clarify, the following edits could be considered: “submission of ePI: PI is submitted to the authorities in electronic format, evaluated in this format, and is therefore already in the expected ePI format once the evaluation procedure is complete”. In this case, clarification is sought if the legally approved version would still be the PI, or the ePI, since all evaluation process have been done on the ePI version.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Implementation throughout the EU simultaneously is first of all not realistic and second could cause complications that will be negative for the further development of ePI. However, there should be a clear timeframe and this should be accompanied with clear communication to avoid any confusion at the patient level.
The rationale of the significant burden for micro, small or medium-sized enterprises can be followed but we must not underestimate the impact of ePI even for big international companies. Flexible timelines are a must to make ePI possible.

line 299: will commit - earlier in the document is stated ePI recommended: could this be aligned in the document?

Line 310: “Once a common standard and governance process are established, stakeholders must plan for their implementation in their jurisdiction according to a roadmap, including timelines, determined at HMA and EMA level”. Clarifications is sought for the estimated deadline for this ePI project to be implemented in the EU by MAHs.

Line 319: Will the support be given to pharma companies for the implementation? Conversion tool?

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Line 342: Start the sentence with: "For centrally authorised medicines..." or add a second sentence for nationally authorized products.
One should not forget that there could be specific country details in the PL (e.g. AE reporting details) but the language of the PL is the same: French PL with AE reporting details in France, and French PL for Belgium with different AE reporting details.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Line 346: We suggest that as a second step, once all the SPOR services will be up and running (SMS and PSM) in addition to the fragmentation, the drop down menu fields should be added to connect the ePI to the EMA master data management system.

Enter any general comments you may have:

Having the electronic system would also allow continuous updates, such as new uses for medicines, updates on safety, or changes to manufacturing arrangements.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- European Institution
- EU agency
- Non-EU regulatory authority

◉ Other

If other, please specify:

Pharmaceutical Industry (Trade) Association

Name of your organisation:

Plasma Protein Therapeutics Association (PPTA)

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Questions from PPTA:

- Will EU customs be using the ePIs database as a reference to accept product importation? PPTA considers this as a major implication, as it will be common that printed PILs in packs will be of an older version compared to the ePI.
- Methods which customs currently use to manage discrepancies between stock imported and local databases (if any) will not be applicable in these cases - how will this be resolved with ePI and PIL-divergent information?

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

- As far as PPTA understands, there is no fixed timeline provided at the present for when the 'system' will need to be updated with the ePI. Even with fixed timelines, individual implementation and 'go live' timelines could very well differ for individual European Member States (MS), depending on how quickly MSs approve and implement it at the national level.
- PPTA recommends developing additional industry guidance on which 'approval date to adopt' for Centrally Authorized Products – EMA's Committee for Human Medicinal Products (CHMP) opinion or the European Commission decision? As an example, for major variations where, the EC Decision is provided within 45 days of the CHMP opinion; in case of non-major variations, the CHMP opinion date is often adopted as approval by Marketing Authorisation Holders (MAHs) and MAHs receive the EC decisions rounded up on an annual basis.

Enter any general comments you may have:

> The key principles appear to be in line with the aim of developing and delivering electronic product information (ePI) for human medicines authorised in the EU. However, as this is a high-level 'principle' document, more concrete guidance, with the necessary technical and logistical details as well as implementation steps and deliverables will need to be developed in due course.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ Other

Name of your organisation:

EURORDIS

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

It is a good initiative to have an ePI for all medicines in the EU, both centrally and nationally authorised medicines. A longer-term goal would be that the ePI always include the SmPC, the label and the PL.

A general comment is the significance of the carbon footprint of this action - will it be measured with an intent of managing it? While we may be cutting down less trees, will we be heating up a cloud somewhere to a boiling point?

In the points below, some are repeated as they pertain to more than one principle. Thank you.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

It is good that the ePI can be updated rapidly. A longer-term goal should be that the ePI always include the SmPC, the label and the PL.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

It is good that the information will be available through various technologies and applications, including mobile scanning technology.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

It should be readable via existing devices for the visually impaired like the "handicap0" in France.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

The available information might vary from product to product. There will not be a legal obligation to use the ePI so early adopters may follow the EMA roadmap, while others may not. A longer-term goal should be that the ePI always include the SmPC, the label and the PL.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

There needs to be an implementation plan as well as communication on what can and cannot be done with the ePI. It needs to be made clear that ePI information cannot be "cut up" and be mis-represented as being the whole ePI (ie, "spurious claims", etc). User security may be a concern, whether it is an open format document (google docs type) or not. How can people be assured that their data is not being shared, ie, ePI availability on third-party apps?

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

User security may be a concern, whether it is an open format document (google docs type) or not. How can people be assured that their data is not being shared, ie, ePI use on third-party apps?

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

There needs to be an implementation plan as well as communication on what can and cannot be done with the ePI. It needs to be made clear that ePI information cannot be "cut up" and be mis-represented as being the whole ePI (ie, "spurious claims", etc).

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Can this be part of a multi-stakeholder communication scheme, ie for reporting adverse events or drug/drug interactions, with EMA, the healthcare provider and/or the manufacturer also? (claims of "better delivery of the latest information" leads one to believe in the intra-operability of the scheme). It is clear that the implementation of the ePI will vary greatly between EU countries, both in how long it will take and how many languages it will be in. Will EMA ensure the translation into some languages, at least of the centrally authorised medicines? We understand that this is usually performed by the European Translation Centre and double-checked by National Competent Authorities.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

It is clear that the implementation of the ePI will vary greatly between EU countries, both in how long it will take and how many languages it will be in. Will EMA ensure the translation into some languages? At least of the centrally authorised medicines? We understand that this is usually performed by the European Translation Centre and double-checked by National Competent Authorities.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

> Can this be part of a multi-stakeholder communication scheme, ie for reporting adverse events or drug/drug interactions, with EMA, the healthcare provider and/or the manufacturer also? (claims of "better delivery of the latest information" leads one to believe in the intra-operability of the scheme).

Enter any general comments you may have:

> There needs to be an implementation plan as well as communication on what can and cannot be done with the ePI. It needs to be made clear that ePI information cannot be "cut up" and be mis-represented as being the whole ePI (ie, "spurious claims", etc).
>
> We did not specify specific lines above as most comments go to the concept of each principle more than one line or another. Thank you.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- ○ European Institution
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- ○ Other

Name of your organisation:

Uniklinik Freiburg, Centrum für Chronische Immundefinienz

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

The standard should not be only a format different parties agreed on, but there should be a registry database (similar to the german "Rote Liste"), which is maintained by the EMA, with a given format and agreed on variables, which can create different outputs for different applications e.g. a structured format suitable for electronic handling but also a semi-structured format easily readable for patients.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

New point and objective: enable standardized and unequivocal documentation of patient's medication independent of national or privat medication registries, locally varying commercial names by assigning a unique code to every registered medication in ePI format.

Enter any general comments you may have:

Introducing a code for every medication to enable standardized and unequivocal documentation of the patient's medication for patient registries, epidemiological studies, european citizens treated in several contries, electronic patient records.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

BAGSO (German National Association of Senior Citizens' Organisations) representative for AG Beipackzettel

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

Terms such as package insert (also in German “Gebrauchsinformation”) and ackage leaflet (in German “Packungsbeilage”) are used inconsistently. Accordingly, we recommend that, product information be used as an umbrella term encompassing both, technical/professional information for doctors and health care professionals and that patient information be used to designate the package leaflet (because it doesn't exclusively refer to the enclosed leaflet).
What is the difference between Internet and an electronic platform – is the electronic platform possibly not Internet dependent?
Why does this project only refer to the structure; is the structure more important than the content? Why is the ePI not also considered to be an opportunity to improve in an integrated way contents that are in urgent need of improvement? Any parallel developments with respect to changing the contents of the patient information should be closely linked to this project.
An EU definition of ePI is perceived as fundamentally useful, but we foresee great difficulties in establishing a unified framework. After all, harmonization across Europe will be very difficult, given the different health systems and the existing national ePI systems.
That is why we are proposing to evaluate and compare the existing systems, adapt them where necessary and consolidate them under one umbrella, using the existing systems as a starting point.
The aforementioned advantages of ePI are only attainable if at least the existing requirements for content clarity and legibility are implemented consistently and appropriately, which is not the case at the moment. Discussions should be resumed and implemented within the framework of this initiative, whereby, for example, a feedback function (focusing on legibility, design, clarity, visualization, elimination of foreign words) might be useful. At this point in time, structural improvements should not be the only thing to be tackled; rather, the opportunity should be used to develop new approaches for the contents as such.
It is unreasonable, for instance, to expect patients to read 10-20 A4 pages, particularly if they are receiving multiple medicine therapies.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Which interest groups have reached an agreement on the envisaged EU standard? Where is the patient – how are patients represented? How exactly does the procedure work? Will this procedure be too technical for patients or their representatives? Who will be responsible for making this procedure and its implications for the standards more transparent to patients? Ideally, patients or their representatives from all EU countries should be involved; this should therefore be made available in the national language. Since participation and involvement both have to be facilitated, we insist on a process that is easy to understand. The effort should also be reasonable and feasible for volunteers!
The wording for creating the technical basis remains unclear; what exactly is meant by distribution of trusted information?
Amendments should not only be considered for regulatory procedures. Modifications to the product information should be clearly marked so that users are informed about new developments. In the case of chronic diseases in particular, the patient may not read the patient information each time a new prescription is issued and should therefore be specifically alerted of any new changes.
The standard should not be too complex; integration with other systems such as SPOR should neither delay implementation nor prevent the flexibility often needed for clarity. We also promote the development of national portals that can be easily accessed by country patients and are particularly user-friendly, especially for the elderly. The aspect of user-friendliness must be the main objective of ePI systems. This is the only way to achieve widespread use and would represent a milestone in patient care. A central standard for these portals would certainly make sense, as they could operate under a single roof or umbrella, which would also make it possible to include references to other languages.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

While the idea of an EU standard is certainly commendable, this postulation does not meet the actual demands of the different health systems in Europe.
We do not consider the justification of the advantages to be sufficient for patients and this point still needs to be finalized. The only advantage in this case is that the information is always up-to-date. However, only if changes to the information are highlighted, its timeliness can also be a real patient-relevant advantage.
Accessibility (e.g. audio versions, simple language, sign language, single-handed operation) ought to be mentioned as an important point here.
In this context, the extended accessibility of the information to relatives or caregivers could also be mentioned.
Advice to assist in the decision-making relating to treatments would be desirable, but the information must be available before or during the doctor's consultation and should also be easy-to-understand. Until the flow of information is adapted to the process, this is not an option. Unfortunately, it is impossible to realize this advantage given the current situation, as the existing care conditions do not permit it. This would first require the discussion of approaches towards new information pathways, which in turn would have to be implemented by the respective health system.
How exactly should the individualized adaptation of the information be designed? What does structured nature really mean? Does this simply reflect the previous structure in digital form?
Information in digital form alone will not be able to counterbalance other statements unless contents and clarity as well as forms of presentation (e.g. integration of videos) are significantly improved. This goal cannot solely be attained with structural improvements.
Any measures should also be subject to scientific evaluation in order to determine whether the measures and changes do indeed deliver these benefits.
Concerning the mission of safeguarding public health, we believe that this goal cannot be achieved without substantive improvements to the contents.
The latest version cannot be rolled out seamlessly and quickly in all locations, as comprehensive Internet coverage is still incomplete. A platform should also be able to operate without an Internet connection.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Accessibility and barrier-free accessibility (e.g. audio versions, simplified language, sign language, one-handed operation) should be implemented by the UN Convention on the Rights of Persons with Disabilities, with the help of appropriate experts and stakeholders.
Third-parties should not implement the necessary measures or provide the formats – who should? We cannot, for example, delegate responsibility for these formats to charitable groups, and even less so to for-profit companies. Such formats must be made available as standards on the official platform. This is the only way to guarantee that updates are actually performed. This also allows the relevant patient organizations to be brought in.
How can structure and design contribute to greater accessibility? As far as clarity is concerned, design may be able to make a small contribution, but no substantial improvement will be achieved without improving the contents. What use is it to patients if the information can be found and read but cannot be understood?

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

We also believe that a paper version is still necessary. It represents a core service; the digital version is currently still only an add-on option. This is due, among other things, to the demographic population structure and the disparity in access to Internet.
From the patient's perspective, the ePI should also be mandatory for all available medicines at the national level, as we assume that this will not be implemented voluntarily by all companies without being a mandatory obligation. The digital version would not be useful or user-friendly for patients without complete coverage, because they would not be able to find their medication at all if in doubt. This also applies to the availability of all medicines, both prescribed and OTC remedies.
In parallel, substantive changes must be considered, as these should at least be made within the existing framework. After all, structures that could block these improvements in a next step must not be introduced first. In particular, the possibility of a digital version shall not induce to further lengthening the content. Likewise, the option of linking to a dictionary should not be misused to make the texts unclear or to leave them as they are.
It makes more sense to combine modifications to content and form than to simply work on the structure alone.
There are also specific advantages for medicines that are exclusively used by professionals, e.g. vaccines or medicines intended for hospitals (but hospitals need digital versions). In this case a pure e-version is quite feasible.
The printout of patient information in the pharmacy would be one way of gradually eliminating the paper version as a leaflet included in the packaging.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

As far as we are concerned, however, it is desirable that additional formats such as videos, etc. can also be added alongside the regulatory texts. These formats should not only cover administration, but also indication and disease.
As far as any subsequent use is concerned, it is necessary to clarify how updates will be ensured in such cases. Using links would make more sense from our point of view. But this is incompatible in the context of trusted information or platform. Ultimately, the patient might find a wide range of information of a dubious nature and would not understand what information to trust. Copyright issues also need to be addressed.
Integration with software systems, e.g. of pharmacies, should in principle be possible, but should be monitored and validated.
This means that subsequent exploitation of the system is not impeded, but should only be actively promoted if they clearly add value for patients or for the course of therapy.
Advertising content should not be permitted, but useful and meaningful information and formats for patients should be added. Technical information and content for professionals should also be accessible on the platform (e.g. as already possible for FASS in Sweden), transparent and accessible to everyone. A dictionary would also be welcome, but it should not be too long and should not be used as an excuse for including complicated texts. There should be a direct link from the patient information to the explanation.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

The ePI should nevertheless provide a personalized user experience, e.g. the creation of medicine lists by the patient. There should also be an option to obtain information concerning any changes that the patient wishes and actively requests.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Implementation must be mandatory at the national level, because otherwise it cannot be assumed that all manufacturers will participate.
A gradual and stepwise deployment in individual EU countries makes sense, but in this case the whole system should be operational in one single country. The portal will only be exploited if patients are able to find their medicines. That is why all medicines including generics, OTC remedies and possibly also medical devices should be included. For patients, these different factors are often not apparent or indeed irrelevant.
As far as websites are concerned, the EMA portal in particular is anything but patient-friendly in our experience. The use of established portals (Red List, FASS, etc.) would therefore be preferable. This consultation should be open to and discussed with the portal and the operators, and should not be pre-determined at the EMA level. We do not have any objection to industry participation in the portals. What is important is regulatory supervision, and we also urgently advocate supervision by patient organizations. Third-party providers, on the other hand, would only dilute trust. It is unclear, what exactly is meant by to reproduce.
A national portal would be easily accessible for country patients. In the first instance, these should be designed for patients and the wider population, such as relatives and caregivers, which entails a particularly user-friendly design, particularly for the senior population. These portals shall operate under a unified EU-wide standard, but the standards should be especially geared to patients, so a clear structure is essential. This approach allows the accommodation of different cultures in the handling of information and data.
The electronic supply systems for use in health care systems are currently largely not yet implemented correspondingly. It would be ideal if pharmacists had access to patient information. As previously mentioned, the printout of patient information in the pharmacy would be one way of gradually eliminating the paper version as a leaflet included in the packaging.
In addition to the different health care systems, there are also other issues to consider, such as different marketing authorizations (NP, MRP, DCP) as well as disparities in the German Medicine Advertising Act. We would welcome a refinement, so that in addition to the officially approved texts other information or additional formats can also be provided (videos, pictures, etc.). A framework governing this should be established and a monitoring process introduced to exclude advertising content. Random sampling could be carried out by regulatory authorities and patient representatives.
A regular and scientifically monitored review of the use and user-friendliness of the portal is urgently recommended and ought to lead to a formulation of concrete recommendations for improvement. What is important here is the possibility for citizens to participate, so citizens should be able to provide feedback.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

The wording obviously excludes established portals such as Red List or FASS. This is absurd, because one should use well established platforms! It is precisely here that a great deal of technical expertise is available for this standard.
What is the specific timeline, when should the development plan become available?
Unfortunately, there is no plan for the roll out in parallel with the implementation plan. How should ePI be introduced? Are there any plans for publicity, dissemination and increasing awareness of the potential of ePI? We believe it would be useful if the reference to this ePI appeared on the package leaflet.
As mentioned above, existing national portals should also be evaluated.
The statement on the use of ePI in the authorization procedure should in no way contradict the established common standard and the joint evaluation and development of existing platforms.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

In principle, we welcome the fact that the information is made available in several languages.
If national authorities also require patient information to be available in other languages that have not approved these versions through their authorization procedures, who will bear the costs and be responsible for the translation? How will this decision be taken? We are concerned that the additional expense could lead to some products being withdrawn from the market. This could be particularly problematic for smaller companies.
Bear in mind that other languages may be important too, not just official EU languages. For example, here in Germany you would require Turkish and Russian. But here, too, the time and effort required and who will be responsible for this have to be discussed.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

With regard to the interoperability, we would like to draw attention once again to the different health systems.

Enter any general comments you may have:

First of all, we would like to point out that the consultation process as such was not patient-friendly, as it was only available in English, on the EMA portal, and was therefore difficult to find and understand.
Important prerequisites for the involvement of those concerned are the use of national languages and other national information channels. Patient representatives from non-English speaking countries are seldom involved in the EMA, and have therefore so far been severely disadvantaged.
The ePI project raises the question of the initial objective of the EU Commission to improve product information, i.e. in particular patient information should be user-friendly and contribute to therapy safety and adherence – what is the state of this now?
Why is the ePI not also considered to be an opportunity to incorporate contents that are in urgent need of improvement?
The overall benefits of ePI for patients should be better defined, elaborated and taken into account.

So here are our general demands again, as they stand:

First and foremost, patients want to know:
- How do I take my medicine?

Additional requirements:
- Shorter texts
- Sense of safety when taking or using the product
- Information about the disease and the effect / benefit of the medicinal product
- Patient-friendly language
- Visualization:
  - Structured, concise presentation
  - Legible font
  - Use of images and pictograms
  - Use of information and advice boxes
- Easy to use search function

- Individualized information
- Availability and accessibility
- Access to more information

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: b8d06e37-684d-41bd-9bcf-7f3ce5f2725f
Date: 10/02/2019 15:53:53

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

HUA-Txagorritxu

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Enter any general comments you may have:

The ePI should contain an image of the pharmaceutical form (with the information necessary to identify without doubt and electronically-shape, size, colour, set of numbers and letters) this drug among the rest. It could be therefore scanned by a smart phone and check in a APP the correction of an hypothetical prescription.

The ePI should be place in a way that any pharmaceutical form could be identify, for example in any blister. The code bar with the ePI and/or national identification code should be place in the primary (inner) package in any individual vial or pharmaceutical form.

The ePI should provide easy symbols to patients to know how to take their drugs, PE: with food, without food.

It should be easy for the electronical records or data bases to identify between the drugs taken by a patient which one could produce an adverse drug reaction. The same for the drug interactions.

In the way the ePI is organized and stored it should be easy to compare drugs in efficacy or safety by health proffesionals.

Thank you for the oportunity to share our proposals with EMA to improve patient care.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- [ ] Other

Name of your organisation:

Novartis Pharma AG

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [x] 4.1 Governance
- [x] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

ePI is currently defined in this principle based on a document (statutory PI) and a standard. This is a technical definition. We suggest that the ePI is defined based on the user, the patients, and not on a document. ePI should be defined as 'the information that the patient needs and may want to see for the product he/she is taking'. In practice, this can go beyond what is in the current PI, and can include other documents prepared in the context of risk minimization measures (e.g. patient's card), because of local requirements (e.g. information in the 'blue box') or specific instructions for disposal into a national scheme, as well as visual information that is currently not available (e.g. picture of the tablet or capsule). ePI can also apply to patients in clinical trials, whose information needs are similar.
Rather than principles, the requirements of the ultimate users of the ePI should be defined and used to judge whether the project is delivering.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

Getting the electronic standard is essential to have a usable ePI. We are concerned that the standard being considered is defined as an EU standard. Patients throughout the world have a need for ePI, and we strongly recommend that the standard is defined in an international context:
- There are already global data standards for medicinal products, the IDMP standards, and the ePI standards should be designed within these, and not only with some interoperability as currently suggested (under principle 5.2).
- The EMA should also work with the US FDA to ensure alignment with the Structured Product Label activities the US agency is carrying out in this context, in particular the indexing done by the US agency to enhance access to the electronic product information provided by the companies.
A global standard can ensure that the benefit of ePI to patients can be rolled out beyond Europe into regions where patient information is not as developed (in particular where there is no paper leaflets).

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

This principle is a description of what the ePI is expected to bring to the patient. This information could be added to the updated definition in principle 1.1.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

This principle should be part of the requirements of the dissemination platforms for ePI,

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Novartis wants to highlight that resources are currently invested to support the preparation and supply of paper leaflets to the patients. Any activities towards a parallel process for electronic leaflets will require extra resources and will affect the running of businesses.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

As highlighted under principle 1.2, regulator-approved information may not be sufficient to provide to the patient the information that he/she may need for the product. It is not clear what this principle is trying to achieve.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

The principles for the governance are currently very limited, and the schema provided in the document is confusing. When it comes to governance, Novartis would expect the governance to cover principles such as:
- ownership and maintenance of the data standards
- ownership and maintenance of the information. All elements of the ePI will belong to the authorisation holder and not to the regulatory Authority.
- control and validation of the information made available to platforms.
- control and vetting of 3rd party applications allowed to use ePI elements.
- financing of the system.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

This should be included in a separate document discussing implementation.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

This principle should be part of the requirements for the data standard and for the dissemination platforms for ePI.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

This principle is part of what should be taken into account in the development of the standards.

Enter any general comments you may have:

Novartis is a member of EFPIA (European Federation of Pharmaceutical Industries and Associations) and is generally aligned with the comments submitted by the Inter Association Task Force on Product Information on this consultation. However, we are highlighting in this response comments specific to Novartis's strategic priorities.
As a global pharma company, Novartis is keen to be able to bring to all patients, regardless of the region in which they live, the benefit of electronic product information. Our comments therefore relate to areas where when we believe the agency's principles seem too narrow, driven more by regulators efficiency rather than patients utility. We strongly believe that an ePI standard that is developed taking greater into account of the needs of patients can ultimately enable patients to have at their fingertips the right information, and this throughout the lifecycle of a product. This would include from the first clinical trials to the subsequent commercial rolling out of the medicinal products including in regions where paper leaflets do not exist. The data standards must therefore be developed with this in mind. How the ePI standard is then implemented should be a separate process discussed at regional level, and we are looking forward to working with EMA and the EU regulatory network on defining how best to implement ePI in the EU. Our comments reflect this position.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Amgros I/S

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
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- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

- Implementation of updates seem more flexible and aligned
- Approval date and immediate upload on regulator's websites should be ensured resulting in the shortest possible time from PI approval by the regulators to upload and availability for patients and healthcare professionals.
- The need for document history, change log or similar should be considered

Package leaflets: Today there are requirements for electronic package leaflets in the EU. Could these replace the paper package leaflet? The current requirement for the paper package leaflet prevents the development of joint Nordic packages and registrations, since there is no space for 3-4 languages. Joint Nordic packages and registration is a great desire in the Nordic countries to secure supplies of old medicines with low turnover.

Summary of product characteristics (SmPC):
When the health professionals use foreign packages (nonlicensed medicine), they need an SmPC in English to ensure patient safety. It is not always possible to obtain an English SPC for the nationally approved medicines. We would wish that all the nationally approved medicines have an English SmPC available on the EMA's website.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

- A lot of our medicinal products are dispensed on (hung on) fluid trolleys (for infusion bags) in hospitals, i.e. the package leaflet does not accompany the product on these trolleys.
- Our medicinal products (= SAD medicinal products) are administered by health care professionals (restricted hospital use) and are often handled in hospital medicine dispensing/preparation rooms, i.e. the package leaflet is often thrown out in the dispensing room and does not accompany the product to the patient.
- Our medicinal products (SAD medicinal products) are not meant to be handed out to patients being discharged from hospital/outpatients, i.e. patients receive the medicinal product while being cared for and treated in hospital.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

- Most patients have access to digital medias and are used to seeking information digitally including the contact with GP's
- ePI should ensure direct access to the latest regulator-approved PI.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

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- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

Not-for-profit European association representing the statutory social insurances

Name of your organisation:

European Social Insurance Platform - ESIP

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [x] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [x] 3.3 Data protection
- [x] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [x] 5.1 Multilingual ePI
- [x] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

We strongly welcome the idea to improve the access to updated information on medicines for the users (patients, healthcare professionals, etc.). However, we also agree that the format of ePI needs to be defined in advance, taking into account where the data will be stored and what infrastructure will be put in place.
In any case, in our view the design of the solution must be subject to a high level of security and data protection in order to prevent users' enquiries from being tracked, especially where mobile applications are used as a tool to access the ePI (lines 178-179).

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

The choice of the common EU standards must follow a transparent procedure, especially when selecting stakeholders' involvement. The range of stakeholders involved must be balanced.
As a European electronic standard has to be developed and the semi-structured format will contain controlled vocabulary (code system), it is necessary that this code system is free (no license fee for usage).

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

We welcome the initiative to provide citizens with an improved access to independent, official, trustworthy and updated information on medicines. It could help improve adherence to treatment, efficiency and quality of care and patients' safety.
It is mentioned in lines 166-169 that "ePI information can flow to other systems, such as electronic health record and e-prescribing system". As ePI must not be used as an entry point to the electronic health record, it should be subject to appropriate cybersecurity measures. Furthermore, ePI should be easy to identify and seamlessly accessed from prescription software and electronic health records to provide maximum benefit.
Finally, as already mentioned above, appropriate data protection measures should be applied to prevent users' enquiries from being tracked, especially where mobile applications are used as a tool to access the ePI (lines 178-180).

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Statutory health insurers strongly support the aim of taking into account the needs of people with impairments and those with low literacy levels. ePI indeed has the potential to be more easily accessed by using supporting (software) systems.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

It is very important to maintain the paper format of PI, as some inequalities remain in the access to digital solutions. The elderly, people in rural areas, disadvantaged groups may not always own a smartphone or a computer. Low literacy or simple choice can also explain those inequalities in use of digital solutions. Moreover, people should always have the possibility to access a paper version of the leaflet in case they temporarily do not have access to digital technologies.
In the absence of any legal obligation, we wonder what would be the incentive for the manufacturer to create an ePI. Moreover, how can we ensure that the necessary updates to the ePI are carried out, and in a timely manner? It should be considered at least to include a legal provision to ensure that the PI and the corresponding ePI are updated in parallel in a systematic way, in the case that the manufacturer chooses to create an ePI (addition to line 216).
Finally, we warmly welcome the idea to include a statement in the paper format of the PL directing users to the ePI as the most up-to-date version of the PI. The paper format of the PL could also include the date of the latest PI update (addition to line 217).

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

We strongly agree that ePI should only include regulator-approved information in order to prevent promotional information. However, we would like to emphasise that even if no new content is added, there could be a risk of disguised advertising when conceiving the layout (colours, images, videos, etc.). This needs to be taken into account when the common EU electronic standard is defined regarding the possibilities for individual design: the information needs to be presented in the most neutral, objective and harmonised/standardised way to prevent the risk of disguised advertising.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

We agree that any technology used by the user to access ePI must comply with the European data protection legislation (in particular Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725). Especially where personal data are involved (e.g. when access to the ePI is made via a mobile phone application, as considered in lines 178-179) adequate data protection and security measures need to be tailored to the solution chosen. Those measures should be proportionate to the risk and to the objective, taking into account the fact that the personal data involved is sensitive. Third parties' applications must be prevented from linking the access request to the ePI of a certain medicine to an individual, which would e.g. open the door for promotional activities.
This is especially relevant in a context where Member States are still adapting to the new data protection legislation and where discrepancies can be expected. These considerations should be better emphasised in the key principles on ePI in the EU (addition to line 248).

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

As explained above, we wonder how the responsibility of creating the ePI will be implemented in the absence of a legal obligation.
Furthermore, we would like to reemphasise that even if ePI becomes the primary source of information (see line 295-296), it should not replace the paper version of the PL.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

We welcome the intention to make the information available in all necessary languages, to the benefit of both patients and healthcare professionals.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

We welcome the intention to progress towards a better interoperability of the different e-health initiatives. Consistency is very important for their success and achieving the general objectives: improving the quality, accessibility and efficiency of health care.
289-296: and 299-302: The roadmap needs to include a robust strategy for dealing with legacy products, especially with regard to SMEs. During a transition period, care should be taken to avoid bias in search results if not all products are included in the ePI database. It should be ensured, for example, that generic and older alternatives are also presented alongside newer products in broad searches (for example those looking for indications or side effects). A mandatory warning that the results may be incomplete is not adequate.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

I think that older EMA Web page was easier to use than the newest. Nowadays for me is difficult to find the summary of product characteristics in the page. Even some medication don't have any summary of product characteristics. Easier "search" just to summary of products characteristics with all the drugs approved by the EMA should be a good implementation.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

For healthcare professionals is so annoying not having any open access with the complete studies of any drug. Using Sci hub is usually the best option, I think that we should work on having something like it, but legal

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

For finding any complete information about any drug Y I u should go to your own agencie, in my case AEMPS, and older medication don't have any e-data. A good idea were to have links from any drug you search the EMA webpage to different language data.

Enter any general comments you may have:

It is important to work on having a good quality and, even more important, easy to access information for drugs. That is the only way to make people avoid searching wrong data just googling it, instead of using oficial sources, because nowadays it is easier.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ EU agency
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- ○ Other

Name of your organisation:

University of Leeds

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
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- ☐ 2.2 Accessibility
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- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

The 'Background' notes the wide-ranging actions from the Shortcomings Reports related to enhancing readability, improving patient input in development and testing, promoting best practices and developing an electronic format. It is important that the necessary initial focus on the latter aspect does not prevent us from looking at the wider issues of making the content of the ePI more readable and improving the testing process.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

The rationale notes that the nature of ePI will offer new opportunities to better tailor product information. I presume this relates to tailoring information which does not affect the overall content i.e. tailoring for gender, age and specific condition. However, in addition, the benefits of more sophisticated tailoring could be noted, such as the scope and depth of information that individual patients require.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

It is stated that the implementation and use of ePI must comply with the legislation in force. I would challenge the notion that it is a given that the existing legislative framework should continue to be the basis for developments. The current regulations are from 20 years ago - and much has changed in the wider world since then - continuing to have to comply with these out-dated regulations is holding us back from meeting the needs of patients and the public.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

Under 'Processes' no mention is made of the differing lay-out needs for hard copy versus on-screen information – key principles need to be set out for how best to present information on screen. The relevant principles in the 2009 Readability Guideline are solely focussed on hard copy information.

Enter any general comments you may have:

Declaration of interest: I am co-founder and academic advisor to Luto Research, which develops, refines and tests health information materials.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- ○ Other

Enter any general comments you may have:

Pi must be accessible to patients without IT

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

This could be via QR code .. can be read and printed or heard using phone computer .. or with phone number to hear an audio version

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

It should be standard format eu wide

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Should allow access to all .. can be printed at pharmacy for patients without IT

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

As above

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

As above

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

Translated into a selection of languages as required

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: c793ff8c-6130-45a2-a008-323be140a358
Date: 07/02/2019 14:04:39

Public consultation on key principles for electronic product information for human medicines in the EU

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- ( ) European Institution
- ( ) EU agency
- ( ) Non-EU regulatory authority

- ○ Other

Indicate the key principle you would like to comment on (select all that apply):

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- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

leaflet, smpc should be made accessable by QR code

Enter any general comments you may have:

excellent initiative, the sooner the better thank you

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: cad169c8-ecb6-461f-a1bc-46230c06bfd3
Date: 31/01/2019 13:41:13

Public consultation on key principles for electronic product information for human medicines in the EU

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- ( ) Other

Name of your organisation:

IQVIA

Enter any general comments you may have:

In the new website, daily approvals are very complicated now. hope all the approvals cover in monthly meeting along with meeting details.

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

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- ○ Other

Name of your organisation:

Danish Medicines Agency

Indicate the key principle you would like to comment on (select all that apply):

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- ☑ 1.2 Common EU electronic standard
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- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

In line 86 it is specified that “ePI is … product information …”.
In order to comply with this definition, please amend the wording of line 91 by adding the words highlighted in the following: “ePI refers to product information in a semi-stuctures format”. Likewise, in line 96, please replace “ePI refers to the structure of …” by “ePI is characterized by the structure of …”.

Line number 88: For clarity reasons, we also suggest to include apps in the examples of how ePI can be disseminated: “ePI is adapted for electronic handling and allows dissemination via the world wide web, apps, other e-platforms and print.”

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

We agree there is a need for at common standard as a first step in this important work. The common standard has yet to be described and defined further in IT and technical terms. A suggested format is XML (mark-up language) and terminology from the referentials-part of SPOR. This seems workable for both industry and NCA’s in general and suits a variety of IT solutions. Past experiences regarding. With reference to the EMA PIM-project (product Information Management project) we advice that experience from this project be taken into consideration throughout. The future specification ISO TS 23261 - Health informatics - Requirements for accessing digital medicinal products information by using the existing data carrier, based on ISO TS 16791 Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers is relevant.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

The principle acknowledges the importance of taking into account the need for both patients and HCP (health care professionals) to access the product information corresponding to the exact batch of medicinal product in question. Some information in earlier versions of the PL (e.g. regarding composition and instructions for use) remains relevant throughout the shelf life of the stocks/packages relevant to those PL's. Therefore, not only the latest PI is relevant. The operational solution to this needs further elaboration in the principles, also in terms of sharing the ePI information throughout relevant eHealth initiatives ensuring the correct PL is shared for the exact batch of medicinal product in question.

In line 152/153: To underline the importance of the communicative effect of the ePI, we suggest that the following be added to the this bullet: "better delivery of user tested information so that the right information is available to the right patient/consumer at the point of need in a format that is easy to understand.

In. line 165/166: We suggest to include the following sentence: "The structured nature of ePI will offer new opportunities to better tailor product information to the needs of individual patients/consumers using visualisation and easily understandable icons where possible in order to support its communicative effect."

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

We agree that the ePI is and should be a supplement to the paper version of the product information leaflet as also stated in Directive 2001/83/EC art. 58.
Furthermore we find that this is an important requirement for those with limited IT-skills and/or -access and in the event of general IT-failure.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

Given the fact that ePI itself contains no personal data and should be published as open data, data protection is not an issue for the key principles.
The requirement for any processing of personal data in relation to ePI to comply with applicable European data protection legislation is not based on and should not be presented as being based on the key principles for ePI.
Principle 3.3 as currently described is not specific or defining for ePI, and we therefore suggest to leave it out.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

We agree that various scenarios can co-exist during the implementation period. We strongly advice that all NCA's be invited to take part in the outlining of the governance structure of the ePI project as such. In order for the project to succeed, despite no legal obligations to implement ePI, onboarding of the parties is essential.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

We agree there should be a roadmap to guide the implementation. The roadmap should take into consideration the different levels of readiness characterizing the NCA's in terms of both economy and digitalization. Again we stress the importance of inviting all interested NCA's into the drafting and agreement of the roadmap to ensure the necessary onboarding.

The responsibility for creating ePI or converting approved PI to ePI lies with the pharmaceutical companies. A roadmap also needs to take the differences in readiness and ressources between companies into consideration in order to be successful.

It is indicated that NCA's support industry during the implementation of ePI. We suggest it be further elaborated what kind of support and to what extent this is referring to.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

The principles does not describe concrete solutions to ensure interoperability. We recommend using existing initiatives and format as much as possible (e.g. XML, SPOR).

Enter any general comments you may have:

In order for the ePI to become an efficient communicative tool in a real world context, we suggest to consider that a new section could address this. We suggest it could include the use of the best fitted formats for this purpose (e.g. pictures, icons) and that the efficiency of the new formats be tested in a test-design that takes the real world context of the user into consideration.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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Your email

[redacted]

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- ○ Member of the public
- ○ Patient/consumer
- ◉ Patient/consumer organisation
- ○ Healthcare professional
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- ○ Media
- ○ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- [ ] Other

Name of your organisation:

International Painful Bladder Foundation

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [x] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

at the moment there is nothing "common" about anything electronic in the EU in the field of healthcare!! This has to change. The same standards must apply in every EU country across the board.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

people must be able to find information without spending hours or days hunting for links. there are undoubtedly many interested parties who never ever find it.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

the language used in all communications must be simple and comprehensible to all. Less EU jargon please!

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: d8015b0a-d781-478e-a437-966dd4280ae5
Date: 26/07/2019 15:01:04

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

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- ○ EU agency
- ○ Non-EU regulatory authority

Other

Name of your organisation:

European Association of Hospital Pharmacists (EAHP)

Indicate the key principle you would like to comment on (select all that apply):

- 1.1 ePI
- 1.2 Common EU electronic standard
- 2.1 Expanding access to information
- 2.2 Accessibility
- 3.1 Complementing paper package leaflet
- 3.2 Open access to regulator-approved information
- 3.3 Data protection
- 4.1 Governance
- 4.2 Flexibility in implementation
- 5.1 Multilingual ePI
- 5.2 Interoperability

Enter any general comments you may have:

Overall, EAHP welcomes the draft key principles for electronic product information (ePI) for human medicines in the EU. The Associations agrees with the elements put forward in principles 1.1. to 5.2. Given that the SmPC forms an important element of the ePI, EAHP would like the EMA to consider the improvement of the content. The SmPC submitted by a marketing authorisation holder at the time of marketing authorisation application forms a crucial basis of information for healthcare professionals, such as hospital pharmacists, on how to use the medicinal product safely and effectively. This information is frequently being used, in particular in the hospital pharmacy for the compounding of intravenous medications. The accuracy of the gravimetric method which is applied by hospital pharmacists in such cases depends on an accurate determination of the density of the drug solution being used. Unfortunately the SmPC rarely includes this data, forcing hospital pharmacies to contact the manufacturers directly. This approach is often time consuming and the quality of the data received can vary considerably. The inclusion of data specifying the density of a drug solution in the SmPC would increase patient safety and consequently should be considered as an action linked to the delivery of real-time electronic product information.

In addition, EAHP would like the EMA to consider the inclusion of extended in-use stability data of a medicinal product as preferably a mandatory part of the SmPC. Hospital pharmacists feel that there is a missing liability for pharmaceutical companies to present extended in-use stability data together with the application for EU approval of their products. The lack of such data leads to high amounts of discard which has a serious impact on hospital resources and the environment. For instance, the summary of product characteristics (SmPC) for Durvalumab (Imfinzi®), Atezolizumab (Tecentriq®) and Nivolumab (Opdivo) indicates a 24-hour stability period across European countries. However, monoclonal antibodies of this type have almost always a good extended physical-chemical stability under controlled conditions (such as absence of light, cooling and smooth handling). This has already been established in regard to Nivolumab (Opdivo) for which independent scientific data about extended stability exists. This information has however not been considered since the original data is still provided in the SmPC. Hospital pharmacists consequently feel that there is a tendency towards the inclusion of an arbitrary 24-hour limit on the shelf life of a product in the SmPC even though the product could still be safe and stable to use days later.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- EU agency
- Non-EU regulatory authority

- ○ Other

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

KNMP agrees with the definition of ePI.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

KNMP supports the formulation of a common standard.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

KNMP supports the idea of increasing access to up-to-date, reliable and unbiased medicine information for patients/consumers, in order to have the information available to the right patient/consumer at the point of need, and to increase support in informed-decision making and thereby contributing to medication compliance. For this reason the KNMP already offers medicine information on their public website www.apotheek.nl. This website provides easy accessible and easy to understand information on medicines. This information is based on the decision support information for medication surveillance by physicians and pharmacists. In this way pharmacists and patients have access to complementary drug information from the same source. However, we do state that this online medicine information should always be used in addition to the consultation with the pharmacist and the package leaflet.
In order to ensure that ePI remains a source of trusted and non-promotional information, it will be crucial that citizens, using the various technologies and applications to access ePI as an intermediate, will be directed to independent sources such as the official websites of EMA and/or national competent authorities. It should also be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

KNMP emphasizes that for some patients the ePI is not easily accessible.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

KNMP strongly supports the principle that ePI complements the use of paper package leaflets, and that it does not intend to remove or substitute the currently available paper format. As pharmacists we see that the paper package leaflets are today widely used by a very diverse group of citizens, including parts of the population with limited access to digital tools such as certain elderly and people with limited financial resources. In addition, the digital literacy levels vary still strongly across the population of all EU countries. Due to its importance, it is crucial to ensure at all time that product information is made universally accessible.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

KNMP welcomes that ePI is intended for the delivery of regulator-approved medicine product information only, that it will not be used to deliver promotional information and that it should always be published as open data, freely accessible for use and reuse. For the website www.apotheek.nl this is also a very important issue: there is no promotional information and the information is freely accessible.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

It should be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities. At the same time, it has to be clarified how software, apps or websites will process and store citizens' data when searching for a medicine's ePI – be it a search query or by scanning a medicine's barcode linking to the ePI.
The appropriate application of European data protection legislation should at all times be closely enforced and monitored in these third-party applications.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

KNMP supports that ePI will be made available to users through websites at EMA and NCA level. We also welcome the integration, where applicable, in eHealth systems such as electronic health records and eprescribing systems. Today, Summary of Products Characteristics (SmPC) information is in several EU countries already directly electronically available in software programmes and/or applied in scientific databases of healthcare providers. This improves the user-friendliness and accessibility of product information for healthcare providers. In addition www.apotheek.nl and the website of the Dutch CBG with their SmPC information are already linked.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

KNMP welcomes the acknowledgement of a necessary flexible approach towards the implementation of ePI across European countries. European community pharmacists are committed to contribute to an appropriate and timely implementation of ePI in their practice.
When implementing ePI, EMA and national competent authorities should also ensure that pragmatic solutions will be in place to address the potential issue of outdated paper PLs compared to updated ePI's.
KNMP wishes to remind that the printing of paper PLs is a legal obligation for marketing authorization holders, and strongly believes that this should be conserved. Community pharmacists are concerned that, as last point of contact with patients in the medicines supply chain, the implementation of ePI might introduce both a direct financial cost for pharmacies as well as time loss in practice that could be better spent on caring for patients, when potentially having to print an updated paper PL for many of the medicines dispensed. Also when it comes to liability, the introduction of ePI opens new questions that need to be clarified.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

The ePI offers a unique opportunity to meet special patients' needs, including multi-lingual choice options. We encourage national competent authorities to consider linkage to all available EU language versions (as well as Norwegian and Icelandic) of the ePI on their websites, so that European citizens can at all time access the ePI in their language of choice in the community and country of presence.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

KNMP welcomes the focus on interoperability with existing EU and global initiatives in the implementation of ePI in Europe as a measure to ensure a pragmatic implementation process and harmonised access for patients and healthcare providers across EU.
In the implementation process of any digital technology in healthcare, we would like to stress the need for early involvement of experienced end-users such as community pharmacists to ensure endorsement, support and commitment of all users involved.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: e0e8006b-09dc-4523-b2c7-be2d76b13c23
Date: 01/02/2019 14:37:15

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

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- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (•) Other

If other, please specify:

I am patient , HCP and Pharmaceutical industy professional

Name of your organisation:

Enter any general comments you may have:

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

CIMA system in Spain it is sufficient, as a patient I think CIMA is a system that works very well and I think patients have full access to last PIL As a HCP I think CIMA is a system that works very well and I think patients have full access to last SmPC and as profesional of industry I use CIMA as database since is the better system to access to the last approved SmPC

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

CIMA in Spain is perfectly acessible for patients, HCP and industry professionals

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

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- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ( ) Other

Enter any general comments you may have:

> It should be useful for patients and prescribers to include not only the label but also photos or artworks of the packaging material per country (primary and secondary).

Indicate the key principle you would like to comment on (select all that apply):

- [x] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [ ] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

> In order to comply with "a common standard for ePI in the EU: technical features (including mark-up language, controlled vocabularies and interoperability specifications) agreed by regulators and stakeholders.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: edd1fff8-dcb4-43a3-9256-c42d456c0da5
Date: 31/07/2019 14:46:25

Public consultation on key principles for electronic product information for human medicines in the EU

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- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Line 211-212; People not only have digital illiteracy but also include geriatric population for whom difficult to read the leaflet and understand the medical terms.

Solution: We can integrate local terms or layman's terms as well as a graphical extracts of the function of the medicine and side effects in the PL. Graphical presentation are easier to understand.
An important section of the PL can also be translated in English since last 5 years their has been an exodus of immigrants in Europe .

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Lyfja Granda (pharmacy)

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
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- ☑ 2.2 Accessibility
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- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Still there is a fraction of the population not connected to internet

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

Latest approved version of the leaflet is already available in Word or PDF format.

Enter any general comments you may have:

Will this make it possible for small population area to import/distribute packs from f.ex Germany without amending the labelling on the carton?

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

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- ○ Other

Name of your organisation:

The Danish Patient Compensation Association

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☐ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Addition to line 159: Patients/consumers and healthcare professionals using ePI can be fully confident that they hold the latest information about benefits, risk, use and information about their patient/citizen rights if they endures harmful side effects from medicin.

Enter any general comments you may have:

It is important that the citizens in EU know their rights if they endures harmful side effects, and it is just as important that the healthcare professionals is aware of the possibility in the concerned member country, so they can guide the citizens.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: f8fc7c8e-12f9-4d09-93ab-9e029e2db88b
Date: 26/07/2019 13:40:06

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- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Research-Based Pharmaceutical Companies (vfa), German Pharmaceutical Industry Association (BPI)

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☑ 3.3 Data protection
- ☑ 4.1 Governance
- ☑ 4.2 Flexibility in implementation
- ☑ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

An EU definition of ePI is perceived as fundamentally useful and we agree on the definition. As stated in the key principles, a definition is required to avoid misunderstanding and guide the expectations of all involved parties. Perhaps this definition could be reviewed by patient groups in order to be improved in understandability.

An electronic format is of great advantage. Especially patients/consumers benefit from the delivering possibilities and new functions like e.g. increasing font sizes, using search functions, availability of documents in formats compatible with patient’s reading tools. To enable the usability in different settings, the focus should be on structured xml-based formats, compatible with patient-centered apps, that are already established and well known in the relevant groups.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

We agree on the general principle of a common approach and standard for ePI in a structured or semi-structured format. QRD templates should be made available as eQRD templates including precise requirements/recommendations also for free text (style guide as prerequisite for easy conversion of unstructured documents (like word) into structured xml format).

After all, harmonization of different standards across Europe will be complex, given the different existing national ePI systems. That is why we are proposing to evaluate and compare the existing standards, adapt them where necessary and consolidate them under one umbrella, ideally using the existing systems as a starting point.
Furthermore, the standard should be integrated with the development of other systems such as SPOR. But the integration should neither delay implementation nor prevent the flexibility often needed for clarity.
Patients also promote the development of national portals that can be easily accessed by country-specific patients and are particularly user-friendly, especially for the elderly. The aspect of user-friendliness must be the main objective of ePI systems. This is the only way to achieve widespread use and would represent a milestone in patient care. A central standard for these portals would certainly make sense, as they could operate under a single roof or umbrella, which would also make it possible to include references to other languages.

Any ePI system needs to be GxP-validated for the use in the context of pharmacovigilance, quality control and production. In the roadmap this aspect needs to be addressed and sufficient time and cooperation with pharmaceutical industry and regulators foreseen.

For transparency sake, it is important to clarify which interest groups will reach an agreement on the envisaged EU standard. The processes must be set up in a way that includes patients and ensures that a wide range of patients is represented.

For getting this inclusion of patients more efforts need to be spent to explain the procedure in detail. Currently this procedure and the required technical knowledge is not clear. It would be beneficial, if patients or their representatives would be involved to provide information on tools, that are currently in use. This could help to avoid defining standards, that are not compatible with already established and well known tools within the patient society. Ideally, patients or their representatives from all EU countries should be involved. Providing the information in the national language and a process that is easy to understand would help a broader participation and involvement. The effort should also be reasonable and feasible for volunteers!
Amendments could help streamlining the regulatory procedures as well as notifying the patient of changes. It should be considered in which way modifications of the product information should be communicated to patients.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

The actual demand of the patients in different health systems in Europe is accessible up-to-date information which is tailored to the needs of the reader, e.g. patient/consument/relative. This also involves taking into account the Internet coverage, which is still incomplete in some EU-member states. Therefore, ePI-platforms or solutions should include technical options that allow to operate without an internet connection, i.e. saving ePIs for offline use. For example, the German pilot allows storing any ePI that has been read on the mobile device.

Electronic information can be easily changed and therefore can be kept always up to date. However, it should be considered how changes to PI should be communicated as this would be a benefit for patients.
To enable accessibility, the right (national) platforms and channels for patients still need to be identified by involving patient groups. Hence, this point still needs to be further elaborated. Accessibility means documents prepared for patients reading tools, simple language, sign language and single-handed operation is an important point for public health.
Electronic formats could help to use additional forms of presentation (e.g. integration of videos).

To benefit from the mentioned advantages of ePI, existing requirements for content clarity and legibility ought to be implemented consistently and appropriately. Discussions on understandability might be resumed and implemented within the framework of this initiative, as all relevant parties are sitting at the table. An initial review process on the structure should involve patients/consumers and could be integrated on a continuous basis with for example, a feedback function (focusing on legibility, design, clarity, visualization, elimination of foreign words). Maybe already at this early point in time, the opportunity could be used to develop new approaches for the content rather than just tackling the structural improvements, i.e. reading 10-20 A4 pages for multiple medicine therapies is problematic.
Any measures should also be subject to scientific evaluation in order to determine whether the measures and changes do indeed deliver these benefits.

As stated in line 178-179 of the EMA draft document the ePI should be made available by mobile scanning technology (apps) such as 2D barcode scanners. By using the 2D barcode which is also used for serialization (Datamatrix code with the unique identifier required by the Falsified Medicines Directive) no additional data should be encoded within this code but the included product code should be used for linking to the ePI. This is the way of linking we use in the German e-leaflet project GI 4.0.
As stated in line 179-182, batch-related product information might be of special importance especially if there is a change of excipients. Therefore, it should be guaranteed that the patient/consumer has access not only to the most up-to-date version but also to the information which is of relevance for the specific batch (e.g. when excipients change). There is a clear need to think on how to best inform patients about such changes.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

We welcome the creation of PI that is accessible to everyone. For now, the changes evoked in this public consultation are limited to allow a bigger font and documents prepared for patient’s reading tools. Patient health could really benefit from today’s technologies. Indeed, the use of interactive and educative videos or other tools could help patients to better understand their disease and how to take their treatment.
Accessibility and barrier-free accessibility (e.g. documents prepared for patient’s reading tools, simplified language, sign language, one-handed operation) should be implemented according to the UN Convention on the Rights of Persons with Disabilities, with the help of appropriate experts and stakeholders.
Clear requirements, e.g. validation and/or predefined tests, need to be performed for the formats. Ideally, such formats should be established by including patient organizations. Afterwards, the established standards should be made available by official means, e.g. European or national platforms.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

It is understandable that the implementation of the ePI must currently occur within the framework of the European legislation. In order to be able to offer the ePI to the EU patients as soon as possible, it is strongly recommended that an opening clause in the EU directive should be considered to allow for leaflet-free boxes. There should be a stepwise approach for abolishing the requirements of paper leaflets. Specific supply channels or disease areas are prone to serve as pilot. Also from patient’s view pure e-versions are seen as feasible for medicines that are exclusively used by professionals, e.g. vaccines or medicines intended for hospitals that use digital versions. Medicines dispensed in hospitals only are already being tested in a pilot. This approach could be extended to medicines in other settings where the medicine package is not directly distributed to the patients. These include vaccines which would additionally benefit since shortages might be prevented by avoiding repackaging the paper leaflet after shipment from one EU Member State to another.
We recommend adding the statement that for patients with low digital literacy or limited internet access the PL should be available as print-out, e.g. in pharmacies at the point of sale. The print-out of patient information in the pharmacy could also help to support an evaluation phase for a later transition from the paper version included in the packaging to an electronic leaflet and therefore we do not lose sight of patients with low digital literacy or limited internet access.
In general, it would be useful if the reference to electronic product information appears on the paper package leaflet.

In order to support a rapid dissemination of ePI, we share the opinion that incentives for manufactures, that are early adapters in the area of ePI, would be helpful. Examples could be the extension of timelines requested by the HA for updated paper leaflet in the box in case of an electronic version being available; an option of leaflet-free boxes for certain medicines (e.g. hospital-only medicines) as well as processing variations electronically in ePI documents. Other incentives could be cost compensation from EMA or national authorities (reduction of fees) considering the costs for the companies for conversion of unstructured documents into structured xml-formats.
This all could help, providing for a high number of medicinal products from the start. If the transition period is too long, patients would not be able to find their medication and would stop using the electronic version of PI.

We suggest to carry out an information campaign for patients and healthcare professionals on the availability on ePI to get familiar with the ePI system and directing them to the location of the ePI version of the PI.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

We agree that any element of promotional nature should be excluded. However, not everything that is out of the current scope of ePI should be automatically considered to be promotional.

There should be a fast way to deliver additional information connected with the product information, e.g. risk minimization material or educational material. Such materials are also approved by the authorities. Also, inclusion of videos with instructions for proper use of medicines as well as information on indication and disease would be of benefit for the patients. However, we agree that additional formats such as videos can only be added alongside the regulatory texts.
In general, it is necessary to clarify how updates will be ensured and indicated for the user. Clear rules need to be implemented how this could be put into practice in the context of trusted information or platform. In case of integration with other software systems (e.g. pharmacies) or digital tools from third-parties, that use ePIs, it has to be ensured, that the displayed version is in agreement with the approved version. As we are situated in a highly regulated environment, all integrations into software systems or electronic tools require to be GxP-validated.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.3 Data protection:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

We agree, that all processing of ePI need to strictly follow applicable European data protection legislation. This should permit a personalized use of ePI, e.g. the creation of medicine lists by the patient.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

After all, harmonization across Europe will be complex, given the different health systems and the existing national ePI systems. That is why we are proposing to evaluate and compare the existing systems, adapt them where necessary and consolidate them under one umbrella, ideally using the existing systems as a starting point. A gradual and stepwise deployment in individual EU countries makes sense. But the whole system needs to be integrateable and operational in each single country.

As far as websites are concerned, the EMA portal is not patient-friendly in patient’s experience. The use of established portals (Red List, FASS, etc.) would therefore be preferable. A result from this consultation should be that the future portal and operators should be open for selection and to be discussed and chosen by all relevant parties. It should not pre-determined at the EMA level. The portals should be reviewed by patient organizations and supervised by relevant authorities. Third-parties that want to enable patients /consumers accessing the ePI, need to GxP-validate their tool. All validated tools could be listed on the trusted (national) portals.

It is unclear, what exactly is meant by “to reproduce” (Line 267).

Besides the electronic supply systems PLs could be printed out in the pharmacy as trusted source. This could help to gradually eliminate the paper version as a leaflet included in the packaging.

A regular and scientifically monitored review of the use and user-friendliness of the portal is urgently recommended and ought to lead to a formulation of concrete recommendations for improvement. What is important here is the possibility for citizens to participate, so citizens should be able to provide feedback.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.2 Flexibility in implementation:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

A flexibility in implementation is important and agreeable if a clear and appropriate roadmap is available. That processes might take some time and available solutions should accompany the development to gain more trust and to increase digital health literacy. In addition to what is proposed in the draft key principles, platforms for ePLs already in use in some member states should be integrated as trusted source into the roadmap of the European system.

The roadmap that will be developed, needs to have a clear vision of manageable dates to have systems in place. This goes along with a precise defined stepwise approach of delivering ePI within an acceptable time frame. Also, the capacity and resources of small and medium sized companies to electronic product information should be considered.

There should be incentives regarding regulatory procedures (e.g. variations, release of regulatory fees, release of timelines requested by HA for updated paper PL in a box if an electronic version is available, option for leaflet-free boxes for hospital-only medicines) for pharmaceutical companies to join to ePI requirements, so that all companies will participate and see an advantage using the electronic product information.

The wording should specifically include established portals such as Rote Liste (German compendium) or FASS. By that, the technical expertise can be used.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.1 Multilingual ePI:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

In principle, we welcome the fact that the information is made available in several languages.
If there is no common text basis of the PI (i.e. nationally approved medicines – in contrast to medicines approved via MRP/DCP or centrally approved) it should be considered that the content of the nationally approved product information may vary in the respective countries. If you offer PI in different languages or translations of nationally approved PI it should be clearly stated that the PI approved for its respective country is valid/legally binding.
We would welcome more clarification concerning the proposed translations of the information of nationally approved products. While we fully understand why the EMA let the national health authorities organize the translation of the ePI we would appreciate a more precise guidance on how it will be handled. Indeed, for the sake of interoperability we foresee that more governance would be of major interest.

If national authorities also require patient information to be available in other languages than for authorised products, it would be a high burden for industry. It can hardly be afforded by industry to perform certified translations. Patients are concerned that the additional expense could lead to some products being withdrawn from the market. This could be particularly problematic for smaller companies.
The use of a validated translation tool may be considered. Systems using artificial intelligence could be educated in a way that the required information could be made available easily.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

Regarding the interoperability, we would like to draw attention once again to the different health systems.

ePI should interface with many ongoing and foreseen eHealth initiatives. That`s why the system needs to be GxP-validated to be sure that the information of electronic product information is distributed unchanged to the single portals. The interfaces between the systems need to be validated and there should be a tracking system in order to see where the information of ePI is implemented in different eHealth initiatives. As the information officer in Germany is responsible for product information, a comprehensibility of the distributed information is necessary.

ePI should be interoperable with SPOR data management service. It should be considered that the information should be legible and good understandable for patients. Terms laid down in the ISO Standards to reflect the product or substance or referentials might be too complicated to understand.

Enter any general comments you may have:

This comment reflects the experience of the German pilot project “Gebrauchsinformation 4.0”:

Besides the two definitions for ePI and common EU electronic standard, a more general glossary with definitions would be helpful for interacting with all involved parties, especially patients/consumers. Then these terms should be used consistently to avoid any misunderstandings.

Rationale:

- Terms such as package insert and package leaflet (in German “Gebrauchsinformation” and “Packungsbeilage”) are used inconsistently. Accordingly, we recommend that, product information be used as an umbrella term encompassing both, technical/professional information for doctors and health care professionals and that patient information be used to designate the package leaflet (because it doesn't exclusively refer to the enclosed leaflet).
- The difference between Internet and an electronic platform should be explained – is the electronic platform possibly not Internet dependent?
- Apps are not specifically mentioned but play a big role in the patients live. Are they seen as part of Internet or electronic platforms?
- Some technical terms, i.e. “creating the technical basis” or “distribution of trusted information”, remains unclear and could use some explanation.

For future consultation processes, we would hope for a process manageable for all interest groups. This time, all information was only available in English and shown on the EMA portal and was therefore difficult to find and understand. To increase transparency and encourage a broad patient representation all documents should be provided in further national languages and more information channels. The ePI and development of central systems is aiming to increase user-friendliness. It is paramount to involve future users to get their feedback and to gain their trust into this system. It must also be “their system”.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

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Your name

[redacted]

Your email

[redacted]

You are a:

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- ○ Patient/consumer
- ○ Patient/consumer organisation
- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ◉ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

Amneal

Indicate the key principle you would like to comment on (select all that apply):

- ☐ 1.1 ePI
- ☐ 1.2 Common EU electronic standard
- ☐ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☐ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☐ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☐ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

line 202, if ePI is merely complementing the paper, there is no incentive for the industry to comply as it only increases the workload. Secondly, ePI can be updated quicker but still old packs may be in the supply chain for a long time with different information and this would create confusion. Thirdly, EU rate of poor reading skills in general is in line with e-illiteracy or access (16.4 vs 15, as per Elinet and Statistica) and pharmacies would always be able to print a leaflet upon dispensing if desired so there should be no need for a paper leaflet in the pack. Lastly, paper leaflets in every pack are a huge burden on the environment. Apart from the ones that are not read in the packs, there are millions destroyed as leftover stock every year because of updated PI, usually safety data. All in all, I would strongly suggest that if ePI is taken forward, it should become mandatory and replace the paper leaflet.

Enter any general comments you may have:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contribution ID: f6854ef8-7a5e-40d6-b394-e4a87f106d0f
Date: 31/07/2019 23:13:30

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- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ○ Other

Name of your organisation:

PAINT-Consult, Wenigenjenaer Ufer 12, 07749 Jena, Germany

Indicate the key principle you would like to comment on (select all that apply):

- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☐ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

We at PAINT-Consult agree to the definition of ePI .

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

We at PAINT-Consult welcome a common electronic standard for the dissemination of product information about each medicine used in the European Union, in addition to the existing methods. However, we must raise our concern in relation to development of a completely new electronic standard and agree to the concerns voiced by Mr. Bachmann during the EMA–HMA–EC workshop held on 28 November 2018 relating to the expected major difficulties and problem of building a “new cathedral” - a common electronic standard for ePI. It would more effective to use current solutions as much as possible, rather than to reinvent the wheel. The area of IT is hallmarked by the rapid pace of change; thus it seems certain that within a couple of months of commencement of the new ePI EU electronic standard, the intended solution may already be outdated due to incomplete involvement of stakeholders, time consuming procedures from time of call for bids up until the completed solution, existing regulatory files not being available in an ePI structure, etc. The pharmaceutical area has already had its share of cost-extensive EU projects with negative outcomes. Furthermore, private IT business and solution providers could do this significantly quicker, with a focus on existing solutions which could significantly reduce time and costs; therefore, already available open data solutions allowing interoperable work with other e-health systems should be employed wherever possible to achieve the intended goal in a more cost- and time-efficient fashion. For example, see ePI projects already being provided at national level. Moreover, it cannot be assumed that we are confined to just one solution carved in stone for any time.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

“Availability of regulator-validated ePI will counterbalance unreliable and spurious claims about medicines ...” would be a welcome feature of ePI; however, this intended new service will be always in competition with unreliable and spurious claims as they cannot be completely eliminated. Furthermore, the EU ePI will be also in competition with product information about the same medicines used in other non-EU countries/areas with same languages, such as USA, Canada, Switzerland, Australia and South America. Product information used in non-EU countries/areas often differs in comparison to EU versions in information covering indications, contraindications, special warnings and side effects. Therefore, the EU must ensure that users of ePI know at all times that this product information is an EU approved version.

Please note, with regard to the draft key principles mentioned in 2.1 under “Implication” to ensure that the most up-to-date ePI version should be always easily available: “To achieve this principle, ePI should be made available through various technologies and applications, including mobile scanning technology (such as a 2D barcode) on the medicine package.” The provided example “2D barcode” is misleading and should be changed into “2D code” as this code does not contain any bars.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

We agree that currently ePI shall not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of 202 Directive 2001/83/EC1) to provide a package leaflet in or on the packaging of all medicines.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

We also agree to: “ePI is intended for the delivery of regulator-approved medicine PI only. The content of ePI should be identical to the latest version of the PI approved by regulatory authorities. ePI will not be used for delivery of promotional information. ePI should always be published as open data, freely accessible for use and reuse.”
However, an additional statement must be provided stating that the date of last update must be always provided in conjunction with every product information, to ensure users have the latest version. If users print out the product information or save it in a file, they should have the last update information visible in the document. In case of centralised approved medicines, for example, the date of last update is currently only published on the website of the EMA, but not within the product information files.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

We recommend for the short and medium term that ePI be used as is done currently with EU product information - to convert the PI to ePI once the regulatory procedure is completed. Any extension or publishing during the approval procedure should not be discussed before the system works properly and clear agreements exist governing what must/should be published at what stage of the procedure.

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

The global harmonisation of product information should be initiated and completed as soon as is possible, in parallel to the creation of the EU ePI electronic standard – to prevent different contents appearing in product information in different areas of the globe for identical medicines. See comment to 2.1 "Expanding access to information".

Enter any general comments you may have:

Despite the positive and welcome initiative of introducing EU ePI system, improvements to current package leaflet texts – especially their total volume of text and that caused by the QRD template – have yet to be performed, even though this was outlined as a need in the European Commission report published in March 2017 and in the EMA action plan of November 2017 [1, 2]. The current average volume of text in EU package leaflets is around 2600 words and the QRD template text intended for each EU package leaflet contains already 840 words [3-6]. Since 2012, three readability test studies have been published (in total 1538 participants) establishing that using a 200-word template would significantly improves package leaflets and reduces the volume of text by around 15 % in all EU package leaflets, without deleting medical specific information. This alternative version is based on the QRD template, but optimised by avoiding repetitions and long sentences [7-10]. According to the PAINT3 study with 5091 participants and the PAINT1 study with 1105 participants, every decrease in the volume of text leads to a significant:

- increase in patients' motivation to read package leaflets
- decrease in the time required to locate the provided information
- increase in patients' trust in using the medicines [10, 11].

Last but not least, any text compression of current EU product information would noticeably ease and support the use of ePI via modern electronic media, such as tablets and smartphones - a highly important issue that the QRD group of the EMA should use as an inducement to begin implementation of the proposed and scientifically proven shorter template version.

1 European Commission. Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. http://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf (accessed July 16, 2019)

2 EMA. EMA action plan related to the European Commission's recommendations on product information. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/11/WC500238305.pdf (accessed July 16, 2019).

3 Wolf A, Fuchs J, Schweim H. Implemention of the European QRD template in package leaflets of centralized approved medicines. Therapeutic Innovation & Regulatory Science 2016, 50(1):106-114. https://journals.sagepub.com/doi/abs/10.1177/2168479015620247 (accessed July 16, 2019).

4 Fuchs J, Kraft S, Vettermann A, Reiche M. Typographic changes in package leaflets of the European Union based on the example of German versions between 2005 and 2015. Therapeutic Innovation & Regulatory Science 2017, 51(4):431-438. https://journals.sagepub.com/doi/abs/10.1177/2168479017699654?journalCode=dijc (accessed July 31, 2019).

5 Wolf A, Fuchs J, Schweim H. QRD template texts intended for package inserts - Development from the first QRD template up to the new draft of July 2012. PharmInd 2012, 74(9):1540-1549. https://www.paint-consult.com/fileadmin/editorial/downloads/publikationen/PAINT-Consult_QRD_template_development.pdf (accessed July 31, 2019).

6 EMA. Product information templates; Centralised procedures - version 10.1 - 6/2019; MR/DC/Referral procedures - Rev. 4 - 2/2016. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59 (accessed July 31, 2019).

7 Fuchs J, Scheunpflug C, Götze E. The influence of the European Union's template on the use of package inserts compared with a shorter model template. PharmInd 2012, 74(1):126-136. https://www.paint-

consult.com/fileadmin/editorial/downloads/publikationen/PAINT-Consult_The_influence_QRD_template_shorter_model-template.pdf (accessed July 31, 2019).
8 Wolf A, Fuchs J, Schweim H. Readability of the European QRD template - The European QRD template version 8 in comparison to its predecessor and a shorter model template. PharmInd 2014, 76(8): 1312-1322. https://www.paint-consult.com/fileadmin/editorial/downloads/publikationen/PAINT-Consult_Readability_European_QRD_Template.pdf (accessed July 31, 2019).
9 Fuchs J, Hippius M. Inappropriate dosage instructions in package inserts. Patient Education and Counseling 2007, 67:157-168. https://www.sciencedirect.com/science/article/pii/S0738399107001036 (accessed July 31, 2019).
10 Fuchs J. The way forward in package inserts user tests from a CROs perspective. Drug Information Journal 2010; 44(2): 119-29. https://www.paint-consult.com/fileadmin/editorial/downloads/publikationen/PAINT-Consult_The_way_forward_in_package_insert_user_tests.pdf (accessed July 31, 2019).
11 Fuchs J. Patient information via package inserts within the European Union - pages 24 to 26. https://www.paint-consult.com/fileadmin/editorial/downloads/vortraege/PAINT-Consult_Presentation_chin_Deligation_Bonn_2010_engl.pdf (accessed July 31, 2019)

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- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution
- EU agency
- Non-EU regulatory authority

- (●) Other

If other, please specify:

Charity

Name of your organisation:

Royal College of Physicians (RCP)

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [ ] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [x] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

There needs to be widespread consumer testing of the ePI, particularly with older patients who are often on polypharmacy. They may have cognitive deficits and face major difficulties with reading small print.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

There needs to be a clearly defined, single easily searchable website with a Master (most up to date) copy (in whichever language the EMA considers necessary). The national state regulators may well wish to host their own language copies, but this creates a problem of keeping the various versions synchronised/ updated. Moreover, national state regulators may not have an easily searchable website for ePI. An example of a very useful website with easily searchable Summary of Product Characteristics and Patient Information Leaflets can be found here: https://www.medicines.org.uk/emc/

Enter any general comments you may have:

The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Specialty Committee for Clinical Pharmacology and Therapeutics to provide our comments.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission and identity will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Your name

[redacted]

Your email

[redacted]

You are a:

- ○ Member of the public
- ○ Patient/consumer
- ◉ Patient/consumer organisation
- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ○ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

- ( ) Other

Name of your organisation:

CF Europe

Enter any general comments you may have:

I present the Dutch CF Foundation and teh European umbrella organization

Indicate the key principle you would like to comment on (select all that apply):

- [ ] 1.1 ePI
- [ ] 1.2 Common EU electronic standard
- [x] 2.1 Expanding access to information
- [x] 2.2 Accessibility
- [ ] 3.1 Complementing paper package leaflet
- [ ] 3.2 Open access to regulator-approved information
- [ ] 3.3 Data protection
- [ ] 4.1 Governance
- [ ] 4.2 Flexibility in implementation
- [ ] 5.1 Multilingual ePI
- [ ] 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Some comments about the Draft Key Principles for electronic product information

July 25th, 2019

Electronic product information for human medicines in the EU – draft key principles.

A response:
sixty six comments leading to seven suggestions

A collaboration of EMA-HMA-EC started a public consultation on January 31st, 2019. The aim is to collect comments about these Draft Key Principles for the development of electronic Product Information (ePI). [Link to original document - a copy is attached at the end of this report]

This response consists of four parts:

1. ***Sixty six comments***. These are line-by-line comments of the Draft Key Principles (page 13 to 41).
2. The sixty six comments are grouped into ***seven categories*** (page 4 to 12)
3. The seven categories lead to ***seven suggestions*** (page 3).
4. ***A summary*** of this response (page 2).

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1. Summary

A line-by-line analysis of an EMA-HMA-EU public consultation document on electronic Product Information (ePI) prompted sixty six comments (page 13-41). These comments were grouped into seven categories (page 4-12) and have lead to seven suggestions (page 3).

The Draft Key Principles do not make clear who the ***users*** of ePI are (suggestion 1). The document provides ***unfounded characteristics of information*** (suggestion 2), and is unclear about ***the aims*** of ePI (suggestion 3). It makes many ***unsupported assumptions*** (suggestion 4), and does not fully explore potential ***benefits of digital information*** (suggestion 5). The suggested ***process*** is in conflict with other recommendations of the European Commission (suggestion 6), and it is questionable if the ***standardization*** of existing information is really the most beneficial approach (suggestion 7).

It would be very disappointing for all stakeholders if the implementation of the six recommendations of the European Commission (2017) has only lead to this 'proposal for a mark-up language' as a first step.

There is an urgent need to modify information about medicines and embrace the digital realm. The shortcomings in the provision of analogue information about medicines have been formally recognized in 2010. Prescribing errors, dispensing errors, administration errors, and low adherence require swift attention. The correct, safe, and efficient use of medicines are probably the main aims for ***users of information***. The current regulatory process is complex, costly, error prone, and time consuming for ***developers of information***. Both sides could benefit substantially from the development of electronic Product Information - to be used in both analogue and digital formats.

Information about medicines must focus on what people need to achieve. The development of information must strive for inclusion and accessibility for all. In the absence of measures to ensure different user's needs are taken into account, only those of the dominant group are served. Therefore, it cannot be based on a rigidly standardised information content or the current limitations of digital technology.

The next version of the Draft Key Principles should address the aims, approaches, and processes that are required to develop information about medicines that really 'enable people to act appropriately'.

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2. Seven suggestions

These suggestions are based on the seven categories that group the sixty six comments.

Suggestion 1: It is important to clarify who the users of electronic product information are and how they should benefit. All user groups must be involved in the development of ePI; none of the actual user groups should be excluded.

Suggestion 2: People who use information decide if they can trust it and apply it to their situation. Information does not have 'inherent qualities'. It is therefore necessary to find out which information people trust and use before adding more information in an alternative format.

Suggestion 3: Clarify what the aims of electronic Product Information are for each of the user groups. Set performance based standards for every action that needs to be enabled with the support of electronic product information.

Suggestion 4: Investigate assumptions before using them as a basis for decisions.

Suggestion 5: Digital information is not sequential nor text based. It can be modular, visual, and interactive. Users can modify its language, format, mode, structure, and design according to their needs. Allow for these continuously evolving digital opportunities.

Suggestion 6: Make sure that all six recommendations of the EU can be implemented. The development of ePI as suggested in the Draft Key Principles makes it very difficult to consider other recommendations. It seems essential to reconsider the priorities, and start with scoping and benchmarking studies.

Suggestion 7: Standardizing the current legally required information, which is known to have shortcomings, might not be the best option.

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3. Seven categories

The detailed comments are mentioned on pages 13 to 41. In this section, the sixty six comments are grouped into seven categories.

Category 1: Who are the users?

(This category is based on comments 16, 18, 21).

Throughout the Key Principles document, the people who would benefit from electronic product information (ePI) are not clearly defined. The descriptions below show that at least seven different groups are involved. It is unclear if these different descriptors of the various user groups are intentional and indicate different meanings.

The seven groups are:

1. Healthcare professionals: healthcare professionals (line 52); healthcare professionals who travel and work in several EU countries (line 116); users (line 263).

2. Patients/consumers: patients/consumers (line 53); patients and consumers of medicines in the EU/EEA (line 118-119); citizens (line 190); EU citizens (line 171, line 329); patients/consumers with diverse abilities (line 185); blind and partially sighted people (line 186); those with low literacy levels (line 186-187); patients/consumers with low digital literacy (line 211); patients/consumers with limited internet access (line 212); patients who travel and work in several EU countries (line 116); users (line 263).

3. Industry: industry stakeholders (line 69); the pharmaceutical industry (line 79); other companies (line 246); micro, small or medium-sized enterprises (SMEs) and companies producing generic medicines (line 307-308); pharmaceutical companies (line 319); MAHs (line 246, line 272, line 281).

4. Authorities: regulators (line 69, line 280); regulatory authorities (line 221, line 259); national competent authorities [NCA] (line 137); national authorities (line 335); EMA and NCAs (line 174); Members of the European medicines regulatory network (line 245-246); EU authorities (line 258); HMA and EMA (line 302, line 311-312).

5. Combinations: companies, not-for-profit organisations or patient/consumer groups (line 193); patients and healthcare professionals who travel and work in several EU countries (line 116); all parties involved (line 245); users (patients/consumers and healthcare professionals) (line 263); all stakeholders,

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including pharmaceutical companies and regulators (line 299); regulators and stakeholders (line 111, line 142).

6. Non-healthcare: academia (line 69); not-for-profit organisations (line 69); Member States (line 306).

7. Unclear: stakeholder (line 62, 310); third-parties (line 267); third-party providers (line 276).

The inconsistent and vague descriptions of people who have to handle ePI cannot be used as a starting point because these make it impossible to define performance expectations and select criteria for success.

It is important to clarify who the users are and how they could benefit. Make sure that all user groups are involved and that none of actual user groups is excluded.

Category 2: Contents of an ePI?

(This category is based on comments 2, 20, 23)

The description of the information in the ePI varies substantially throughout the Draft Key Principles document. Each of these descriptions asserts that information can have specific characteristics that can be established independent from the users or context.

The Draft Key Principles document mentions the following characteristics of information:

- scientifically validated information (line 54)
- up-to-date information (line 65)
- authorised, statutory product information for medicines (line 86)
- electronic authorised information (line 118)
- trusted information (line 123)
- unbiased, up-to-date, regulator-approved product information (line 149)
- the latest information (line 151)
- the latest authorised information (line 157)
- regulator-validated ePI (line 170)
- an authoritative source of scientific and evidence-based information on medicines (line 171-172)
- regulator-approved information only (line 218)
- regulator-approved medicine PI only (line 220)
- the latest version of the PI approved by regulatory authorities (line 221)
- validated, non-promotional information (line 235)
- as a trusted source for reliable medicines information (line 284)

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There are several phrases that might have a similar meaning:
- authorised, statutory, regulator approved, regulator vaiidated, authoritative;
- scientifically validated, evidence-based;
- up-to-date, latest.
However, it is not clear if 'regulator approved' and 'regulator validated' are identical, or if 'latest' and 'up-to-date' are identical.

A combination of all these descriptors provides the following characteristic of ePI:

> ***'ePI provides electronic, authorised, regulator approved, regulator validated, authoritative, trusted, unbiased, up-to-date, latest, scientific, evidence based, non-promotional, reliable information.'***

However, there is little evidence - if any - that this information is perceived like this by people who need to read product information about medicines. The problem is that it doesn't matter if competent regulatory authorities aim to provide this, *it is the reader who decides if information conforms to their criteria of reliability and trustworthiness*. Even if it is scientifically validated and approved, it might not be trusted.

People who use information decide if they can trust it and if they can apply it in their situation. Information does not have 'inherent qualities' that can be assessed outside its context of use. It is therefore important to find out which information people trust and use before disseminating the same information in another format.

Category 3: Aims?

(This category is based on comments 7, 8, 12, 14, 15, 17, 19, 22, 26, 31, 34, 35, 38, 44, 46, 47, 49, 50, 51, 66).

The aims of the development of electronic Product Information are not clearly stated. It is not clear what exactly needs to be achieved through the provision of electronic product information about medicines.

Instead, the Draft Key Principles document mentions at least nine aims. The aims described throughout the document seem to be beneficial for different user groups, which makes it difficult to assess if they can be achieved. The nine aims are:
- 'it will ensure patients have timely access to up-to-date information.'
- 'to offer possibilities to streamline, simplify and speed up the regulatory process in the creation and updating process.'
- 'to create the technical foundation for the dissemination of trusted information in the electronic world.'
- 'possible to rapidly update ePI, … expected to increase support to patients/

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consumers in informed decision-making, … should facilitate patient/consumer-healthcare professional interactions and discussions about medicines.'
- 'The structured nature of ePI will offer new opportunities to better tailor product information to the needs of individual patients/consumers.'
- 'ePI can be handled electronically and read by machines, ePI information can flow to other systems, such as electronic health records and e-prescribing systems.'
- 'facilitating targeted delivery of the right information to the right patient/consumer at the point of need.'
- 'EMA and NCAs should work towards ePI to fulfil their mission to protect public health.'
- 'The most up-to-date ePI version should be always easily available.'

At the moment, without reliable benchmark data, it is not possible to state what the current situation is. For example, which specific groups of patients at the moment do not have access to any information, and how many do not have access to up-to-date information?

It seems necessary to clarify what the aims of electronic Product Information are for the different user groups. This can only be done through scoping and benchmarking studies that lead to setting performance based standards.

Category 4: Assumptions?

(This category is based on comments 1, 3, 4, 25, 36, 37, 39, 40, 43, 45, 55, 56, 62, 64, 65).

The document mentions several unsubstantiated assumptions. These need to be investigated befoe they are used as a basis for decisions. Two questions about each assumption need to be answered: 'What is the evidence? (is it really true?)' and 'to which extent? (who or what is excluded?)'.

There is very little evidence that supports the following assumptions:
- 'pivotal.'
- 'assists healthcare professionals in prescribing and dispensing the medicine.'
- 'informs patients and consumers about its safe use.'
- 'the electronic format is the most pressing priority.'
- 'Semi-structured' … 'structured elements (e.g. fixed headings and vocabularies)' … 'some unstructured elements (i.e. free text).' 'Unstructured formats.' [= can information be separated in this manner?]
- 'which will allow patients/consumers and healthcare professionals an additional and tailored approach on information for medicines according to his/her need and/or wish by using suitable (electronic) output forms and platforms.'

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- ‘multiple different standards … would generate unnecessary complexity, impede access to information and require multiple interfaces between standards, restricting flow of data.’
- ‘the benefits this format can offer for public health.’
- ‘will support … provision of the latest information on a medicine’s safety, benefits and its conditions of use.’
- ‘will support … better delivery of information so that the right information is available to the right patient/consumer at the point of need.’
- ‘will support … informed decision-making by patients/consumers and healthcare professionals.’
- ‘Patients/consumers and healthcare professionals using ePI can be fully confident that they hold the latest information.’
- ‘to increase support to patients/consumers in informed decision-making about their treatment.’
- ‘and help them to adhere to their medication regimes, ultimately contributing to optimal outcomes.’
- ‘Availability of regulator-validated ePI will counterbalance.’
- ‘often widely spread through online and other forums’.
- ‘the paper PL is particularly important for patients/consumers with low digital literacy.’
- ‘as trusted source for reliable information.’
- ‘may be a significant burden.’

There is very little reliable evidence supporting any of the abovementioned assumptions. The correctness of these assumptions need to be verified before any system can be developed.

Thorough scoping and benchmarking phases are essential to find out if these assumptions are correct, and if they are correct in all contexts. Further empirical research is necessary to provide reliable evidence for decisions.

Category 5: Digital opportunities?

(This category is based on comments 6, 9, 13, 24, 32, 33, 48, 52, 53, 54).

The digital opportunities can be subdivided into five main groups:

a. Mark-up Language

Line 138 and 139 indicate that the ‘mark-up language’ will be the only available technical feature for electronic Product Information. The other two features - ‘interoperability’ and ‘controlled vocabularies’ - still need to be developed.

A mark-up language is a very narrow focus, and this does not really make much use of digital opportunities. It mainly goes back to the xml-based *‘patient information management’* (PIM) system which was halted in 2011 (PIM, 2011). It might be beneficial to evaluate how the experience of the PIM-project

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could benefit the development of the electronic Product Information before embarking on a new xml-adventure. Existing digital formats, such as Adobe PDF and Microsoft Word (and a range of related software applications) include more and more features that integrate a standardised mark-up language too. Choosing the most beneficial standard will require substantial research.

b. Accessibility

Providing information in a digital format requires the adherence to European legislation and international web-standards. The European Accessibility act (2016/2102) provides a good starting point. A harmonised European standard was recently published (ETSI, 2018), and the W3C-Consortium (https://www.w3.org/WAI/) lists the international requirements. These need to be followed, because they are based on empirical evidence how people access digital information. These standards also support people with diverse abilities to use electronic resources.

c. Information contents & key information section

The obligatory order of information in package leaflets will be modified in digital formats. This is unavoidable in a digital environment where information is modular, layered, and top-level information needs to be shown first. The idea of a 'key-information section' as suggested by recommendation 6 (European Commission, 2017, page 8) is essential for electronic Product Information because that is exactly what people expect on the highest hierarchical information level. This addition will lead to a difference between the printed package leaflet and its digital version in both sequence and the number of sections. It is furthermore likely that the digital environment will require more visual information in the form of pictograms, illustrations, and colours.

d. Adding information

The digital environment will add other information to the ePI, because the addition of meta-data is essential for digital use. This consists of digital wayfinding (menu's, hyperlinks, colours), search engine support, and links to other information sources. Without these, an ePI will not optimally use of digital opportunities. Suggesting that it is possible to make information electronically available ***and*** prohibit the addition of information (line 227-228, comment 61) is simply incorrect.

e. Sharing hyperlinks

One of the main features of electronic information is the ability to link to other digital resources and social media. The limited information in the highly condensed texts in SmPC and package leaflet will be linked to a range of other resources. These links could be really helpful for people to find more information about a medicine.

All five above-mentioned topics are not options: they are an integral part of digital information. Mark-up languages, accessibility standards, variable

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contents on different levels, adding meta-data and search engine support, and including hyperlinks are standard and must be used as a basis for the development of digital information about medicines. Ignoring these will reduce and limit the functionality.

Category 6: Process?

(This category is based on comments 5, 10, 11, 27, 28, 29, 30, 41, 42, 58, 63).

Much of this ePI approach is in conflict with 'the principles of good information design' (Sless and Shrensky, 2006; Black, Luna, Lund, and Walker, 2017).

a. Start from what is available: scoping

Most of the information about medicines is already available in a digital format. Not only in PDF and Word on the EMA-website, but also in many digital pharmacopoeia, medicines compendia, and repertories used by doctors and pharmacists. These are all based on standardised digital structures. Ignoring these existing digital resources, and developing yet another one might not be effective. A first step - as the principles of good information design suggest - is to find out first how different people cope at the moment. This 'scoping' will reveal the activities that go well, and those that are more problematic.

b. Find out how well people coop at the moment: benchmark

The activities that are problematic need attention first. These cause the errors, additional costs, increase waste, and intensify anxiety. The assessment criteria and measurement-units need to be established before small scale benchmark tests can be conducted. The test results will provide the data that can be used afterwards to evaluate if a change has really lead to an improvement. Without the benchmark scores, it is impossible to evaluate what the effects of a change are.

c. Involve people right from the start

The Draft Key Principles document implies that it is possible to start the development of a semi-structured format (line 91) without the involvement of patients, consumers, and healthcare professionals. The scoping and benchmarking phases are simply skipped. This is in conflict with the 'principles of good information design' that are mentioned as recommendation 2 of the European Commission (2017).

d. Consider all six EC-recommendations

This above-mentioned three points show a direct conflict between the development of electronic product information and recommendations 2 and 3 of the European Commission (2017). Recommendation 2 suggests to rely on 'principles of good information design' and recommendation 3 states that 'patient input should be further improved'. Developing the ePI as it is suggested in the Draft Key Principles document will make it very hard to implement recommendations 2 and 3.

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These four points indicate that a reconsideration of the priorities for the development process of electronic product information about medicines is essential. The combination of both analogue (printed) and digital information (on screens) needs to focus on 'enabling the user to act appropriately', as it required in Directive 2004/27/EC, article 63 paragraph 2. Not involving people, and not applying principles for good information design is in conflict with the recommendations of the European Commission.

Category 7: Standardising the right thing?

(This category is based on comments 57, 59, 60, 61).

Two questions need to be asked:

a. Is a 'semi-structured format' appropriate?

The European Commission detected 'shortcomings' in 2010, and the NIVEL PIL-report (2013) showed that *'patient's comprehension of the package leaflet and its readability can be improved.'* The PIL-report further concludes: *'Guidelines should include more details on the principles of good information design in which the content and layout are jointly considered.'* The standardisation of the information into a 'semi-structured format' (line 91) is in conflict with this conclusion because it separates the contents from the layout. The semi-structured format should not be developed without taking the visual presentation of information into account. This combination of contents in a semi-structured format and visual presentation must be developed in cooperation with people who are going to use this information: patients, consumers, and healthcare professionals.

b. Is the information content suitable for all circumstances?

The Draft Key Principles state that the legislation will remain the same and that the contents of the information will not change. Line 227 and 228 state that other information cannot be included in the electronic Product Information. It is therefore likely that the electronic Product Information is very similar, or identical to, the information that appears now in package leaflets, in the SmPC and on packaging.

This information is however not suitable in all circumstances. Patients require different types of information in for example hospitals, elderly care homes, and in emergencies. The variation in medicines, and in contexts in which medicines are prescribed and dispensed also require more variation in information about medicines. Standardizing information that has proven to have 'shortcomings' needs to be avoided. It would be more beneficial to consider the users, required actions, and required performance levels first before standardized information is supplied.

The Draft Key Principles suggest that it is possible to develop a 'semi-structured format' without considering its visual presentation. This

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approach is in conflict with the results of the recommendations of the European Commission, and with the principles of good information design.

The information content and digital structure must be considered together, based on the results of benchmark tests with actual users. Parts of the process can be standardized in a protocol. The outcomes cannot be standardized because they depend on people who need to undertake specific actions in a context. However, acceptable performance levels for each action can be standardized.

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4. Sixty six comments

‘Background’ (line 50 to 74).

Comment 1: Line 54. ‘the pivotal source’.
The word ‘pivotal’ needs to be reconsidered. It is questionable if product information about medicines in Europe can be seen as ‘pivotal’ in all circumstances for all users.

There are three main groups who use SMPCs and PILs:

Group 1: Prescribers use an SMPC to prescribe medicines. There is conflicting evidence about this statement. There is some evidence that healthcare professionals do not use SmPCs to prescribe and use other sources (Raynor 2013; Vromans 2013). The first study concluded: *“Qualitative comments showed that in their current format, SmPCs are of low perceived value to prescribers and are not central to the clinicians’ prescribing behavior. Current content and presentation of SmPCs, while meeting regulatory approval standards, contribute little to the safe and effective use of medication in practice.”* The second study concluded: *“Physicians confirmed the importance of SmPCs as a comprehensive source of medicinal product information, but were moderately satisfied with the current SmPCs, utilised it infrequently and were more likely to engage additional sources of information.”* An EMA-survey in 2016 shows the opposite. It concluded that 95% of healthcare professionals across Europe use the SMPC (Brassart and Peppard, 2016). The Nivel stakeholder survey (PIL-S report, chapter 5, page 71) did not ask or investigate if SmPCs are actually used by healthcare professionals.

Group 2: Pharmacists dispense medicines. The information on the pack that pharmacists must read to dispense is pivotal: there is no other source at the moment of dispensing. A 2014 report by the EMA shows how problematic this information currently is. Between 2% and 49% of the dispensed medicines in hospitals is incorrectly dispensed. This leads in 10% of cases to irreversable harm to patients, and it was lethal in 5%. (EMA, 2014).

Group 3: Patients and consumers use PILs about safe use. (van Beusekom 2016; Leemans, 2011). The first study concluded: *“Patient information leaflets were considered discouraging to use, and information difficult to find and understand. Many rely on alternative information sources.”* The second states: *“We can conclude that the actual PIL is read too little. In order to make the PIL more appealing and even more patient friendly than it is actually, taking patients’ needs into account should be a priority.”*

In some studies, prescribers, pharmacists, patients, and consumers seem to have serious problems using SMPCs and PILs, while in other studies these documents don’t cause any problems. The view of the European Commission is that there are ‘shortcomings’.

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Alternative: This first paragraph needs to be rephrased to do justice to the factual use of these documents. There is little evidence that SMPCs and PILs can be characterized in general as 'the pivotal source'.

Comment 2: Line 54-55. 'scientifically validated information'.
The words 'scientifically validated information' need to be reconsidered. Several sections in the QRD-template are based on fear, not on evidence (QRD-template, version 10, 02/2016). Three examples in the text for the package leaflet that are not supported by evidence are:

- [Page 27] *'Do not pass it on to others'*. Although patients might give their medicines to others, the scale of this behaviour is unknown. It is a fear that is not supported by evidence.
- [Page 27] *'Keep this leaflet. You may need to read it again'*. Apart from the superfluousness of this statement - what are the other reasons to keep a leaflet? - it is an advice that is not supported by evidence. If this was important, than it is essential to make it easy to put the package leaflet back into its box.
- [Page 28] The annotated template states that: *"the benefit(s) of taking the medicine could be summarised. … This would be particularly important to encourage adherence to the treatment, e.g. for long-term and prevention treatment"*. There is no evidence that there is a direct relation between the provision of information and actual adherence. This statement is not supported by any validated scientific evidence.

Alternative: Delete the words 'scientifically validated information'. These are incorrect.

Comment 3: Line 55. 'assist healthcare professionals'.
This is an unsupported assumption. The actual use of these documents by different types of readers - medical doctors and pharmacists - is to a large extent unknown.

Alternative: Before a new approach is introduced, it is essential to benchmark the current performance. This 'benchmarking' will show how well actions are performed at the moment, and how well practical use is enabled by specific types of documents. This baseline data is essential to check later if a modification can be seen as an improvement. It is highly likely that there is a substantial variation of the use of SMPCs by healthcare professionals. Not all healthcare professionals are assisted to the same extent in a similar manner.

Comment 4: Line 56. 'informs patients and consumers about its safe use'.
This is an unsupported claim. The assumption is that all patients and all consumers need identically structured and standardized information to use medicines safely. It assumes that patients and consumers - even if they use

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the same medicine - are homogenous groups. And it assumes that patients and consumers actually read, understand, and apply the information in the package leaflet. Most of the literature about package leaflets shows that these assumptions are incorrect.

> Alternative: The aim of information is to 'enable the users to act appropriately'. Authorized information must be provided in formats to:
> - enable patients to use medicines correctly and safely
> - enable consumers to use medicines correctly and safely
>
> Before a new approach is introduced, it is essential to benchmark the current performance. This 'benchmarking' will show how well actions are performed at the moment, and how well practical use is enabled by specific types of documents. This baseline data is essential to check later if a modification can be seen as an improvement. It is highly likely that there is a substantial variation of the use of package leaflets by patients and consumers. Not all patients and consumers are informed to the same extent in a similar manner.

Comment 5. Line 62-63: 'identifying stakeholder needs and mapping ongoing initiatives'.

Identifying and mapping are essential but not sufficient. These are just the first steps to prepare for systematic scoping and benchmarking phases. Identifying needs and mapping initiatives do not provide the right kind of data that can be used as a basis for an information development proces. It is essential to identify and verify what the most problematic issues for ***all*** the ***different*** stakeholders are. A focus on stakeholder's will reveal conflicts between different stakeholders and within stakeholder groups, but it will not help to resolve these.

> Alternative: A systematic scoping phase and a systematic benchmarking phase are essential.
>
> The **scoping activity** will show how people deal with situations in practice. There will be a substantial variation between people. [Not every prescriber will read an SMPC before prescribing a medicine. Which information sources are used? What is the variation between doctors? How does the SMPC fit into activity-patterns?] The scoping phase will point to those activities that are most problematic in practice at the moment. There are many methods to conduct these contextual inquiries.
>
> Systematic **benchmarking** will show how well an information source performs when it is used for a specific action. [A benchmark test will provide exact data if people can find information, can understand it, and can apply it.] Benchmark data can afterwards be used to check if a change can be seen as an improvement. Identifying stakeholders and mapping initiatives will not provide this data.

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Comment 6. Line 62: 'a future electronic PI'.
The phrase 'a future electronic PI' is confusing because the PI already encompasses combinations of electronic information and analogue information. The product information (PI) consists of an SMPC, labelling, and a package leaflet. At the moment, the SMPC and the Package leaflet are already available in a variety of electronic formats. Only the labelling is guaranteed to be on a substrate such as paper, cardboard, blisters, glass, etc.

> Alternative: The aim of the ePI project might not be to develop 'a future electronic PI' but to 'reconsider the provision of information about medicines to increase the use of digital opportunities'. It is very likely that this will lead to a range of product information that takes the user, context, actions, and situations into account. It is not a single 'future electronic PI', but a system that provides people with reliable information about medicines in formats that are appropriate, relevant, and usable.

Comment 7. Line 64. 'the electronic format is the most pressing priority'.
The assumption that the electronic format is the most pressing might be incorrect.

There are several other issues that are directly related to product information such as 'dispensing errors', 'prescribing errors', and 'adherence'.

An EMA report in 2014 (EMA/20791/2014) revealed major problems in the dispensing of medicines in hospitals across Europe. The literature about prescribing errors is increasing (Cousins, Crompton, Gell, Hooley, 2019).

A second pressing issue is the adherence and self-administration errors. There are many definitions, methods, perspectives, and criteria to describe adherence, but there is a fundamental problem with the ways in which patients do not use their medicines in ways that would be optimally beneficial.

Standardising digital formats for information that is currently available in package leaflets and SMPCs will not do much to alleviate any of these problems. Basically, by focussing on the development of an electronic format, these issues become less important, with a delay in progress as a consequence.

> Alternative: Reconsider the priorities and make clear who would benefit from the introduction of electronic formats. The six recommendations of the European Commission need to be considered simultaneously to avoid that decisions to follow one recommendation block progress in others. It is essential to start from the perspective of different types of users and their needs. Starting from current digital opportunities is likely to be less effective because these opportunities are likely to change very quickly.

Comment 8. Line 65. 'as it will insure patients have timely access to up-to-date information'.
This phrase suggests that patients at the moment do not have timely access to up-to-date information. [Note: it looks as if 'insure' is used, where 'ensure' is

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meant?] It is a worthwhile aim that is worth striving for, but would it help to resolve issues related to adherence, dispensing errors, and prescribing errors?

There are four issues here.

a. Is it really possible to 'insure' that patients have access? This is an unlikely aim because achieving this depends on a practical situation and those are extremely varied.
b. Why does the focus shift to patients only? Shouldn't prescribers, pharmacists and consumers have 'access to up-to-date' information too?
c. What are the current risks of 'not having' up-to-date information?
d. The statement suggests that 'patients' can be seen as a homogenous group, and that this urge for up-to-date information is equally important for all medicines.

> Alternative: The interpretation of information varies between people, depends on the situation, and is likely to be partly incorrect. People are very well aware that the information they read might not be the most up-to-date, the most accurate, or the most reliable. Healthcare professionals are trained to check this. Patients gain experience and trust their doctors and pharmacists to provide reliable information. It seems necessary to investigate this in detail in order to provide information that is really effective and beneficial. The general aim to 'ensure that all patients always have access to up-to-date information' might not be attainable.

Comment 9. Line 65-66: 'coordination among the many initiatives ongoing in the EU'.

It is unlikely that the EMA and HMAs can coordinate initiatives of for example Amazon (online pharmacy, PillPack), FaceBook (discussions between patients, advertising), and Google (sequence of answers to searches). Furthermore, this scope excludes initiatives outside Europe. It is really necessary to look globally at this point because electronic information ignores European borders. Patients, healthcare professionals, and consumers do not distinguish where the geographical source of information is, as long as they can find what they need.

> Alternative: Focus on the core activity: providing reliable information about medicines to enable people to act appropriately. It is not possible to coordinate digital initiatives because these initiatives are not bound by European borders.

Comment 10. Line 74. 'to form the basis of follow-up implementation plans for ePI'.

In the light of the sixty six comments in this document, the Draft Key Principles will form a poor basis. The Key Priniciples start from several unsubstantiated assumptions, excludes essential scoping and benchmarking activities, excludes initiatives outside Europe, and ignores non-authorized digital resources.

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Alternative: Please reconsider this statement. In order to have any chance of success, it needs to be reversed:

Step 1 - Start from a thorough evidence base. Scoping studies, contextual enquiries, and literature reviews will provide a more complete description of the situation. The literature gives a clear first indication. There are a few hundred articles about the malfunctioning of package leaflets, and there is not a single article that is moderately positive about its effects. Furthermore, the medical literature as it is available in the medical databases such as PubMed is incomplete, because it does not take other perspectives into account. For example, the financial perspectives (costs and benefits), production perspectives (manufacturing leaflets), and environmental perspectives (waste, sustainability) are not included.

'Shortcomings' was the description of the European Commission in 2010 (2010/84/EU, amendment 18(b)). The current product information about medicines might be more accurately characterized as a 'system failure'. It is not effective for anyone, it is expensive for all, it is environmentally wasteful, and in many cases it is causing irreversible harm or death. There is no data that indicates that the current system of SMPCs and Package leaflets is effective, for an acceptable price, environmentally neutral, and does no harm to patients nor consumers.It only works because there is no alternative. Patients, consumers, and healthcare professionals cannot avoid dealing with poorly designed information and do their upmost best to cope. Unfortunately, despite all good intentions, this leads to high error rates, extra costs, and unnecessary anxiety.

Step 2 – Benchmark the current situation to find the most pressing issues. The selection of the most pressing issues cannot be done without benchmarks-experiments. Benchmarks tests will provide data that can be used afterwards to check if change can be seen as improvements, and if further improvements are required. Without benchmark data, it is impossible to gauge if a change has had any effect.

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Draft key principles on ePI in the EU (line 77 to 140).

Comment 11. Line 77. Key principles.

The Draft Key Principles are not related to the other recommendations of the European Commission (2017). They need to be considered and integrated in order to make sure they don't cause conflicts at later stages. Especially a reference to recommendation 3 *'Improving patient input in developing and testing of PLs'* is missing in the Key Principles document. Standardizing a 'semi-structured format' which is based on the order stated in Directive 2001/83/EC,

article 59.1 is in conflict with the recommendation of the Commission because it does not improve patient input.

Alternative: Integrate the key principles for digital information about medicines within a larger strategy that encompasses the other recommendations of the European Commission.

1.1. ePI

Comment 12. Line 88. 'and allows dissemination via the world wide web, e-platforms and print.'
This part of the definition is strange for two reasons.
1. it specifies media instead of aims.
2. it includes an undefined word 'e-platforms'. This word does not have a univocal meaning and will lead to confusion.

> Alternative: Describe the aim as '… and allows dissimination to optimally enable the users to act appropriately'. In this phrasing, there is a direct relation with the text of article 63 paragraph 2 of Directive 2004/27/EC, but it extends its scope from package leaflets only to all product information for medicines. The information in electronic format will not replace the information on paper: all formats need to be considered together.

Comment 13. Line 91-93: 'Semi-structured format', 'some structured elements (fixed headings and vocabularies), and some unstructured elements (i.e. free text)'.
The assumption is that the structure is provided in a sequential text format (= in words). Lines 103 and 104 state that '*this initiative should not be understood to change the interpretation of the European legislation*.' Lines 119 - 121 repeat this. The legislation for package leaflets states that information in the package leaflet *'must be given in the following order'* (Directive 2001/83/EC, article 59.1). If the 'semi-structured format' will not create new interpretations, than it is unavoidable that this semi-structured format will follow the sequence of the information elements in the package leaflet as it is now.

Three assumptions are made by the choice of this format.
1. 'information is sequential'. The order is set in a Directive. However, digital information can modify the sequence of information according to algorithms based on characteristics and previous behaviour of users.
2. 'information is presented at a single level'. Digital information makes it also possible to present information in different layers.
3. 'conventional text structures are the basis'. The 'fixed headings and vocabularies' are only available as words. Interpretation of digital information is guided by visuals such as pictograms, illustrations, colours, and patterns.

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Starting from the opportunities of electronic information, a set structure in text only might not be effective. A flexibility in structure, modularity on different levels, and the visual basis are common digital standards.

> Alternative: It seems essential to start from the activities that people need to perform when they must handle medicines. This includes at least prescribers, pharmacists, nurses, patients, and consumers. It also includes the people who develop and check information, such as the pharmaceutical industry, suppliers, and regulatory authorities. None of these need 'all the information' at the same time in the same format.
>
> Information needs to be divided in relevant 'chunks' that are presented in a sequence that is relevant to the user, on different levels, and guided by a visual structure.

Comment 14. Lines 91, 92, 93: 'Semi-structured format', 'some structured elements (fixed headings and vocabularies), and some unstructured elements (i.e. free text)'.

Starting with a list of structured elements in text is in conflict with both the 'principles of good information design' as well as with article 63 of Directive 2004/27/EC that states that information *'must enable users to act appropriately'*. One of the principles of good information design is to start from the activities that people need to perform. A semi-structured format with fixed headings and vocabularies cannot – as we have seen in the last 27 years for patient inserts – provide information that is suitable for all patients, in all languages, for all therapies, in all contexts, and for all medicines.

> Alternative: In order to have any chance of success, these need to be changed. In order to 'enable the users to act appropriately' (as is the current legislation), and to follow recommendation 4.2 of the European Commission, it is essential to figure out:
> a. what the actions are
> b. who the people are that must undertake these actions
> c. how these people can be supported to enable them to undertake these actions
> d. set performance based standards to verify if the action is executed appropriately.
>
> Standardizing a 'semi-structured format' is unlikely to enable people. It is essential - as one of the priniciples of good information design - to start from the different perspectives of different users.

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1.2. Common EU electronic standard.

Some comments about the 'Common EU electronic standard' (line 105 to 140).

Comment 15. Line 111: 'controlled vocabularies'.

In the definition, the words 'controlled vocabularies' are ambiguous. They can relate to a mark-up language such as sgml or xml where a limited number of words can have a meaning. Or they can relate to human languages where only a limited number of words can be used, and others are excluded. Only a mark-up language can have a controlled vocabulary. Standardising human languages is always detrimental for clarity over a longer period of time.

> Alternative: Clarify the phrase 'controlled vocabularies'. If 'human languages' are intended than it is not part of the 'technical features'. However, it is possible in the digital domain to modify the language according to the characteristics of the reader.

Comment 16. Line 111: 'regulators and stakeholders'.

In the definition, the 'regulators' and 'stakeholders' are distinguished from eachother. The group 'stakeholders' is not further defined and it is not clear which groups are incorporated.

> Alternative: It would be useful to see 'regulators' as one of the stakeholders. A statement like 'agreed by all stakeholders' would be more accurate. It might be easier to delete 'agreed by regulators and stakeholders' because it seems a superfluous statement. Any standard has to take the perspectives of all stakeholders into account.

Comment 17. Line 116: 'as well as'.

The words 'as well as' suggests that the standard consists of two systems: one to support the interlinked regulatory networks, and one for the dissemination of information for healthcare professionals and patients. This combination is not likely to be functional because the reasons to use a standard vary substantially between these two groups. The regulatory networks, in cooperation with the pharmaceutical industry, develops and controls ***the development*** of information. The second group '***uses the information***' to achieve their aims.

> Alternative: It might be more efficient to separate both systems: one that optimally support the registration of medicines in Europe. This system aims to optimally support the development. And a second system that makes information about medicines optimally accessible for those who need it. This system aims to support the use of information. At least, it is necessary to motivate why a single standard is preferred above two separate ones.

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Comment 18. Line 116: 'meeting the expectations of patients and healthcare professionals who travel and work in several EU countries'.
It is not clear why 'patients and healthcare professionals *who travel and work in several EU countries*' differ from 'patients/consumers and healthcare professionals' who do not. Is it really necessary to make this distinction? If this distinction is essential, on which basis was it established? Is it really consistent throughout Europe? Are 'patients and healthcare professionals who travel and work in several EU countries' a homogenous group?

> Alternative: It seems worthwhile to start from the idea that information is used by 'people who live in Europe', without continuously separating 'healthcare professionals', 'consumers', and 'patients'. [In many practical situations, these groups work together to improve health conditions.]

Comment 19. Line 118: 'A common standard enables the generation and dissemination'.
The words 'the generation and dissimination' indicate again that the system will consist of two separate parts. One to enable the development of information. This requires a dialogue between regulatory authorities and marketing authorization holders. The other system disseminates information about medicines to people in Europe. (See also comment 17.)

> Alternative: The benefits of a combined system need to be clarified. The aims of both parts, the people who have to work with it, and the people who benefit from it are very different. Of course, the results from the 'generation part' form the basis for the 'dissemination part' but both are used in very different contexts. The first part is used in a commercial-legal environment. The second is used in a medical-care environment.

Comment 20. Line 118: 'electronic authorised information'
The word 'electronic' is superfluous because a common standard already refers to an electronic standard'.

> Alternative: Delete 'electronic'.

Comment 21. Line 119: 'patients and consumers of medicines in the EU/EEA'
The description of the people who will be using the dissemination part of the system varies throughout the text. In the section 'Background' (line 50-72) the groups were described as 'healthcare professionals' and 'patients and consumers'. Healthcare professionals were further subdivided into those who are 'prescribing medicines' and those who are 'dispensing medicines'. It is not clear why healthcare professionals are not mentioned in line 118-119.

> Alternative: it is essential that all stakeholders are involved right from the start of the development of the standard. This requires a substantial

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'scoping activity' that aims to find out who the different groups of people are, if they can be seen as homogenous groups, and what their main needs and expectations are.

Comment 22. Line 122-129 'The aims of the common standard are:'.
Both parts of the standard - for the generation and dissemination - are clearly described. What is missing is a rationale why these two activities must be based on a single standard (See also comment 17 and 19).

Furthermore, the dissemination of information is not really the problem. The focus should be on the activities that people are enabled to do with this information. The assumption is that the dissemination will be beneficial for patients/consumers and healthcare professionals, because it will allow for an additional and tailored approach. However, the contents of the information will be similar - or identical - to the information that is provided at the moment in SMPCs and Package leaflets. It is not clear what the specific benefits are of the dissemination of the same information in an additional digital format.

It is unlikely that it is possible to provide a 'tailored approach' because the information of the electronic version must be based on the current legislation. The 'tailoring' is in conflict with the legislation, because it is obligatory that the information is 'full and comprehensible' and 'provided in a specific order'.

Alternative: It seems necessary to add a thorough reasoning why these two aims must be combined into a single common standard. It is likely that 'regulators and industry' might need a different standard from 'users of authorized information'.

The benefits of electronic product information must be specified. It is not sufficient to just to claim that this will allow patients/consumers and healthcare professionals an additional and tailored approach. It needs to be made clear what these groups can do with the digital information in addition to the paper versions.

Yes, information about medicines needs to be tailored to needs and wishes of individual users (patients, consumers, healthcare professionals). However, the legislation clearly states that the information for patients needs to be based on the SMPC (2001/83/EC, article 59), must be full and comprehensible (2001/83/EC, recital 40), and must be presented in a specific order (2001/83/EC, article 59). These three issues prevent the possibility to 'tailor information' if the interpretation of the European legislation will not change.

Comment 23. Line 123. 'Trusted information'.
The information is not 'trusted'. It is 'authorised'. Patients taking part in Readability tests often mention that the information in package leaflets is just there to 'cover their backs'. Patients are very well aware that the information in

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package leaflets is written by the pharmaceutical industry, and are suspicious about its reliability and appropriateness.

Alternative: Change 'trusted' to 'authorised'. Probably even 'authorised product information'.

Comment 24. Line 123. 'The aims of the common standard are: ... to create the technical foundation for the dissemination of trusted information in the electronic world.'

The 'creation of the technical foundation' that only consists of a 'mark-up language', and nothing else seems to set a very low standard that makes little use of digital opportunities.

Furthermore, the legally obligatory information has been found to have 'shortcomings'. Using this information that is known to be insufficient as the basis for dissemination seems incorrect.

Alternative: It seems that the aim could be written as: 'The aim of the common standard is to apply a mark-up language to the existing standardised information'.

Comment 25. Line 124 - 126. 'Which will allow' ... 'tailored approach' ... according to his/her need and/or wish ... suitable output forms and platforms'.

This is an unsubstantiated assumption because 'his/her need and/or wish' has not been established. These needs and/or wishes cannot be fulfilled if they are not investigated beforehand. It is not possible to define 'tailored' and 'suitable' without conducting systematic scoping and benchmarking activities with a variety of stakeholders. And it is very likely that there is a substantial variation within each group of stakeholders. Assuming that 'all patients', 'all consumers' and all 'healthcare professionals' have similar needs and wishes is probably incorrect. The Draft Key Priniciples document seems to suggest that it is possible to develop a common standard without involving patients, consumers, and healthcare professionals.

Furthermore, this approach will make the implementation of point 2 and 3 of the EMA action plan impossible. Basically, the development skips the first two steps of an information design process.

Alternative: Involve patients, consumers, and healthcare professionals in the development of electronic product information before unsubstantiated assumptions are used as a basis. This involvement also complies with recommendation 2 ('principles of good information design') and 3 ('improving patient input') of the European Commission (2017).

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Comment 26. Line 127. 'to offer possibilities to streamline, simplify and speed up the regulatory process'.

This is a very positive approach because it acknowledges that it is necessary to streamline, simplify and speed up the regulatory process. In order to do that, it seems essential to find out through scoping and benchmarking studies where the processes are not sufficiently streamlined yet, not simple enough yet, and slower than necessary. It is possible that digital technologies can be helpful, but it seems unlikely that these three aims can be achieved by introducing a mark-up language for electronic product information only. This raises the expectations too high because it suggests that the development of an ePI could really streamline, simplify, and speed up registration processes. Without looking at other potential factors in scoping studies, this is a high risk approach.

> Alternative: Both the regulators (= the European medicines regulatory network (line 115-116)) and 'the pharmaceutical industry' are not homogenous groups. It is likely that a scoping study will reveal that there is a substantial variety within these groups. Line 136-137 indicates this variety by mentioning the centralised and national levels. Asking a variety of stakeholders in these groups about the possibilities to streamline, simplify, and speed up the regulatory process is likely to reveal many suggestions. A mark-up language is likely to be one, but there will be many other ways too.

Comment 27. Line 130: 'Agreement of a common standard.'

It needs to be made clear who needs to agree on this common standard. If all relevant stakeholders need to agree, than it is essential to make sure that all stakeholders are directly involved. In the absence of measures to ensure that needs of different stakeholders are taken into account, only those of the dominant groups are served.

The double aim of dissemination and improving the regulatory process shows for example a different geographical scope. The regulatory process is only applicable in the European Union and some countries that might or might not apply it (Turkey, UK, Norway, Switzerland, Ukraine). The dissemination process is immediately global because healthcare professionals, patients, and consumers will search the internet and select the most likely reliable source. They are unlikely to distinguish what the geographical origin of information is.

> Alternative: It is necessary to make clear who needs to agree on this standard. There are different stakeholders and different processes that need to be separated because the 'needs' and 'expectations' vary substantially between stakeholders and within stakeholder groups. It is especially important to find out which stakeholders will be 'excluded' by this agreement.

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Comment 28. Line 131- 133. 'which would generate unnecessary complexity, impede access to information and require multiple interfaces between standards, restricting flow of data.'

Is there any evidence that these consequences will occur, or are these mainly 'based on fear'? It is of course beneficial to have a single standard, but multiple standards are very common in most areas and adding yet one more will only increase the complexity. How can EMA be sure that this 'new common standard' will not add to complexity, impede access, and require multiple interfaces'?

> Alternative: Although it is hard to predict the practical consequences of the introduction of a new standard, it is clear that there are both benefits and risks. It seems worthwhile to investigate which standards are currently used to develop electronic product information about medicines. Most countries do have a national pharmacopeia or compendia which are commonly used by prescribers. The pharmacy-information-systems include information for patients too. All are based on standards. Ignoring these existing standards will make it unlikely that potential digital cooperation will be optimal.

Comment 29. Line 136-137 'compatible with use at centralised and national levels.'

The first step is an agreement between centralised and national level. This first step therefore intentionally excludes patients, consumers, and healthcare professionals. It is therefore likely that this standard does not take their needs into account. Trying afterwards – after the standard has been established – to make it suitable for patients, consumers, and healthcare professionals is very likely to lead to failure. It is also in conflict with the second recommendation of the European Commission (2017).

> Alternative: The first steps in any design process are the scoping and benchmarking activities. These are essential to find out which stakeholders are involved, to find out how they cope at the moment, and to get actual data how successful the current performance is. Excluding stakeholders in the first steps is unlikely to be a good start of any project.

Comment 30. Line 138-139. 'available technical features, including those from the EU Telematics projects.'

The ePI project starts from the 'available technical features'. This is questionable. It would be more beneficial to start from the performance levels that need to be achieved through the provision of information: a reduction of errors, an increase in adherence, a reduction of waste, longer term sustainability, etc.

> Alternative: In line 110-111, these features are introduced as the basis of the common standard. In line 139-140 both 'vocabularies' and

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'interoperability specifications' are 'yet to be developed'. So the only thing that remains is the 'mark-up language' augmented by the features of the EU Telematics projects. The focus should be on 'enabling people to act appropriately', not on the available technical features. The first one is a long term vision, the second one will change within months.

2. Benefits for public health.

Some comments about the 'Benefits for public health' (line 142 to 182).

Comment 31: Line 142. 'Because of the benefits this format can offer for public health.'

'Can'? Is it possible to check the expected results first before a new system is implemented on a European scale? It seems essential to clarify the direct relations between the provision of information in an electronic format and 'public health' as a first step.

Alternative: One of the main risks is that the development of the ePI-standard will take a substantial amount of time. During this period, all other initiatives are postponed because there is little point in developing something that might be overruled later by an obligatory system. Based on the experiences with the development with databases and digital resources, in combination with a problematic financial funding system, it is very unlikely that this could take between 5 to 10 years. With sufficient funding, it might be in operation sooner.

This is simply not acceptable for patients. The focus might need to be on these most urgent 'benefits for public health' before embarking on yet another new and costly IT-system. An EMA report describes that medication errors occur in between 2% and 49% of administrations in hospitals based on data collected before 2006 (EMA, 2014). There is no reason to believe that these percentages have changed.

The current legislation states that information for package leaflets must '*enable users to act appropriately*'. Using that legal requirement as a guide for the electronic product information would be a good start. Furthermore, it would be good to develop and implement the database that is required in article 57, 1, l) of Regulation 726/2004. Both these suggestions do not require any changes in legislation, just a stricter adherence to the current legislation. The relations between 'public health' and 'electronic product information' can be investigated simultaneously.

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2.1. Expanding access to information on medicines as a public health imperative.

Comment 32. Line 149. 'because it will expand the dissemination of for all medicines in the EU.'
It is not clear how an expansion of the dissemination exactly benefits public health. There are very substantial 'shortcomings' in the current information, and making the same information available in a digital format might not result in the expected benefits. Just adding more-of-the-same information is unlikely to improve the shortcomings, and benefit public health.

> Alternative: One of the major benefits of information in an electronic format is that it can be modified by the reader so that it better answers their questions. This modification can affect the structure (sequence and level, links), language, and mode (verbal, visual, aural, or combinations of these). There is not much point in providing exactly the same information (as required by the legislation) in the same structure (order) and the same mode (text) in an electronic format.

Comment 33. Line 150. 'among other functions.'
This phrase does not provide enough detail. It needs a concise list of these other functions or at least give some examples which functions are meant.

> Alternative: The following functions could be used as examples:
> a. Reducing the risk of confusability of outer packaging. At the moment, it is likey that both pharmacists and patients have problems to differentiate different medicines because the design of packaging looks too similar. Electronic verification might be beneficial but is not always available.
> b. Integrating information on packaging and package leaflets with electronic information. The 2D barcode might be a possibility, or a specific url-code for medicines.
> c. ePI could check interactions between medicines, contra-indications, and suggest administration schedules based on data-mining across large groups of patients.

Comment 34. Line 151. 'Provision of the latest information on a medicine's safety, benefits and its conditions of use.'
Regulation 726/2004 (article 57, 1, l) already asked for a website with a very similar aim in 2010. It would be essential to find out what is happening with this now, and how it could be made to work for this purpose. This website is mentioned as *'the future European Medicines web portal'* on page 13 in line 348, but it is unclear how ePI will exactly be related to this website.

Alternative: Integration of digital information is essential to reduce investment costs, maintenance costs, and confusion among users (patients, consumers, healthcare professionals).

It is essential to conduct a thorough scoping and benchmark study to establish what is available and how well, or how poor, this functions at the moment. Before it is possible to speak of an improvement, it is essential to find out how patients, consumers and healthcare professionals find, understand, and apply the latest information on safety, benefits, and conditions of use. This might not be equally important for all medicines in all contexts, and these differences could be used to develop appropriate standards and templates.

Comment 35. Line 152 – 153. 'Better delivery of information so that the right information is available to the right patient/consumer at the point of need'.
This statement suggests that patients cannot access the right information at the point of need at the moment, or not in all situations. Is there any evidence to support this assumption? Is it absolutely guaranteed that electronic product information will achieve a 'better delivery' of 'the right' information, to 'the right' patient/consumer, at the 'point of need'? Is there any evidence to support this assumption?

Alternative: Before a statement as 'better' can be made, it is essential to have benchmark data that can be used as comparison. Without benchmark data, it is not possible to be sure that a changed situation can be categorized as 'better'.

Comment 36. Line 154. 'Informed decision making by patients/consumers and healthcare professionals'.
This sentence suggest that this support is not available at the moment. It might be worth looking at practice how 'informed decisions' are taken at the moment, and which role the package leaflet and the SMPC play in that decision. It is correct that paper package leaflets are not available at the conversations between patients/consumers and healthcare professionals. Patient-prescriber, patient-pharmacist, customer-pharmacist, patient-hospital nurse, patient-hospital pharmacist, are some examples of these dialogues. However, the Draft Key Principles document assumes that a single electronic format - that is identical to the current information in the package leaflet and SMPC - will affect treatment decisions.

Alternative: This assumption really needs to be investigated thoroughly before it is suggested that these decisions 'will be supported'. If patients, consumers, and healthcare professionals are not able to make informed decisions, or must make 'better informed decisions', than we need to have accurate benchmarks first. Without benchmark data this suggestion might not be helpful because informed decisions could be influenced by very different information sources.

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Comment 37. Line 158. 'Patients/consumers and healthcare professionals using ePI can be fully confident that they hold the latest information about benefits, risks and use.'

It is essential to examine the current situation and find out how confident healthcare professionals, patients, and consumers are with the current supply of information. Is it really essential for these groups to be absolutely sure that they have the latest version? At the moment the websites of, for example MHRA, EMA, Electronic Medicines Compendium, BCFI, and Farmaceutisch Kompas all link to different versions of the same package leaflet of the same medicine.

> Alternative: It needs to be investigated how important it is for patients/consumers and healthcare professionals to be confident that they hold the latest information about benefits, risks and use? How do they check?

Comment 38. Line 157 'it will be possible'; line 161: 'is thereby expected'; line 163: 'should also facilitate.'

Can we accurately state the expected performance levels, and stop using indefinite phrases that make it very hard to check if any progress has been made?

> Alternative: Make accurate performance based indicators for these vague statements. Without measurable indicators, it is not possible to establish if a change can be seen as an improvement. For example:
>
> a. Modified ePIs will be updated within 24 hours after a change has been approved.
> b. ePIs support patients and consumers to make informed decision about their treatment. The criteria are relevant argument-structures, individual satisfaction, and an increased knowledge about a treatment.
> c. ePIs enhance interactions and discussions between patients and consumers and healthcare professionals. All groups are able to provide a structure for dialogues, use checklists, and a list of questions to check if information has been understood.

Comment 39. Line 161. 'to increase support to patients/consumers in informed decision-making about their treatment.'

This statement differs from the statement in line 154. 'Increasing support' indicates that there is support at the moment, but that this can be increased. The baseline level of support needs to be established through benchmark studies. It is likely that this varies according to the situation, context, and type of medicine.

> Alternative: It is really essential to have accurate benchmark data before these statements can be made. Furthermore, it is necessary to be absolutely sure that ePIs really can deliver this. Decision-making about a

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treatment is a fairly complex activity in which many information sources are required. The addition of ePI might not be the most effective way to support this process.

Comment 40. Line 162. 'And help them to adhere to their medication regimens, ultimately contributing to optimal outcomes.'
This is an unsubstantiated assumption. There is no evidence, not a single scrap, that there is a direct relation between the provision of information and adherence to medication regimen. The provision of information might lead to better outcomes, but this cannot be stated as a general statement. It really depends on the patient, the regimen, the context, the situation, and the expected outcomes.

Alternative: It is essential to have accurate benchmark data before these statements can be made. Investigating the direct relation betwen the provision of information and treatment outcomes has proven to be elusive. Although information is an essential ingredient of every medicine, it is not directly related to the activity of taking medicines safely.

Comment 41. Line 165. 'The structured nature of ePI will offer new opportunities to better tailor product information to the needs of individual patients/consumers.'
This looks at the provision of information from the wrong perspective. It suggests that it is possible to design a structure of information in such a way that it will benefit individuals afterwards. This is an incorrect assumption because the needs of patients/consumers must lead a variation of structures provided by ePI. It is also in conflict with the EU-legislation that states that information in package leaflets must be 'given in the following order' (2001/83/EC, article 59).

Alternative: Principles of good information design suggest that it is essential to start from the perspective of the user in order to 'enable the users to act appropriately'. Starting from a standardized structure of information is in direct conflict with this approach because it will not be suitable for all patients in all situations. It is unlikely that the same structure will benefit the activities of healthcare providers

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Comment 42. Line 166-168. 'Also, because ePI can be handled electronically and read by machines, ePI information can flow to other systems, such as electronic health records and e-prescribing systems.'
This looks at the provision of information from the wrong perspective. In order to flow to other systems, it is essential to establish first what these existing electronic health records and e-prescribing systems do and need to do. Without this scoping exercise, it is very unlikely that a new ePI structure can be easily integrated.

Alternative: Start with a scoping activity to find out which other systems there currently are and how they are used. This will provide a basis to

benchmark the existing situation. After the benchmark studies, and based on their results it is possible to develop a structure that can be integrated into existing systems.

Comment 43. Line 168-169. 'facilitating targeted delivery of the right information to the right patient/consumer at the point of need.'
This statement suggests that this is currently not achieved everywhere across Europe. It is unknown if this aim can be achieved without making clear beforehand what 'the right information' is, who 'the right patient/consumer' is and what the 'point of need' is.

Alternative: It really is more beneficial to turn this around and start from the perspective of people who need to use medicines information. The needs of patients, consumers, and healthcare professionals vary substantially. This variation is caused by different contexts, different expectations, different activities, different medicines, and different experiences. Ignoring all these, and suggesting that a single structured text format will be beneficial for all is an unsupported dream.

Comment 44. Line 170. 'Availability of regulator-validated ePI will counterbalance unreliable and spurious claims about medicines,'
This needs to be investigated before this claim can be made. Yes, there are unreliable and spurious claims about medicines, but a European approach wil not change this in a digital environment where national borders don't mean much.

Alternative: This really needs more research to find out if this is at all possible. The risk for patients of spurious claims needs to be investigated too. This might be overestimated or underestimated, and it might vary per country or per medicine.

Comment 45. Line 171-172. 'often widely spread through online and other forums,'
Is there any evidence that supports this claim, and are there data what the exact influence is on adherence, medication errors, and prescribing behaviour?

Alternative: There really is little reliable research to support this claim. For example, the complete PubMed database only mentions 'Facebook' six times (May 12th, 2019). Other social media are mentioned even less. This needs to be investigated before this claim can be made. It might not be equally applicable to all medicines in all countries.

Comment 46. Line 174. 'EMA and NCAs should work towards ePI to fulfil their mission to protect public health.'
This assumes that there is a direct relation between ePI and public health. This

relation needs to be more detailed because not all areas of public health can be protected through the implementation of electronic product information.

This sentence also shows that 'regulatory authorities' can be further subdivided into 'EMA' and 'NCAs'. It is not clear why that division is especially relevant at this point.

> Alternative: The relation between 'public health' and the provision of electronic product information needs to be clarified. It might be possible to replace 'EMA and NCAs' by 'regulatory authorities'?

Comment 47. Line 177. 'The most up-to-date ePI version should be always easily available.'

The word 'most' is superfluous. Information is either up-to-date or it is not.

'Easily available' depends on the characteristics of the user. It is likely that there is a substantial variation between people who need to evaluate if electronic product information is 'easily available'. This might be possible for young, higher educated citizen, but less so for poorer educated elderly.

> Alternative: It is essential to set performance based standards together with all the other stakeholders. It will take substantial discussions to find a generally acceptable description of 'easily available'. The description is likely to differ according to the situation, for example in hospitals or elderly homes.

Comment 48. Line 178-179. 'To achieve this principle, ePI should be made available through various technologies and applications, including mobile scanning technology (such as a 2D barcode) on the medicine package.'

This is very odd because the information on the inner and outer packaging are part of the ePI. This would mean that the information on the inner and outer packaging must be made available through a 2D barcode on the outer packaging? Why is this necessary?

Furthermore, this would make original packaging essential to access digital information. This availability really depends on the context. A patient in a hospital with a tablet or phone does not have the medicine package. The name of the medicine might be handwritten or printed or on a label on an infusion bag and the 2D barcode is not there.

> Alternative: It is essential to explain 'various technologies and applications'. What exactly is meant? Does this include a website, or a modification of existing websites. Again, it is essential to start from the perspective of the user. Who needs to use information about medicines, what needs to be achieved, and what is considered to be a success? Just stating that 'various technologies and applications' make information available does not help much. Are patients, consumers, and healthcare professionals really able to use a 2D barcode to search for information in all circumstances? Who is excluded?

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2.1. Expanding access to information on medicines as a public health imperative.

Comment 49. Line 183. 'Accessibility to patients/consumers with diverse abilities.'
Shouldn't this include accessibility for healthcare providers too? Or do all prescribers, pharmacists, and nurses have perfect eye-sight, work in perfectly illuminated conditions, and have high literacy levels in all European languages?

> Alternative: A detailed scoping activity is necessary to make sure that the practical issues are correctly mapped out. The World Wide Web Consortium (W3C) has very detailed guidelines and advice on how to achieve this. Please follow these W3C recommendations.

Comment 50. Line 185-187. 'accessible to everyone, including patients/ consumers with print impairments such as blind and partially sighted people (e.g. use of large font size) and those with low literacy levels (e.g. audible formats).'
It is a fallacy that the accessibility of information needs to be based on the 'exceptions' who do not have 'sufficient eye sight' or have not acquired 'sufficient literacy levels'. The whole movement towards an 'inclusive society' - which is one of the key European principles - is ignored by this statement.

> Alternative: It is not really an 'option': it is absolutely essential to make sure that ePI follows the fundamentals of an 'inclusive society'. As stated earlier: In the absence of measures to ensure different user's needs are taken into account, only those of the dominant group are served.

Comment 51. Line 190. 'Current PDF and print copy formats of PI'.
Although the key principles exclude the use of PDF and print copy formats, and characterize these as 'unstructured formats' (line 93 - 94), they have proven to be useful in some situations.

> Alternative: Although it is correct to state that PDF and print copy formats of PI do not well serve all citizens equally, they certainly have their purpose. From the perspective of a patient or consumer, a PDF-document, or a document in Word are also 'electronic product information'. Suggesting that these formats are not part of the ePI creates an unnecessary and confusing division. All information needs to be available in all sorts of formats: whatever suits the user.

Comment 52. Line 192-194. 'In contrast with current PDF and print copy formats of the PI, the availability of ePI will allow third-parties, such as companies, not-for-profit organisations or patient/consumer groups, to convert the PI into accessible formats.'.

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This statement suggests that PDF and print copy formats cannot be converted into accessible formats. That is incorrect. There are several software solutions to make sure PDFs can be transferred into different formats related to accessibility. Patients/consumers are not the only groups who need accessible digital formats. Nearly all stakeholders would benefit from more accessible digital documents.

> Alternative: PDF and print copy formats can be converted into accessible formats in a standardised manner (example: Ghent Workgroup). This is not a reason to abandon these formats. There will be plenty of PDFs and print copy formats used outside the medical product information domain. People will be very used to these.

Comment 53. Line 196. 'ePI will be accessible by design.'
It is nice to see this phrase in a document like this. However, there are several other terms that should be mentioned here. The approach to develop ePI does not stand on its own. It is part of several societal movements that have specific names. A few of these are the World Wide Web Consortium standards for accessiblity (W3C), 'universal design', 'Inclusive societies', and the European Accessibility act.

> Alternative: It seems essential to relate ePI to these developments. Ignoring these is not really an option. Information about medicines really needs to follow the same principles as all sorts of other types of digital information.

3. Existing legislative framework

Some comments about the 'Existing legislative framework' (line 198 to 251).

3.1. Complementing paper package leaflet

Comment 54. Line 205. 'Since the current legislation does not require the use of an electronic version of PI, the use of ePI will not constitute a new legal obligation.'
The EMA-QRD template includes an optional statement: "Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu <, and on the website of {name of MS Agency (link)}>." Line 205 implies that it is possible that a marketing authorization holder does not provide, or does not allow, to publish the product information on the EMA-website?

> Alternative: The ePI does not really add much new information to information that is provided on the EMA-website for centrally registered medicines. For many medicines - and may be even all? - the information

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on the EMA-website is already available in an electronic format: in PDF-format or in Microsoft Word. Is the ePI just adding yet another format with the same information? It seems necessary to analyse which electronic information is already available on the EMA-website, find out which information about which medicines is required, and find out how people currently use the available electronic product information. Starting afresh, without considering what is available and without consulting current users (patients, consumers, healthcare professionals) first, might not be the most effective way.

Comment 55. Line 209. 'PLs are a valuable tool presented directly in the medicines package and therefore provided to all patients/consumers when they open their medicine.'

This statement is incorrect. Many patients in hospitals, nursing homes, and elderly homes do not receive a package leaflet when their medicines are administered. Furthermore, it is very questionable if package leaflets are really a 'valuable tool'. There is not a single scientific investigation that shows that people appreciate the contents or design. There are several hundred articles that show their shortcomings.

Alternative: The 'shortcomings' report by Nivel (PIL-S, 2014) clearly shows that Package leaflets are not very valuable for patients. In hospitals, they are discarded immediately. If pill pouches for multi drug dispensing are used, they are discarded too. It is likely, but it is essential to investigate this further, that the most vulnarable patients do not receive package inserts.

Comment 56. Line 210. 'The paper PL is particularly important for patients/consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access.'

This is an assumption and a gross simplification of practical realities. There is little evidence for this sweeping statement. The design of the outer packaging and inner packaging is probably far more important for the safe and effective use of medicines by patients and consumers.

Alternative: This might be an incorrect assumption and it needs to be confirmed first through systematic scoping and benchmarking. Without these activities it is not possible to check afterwards if any progress has been made. Is it really possible to correctly identify a group of patients with 'low digital literacy' and ignore the internal variation within this group? Aren't there different levels of 'low digital literacy'?

Comment 57. Line 214. 'Generation of ePI does not involve any change to the content of the PI.'

It is clear that there is no intention to modify the legislation with regard to the information about medicines. However, the response of the EMA to the

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European Commission's recommendation in the 'Shorcomings report' states in 2017: *"This represents a unique opportunity to improve the information patients receive on their medicines, within the boundaries of the current legislation."* (EMA, 2017). The EMA suggests that the main improvements are patient's comprehension of the package leaflet and its readability by changing the language itself and the design and lay-out of the information. If the language and graphic design of the information is the only change, how can the three claims in line 151 to 154 be made? (See comments 34, 35, and 36). What does electronic product information exactly add in comparison to printed product information that these three claims can be achieved?

Alternative: The ePI offers several opportunities to make the legally required information easier to find and understand. There are at least five initial options:

a. It is possible to reduce the length of the product information. There is fairly strong research evidence that patients would appreciate a much shorter text (Fuchs, Scheunpflug, Götze, 2012). A lot of information can be hidden in specific circumstances. In combination with the characteristics of patients sections can be hidden. [For example: experienced patients with a chronic disease could choose to select only the information that is changed.]
b. Information can be made visual through the use of illustrations, pictograms, animations, and infographics.
c. The structure can be offered in a user-determined sequence.
d. External links can be included.
e. It is easy to include language options, so readers can select their own language.

These options can later be augmented by 'patient-to-patient' communication, blogs and newsletters, side effect warning schemes, personalised administration advise, and so on.

Comment 58. Line 216. 'The use of ePI will be a recommended innovation; however it is not mandatory'.

This is surprising. It is very likely that the pharmaceutical industry will wait until the practical value of the standard and ePI has been established. Until that time, very little will happen. Possible innovations will not be initiated or continued because it might not be compatible with the ePI standard. This approach will therefore stall initiatives and delay progress.

It is unclear why this is described as 'an innovation'. The only thing the electronic product information suggests is the use of a 'mark-up language'. This mark-up language can hardly be seen as an innovation: XML has been a recommendation of the W3C since 1998.

Alternative: It doesn't matter if it is 'mandatory' or 'innovative' or not. The pharmaceutical industry has already got the obligation to '*enable*

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users to act appropriately' (article 63 of Directive 2004/27/EC). Before any 'innovation' is recommended, it seems necessary to apply this current legislation.

Furthermore, a strict application of the EMA-QRD template and Readability Guideline has proven to lead to information that has 'shortcomings'. It should therefore be allowed and be stimulated to conduct pilot-tests and develop prototypes to find alternatives that really *'enable the users to act appropriately.'*

Comment 59. Line 217. 'The paper PL should include a statement directing to the ePI as the most up-to-date version of the PL.'.

At the moment, there is already a sentence in the EMA-QRD template. This sentence is: *"Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu<, and on the website of {name of MS Agency (link)}>."* It is not clear if the same webaddress can be used. Especially the language-selection of the ema.europe.eu website needs attention because the current EMA website is only available in the English language. This excludes large numbers of patients in Europe who do not read English sufficiently.

Line 179 mentions the use of a 2D barcode as a possible way to direct patients who read the package leaflets to the most up-to-date information.

And it is likely that many patients (and this needs further research) would select the digital version first, even before considering the paper package leaflet.

Alternative: The accessibility of the website needs to be thoroughly reviewed, designed according to best practice, following web standards and legislation, and tested in detail.

It might be possible to include only the 'most important' information in the package leaflet. This 'most important' information depends on the type of medicine, and the context in which it is used. A very short package leaflet can refer to an electronic version that contains all the required information and is presented in such a way that people can select what they want to see. However, the development of this combination of paper and electronic information needs to follow a normal design process that includes scoping, benchmarking, designing and testing activities.

Comment 60. Line 218. Missing information.

The Draft Key Principles document discusses the package leaflet, but does not include a section on the SMPC and inner and outer packaging. Section 3.1 is about the paper package leaflet. There are no sections on the inner and outer packaging, nor about the SMPC. Although these information sources are an integral part of the product information, they are not further mentioned.

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Alternative: It seems necessary to consider all product information for all types of users. The focus on package leaflets in section 3.1, without similar sections about SMPCs and labelling, does not give a balanced description of the issues related to information about medicines.

3.2. Open access to regulator-approved information only

Comment 61. Line 227-228: 'legislation). 'no additional information — either for promotional or other purposes — can be included in the ePI.'
This makes it nearly impossible to develop any applications or websites because it is neccessary to include wayfinding information to make the structure of the information clear. Menu's, buttons, symbols (home, index), search-functions, bookmarks, digital links, pop-up menu's are all excluded because they add information for a specific purpose.

Alternative: This is really a fundamental issue that cannot be dealt with later. In order to make information about medicines available in a digital environment, it is crucial to add a visual structure. This structure helps readers to find where they are, where they can go, and adds support to make strategic reading decisions possible. The current structure of the SMPC, the package leaflet, and the labelling fails to enable people to act appropriately. In order to make any information 'accessible' it is esential to allow that additional information is included in the ePI.

3.3. Data protection

No comments. This is fine.

4. Processes

Some comments about the 'processes' (line 252 to 323).

4.1. Governance

Comment 62. Line 284: 'The regulator should hold ePI data, as a trusted source for reliable medicines information.'
Before this statement can be made, it seems necessary to ask readers of current product information if the regulator is really seen as a 'trusted source for reliable medicines information'. The current product information is mainly written by marketing authorisation holders (MAHs), and it is likely that prescribers, pharmacists, patients, and consumers realise this. The role of the regulatory authorities is not mentioned, not introduced, and not explained.

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Alternative: In order to make this statement and to be really sure that people see product information on a website of a regulator as 'trusted and reliable', it is essential to investigate this. Without reliable and published data, this remains an unsubstantiated assumption that is unlikely to be correct.

Comment 63. Line 285-286: 'A pan-European medicines web portal.'
Regulation 726/2004 (article 57, 1, l) already asked for this website in 2010. It would be essential to find out what is happening with this now, and how it could be made to work for this purpose. This website is mentioned as 'the future European medicines web portal' on page 13, line 348. [See also comment 34.]

Alternative: The development of this pan-European medicines web portal will take many more years before it is operational. Until that portal is fully functional,digital information about medicines is poorly accessible, hard to understand, and difficult to use. The number of errors in prescribing and dispensing, the muddling of medicines by patients and consumers, and poor adherence figures will not be reduced. A pan-European website would be nice, but it is now essential to design the harmful and lethal events out of the system.

4.2. Flexibility in implementation

Comment 64. Line 299: 'All stakeholders, including pharmaceutical companies and regulators, will commit to implementation of the common electronic standard for creation of ePI for all EU medicines.'
This is in conflict with the text in line 215-216 stating that the use of ePI will be a 'recommended innovation; however it is not mandatory.' It is likely that, without a legal obligation, not all stakeholders will be equally enthousiastic.

Alternative: The approach is very questionable and based on hope, not on facts. It is essential to find other ways to convince stakeholders to join the development of ePI. The investment in time and effort should lead to tangible results with clear benefits for specific stakeholders. These benefits could be related to design and language, to improvements in strategic communication with patients and healthcare professionals, and to improvements in registration processes and standards. Other options are the support of disciplinary practices of nurses, doctors and pharmacists. Probably most prominent should be the search for convincing performance data that show that people are really enabled to act appropriately. And the benefits for a society in relation to sustainability and durability need to be considered. Without considering this range of benefits, it is unlikely that all stakeholder will commit to electronic product information.

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Comment 65. Line 306-308: 'In addition, handling ePI may be a significant burden for some Member States as well as certain companies such as micro, small or medium-sized enterprises (SMEs) and companies producing generic medicines.
Before this statement can be made, it is essential to figure out if the handling of ePI really is a significant burden and for whom. This can be done before ePI is standardised and implemented. The different groups of people need to be observed and interviewed in scoping activities, and benchmark tests will reveal the extend in which this burden exists and is perceived as a real problem.

> Alternative: Base the implementation of the ePI on benchmark data, not on assumptions.

Comment 66. Line 310: 'stakeholders must plan'
The word 'must' seems to be in conflict with the text in line 215-216 stating that the use of ePI will be a recommended innovation which is not mandatory.

> Alternative: Make sure that the stakeholders can rely on the status of EMA-documents. Either it is mandatory or it is not. If it not mandatory, there is no 'must plan' for stakeholders.

5. EU context
Some comments about the 'EU context' (line 324 to 372).

5.1. Multilingual ePI
No comments. This is fine.

5.2. Interoperability with EU and global initiatives
No comments. This is fine.

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30 July 2019

Submission of comments on Electronic product information for human medicines in the EU – draft key principles (EMA/849614/2018)

Comments from:

Name of organisation or individual
PHARMIG – Association of the Austrian Pharmaceutical Industry

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	PHARMIG welcomes the opportunity to provide comments on the draft ePI principles.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
202 - 206		Comment: It should be considered to allow for replacement/substitution of the paper format by ePI in cases where medicinal products are administered in hospitals or by a Health Care Professional, e.g. IV injectables. Proposed change (if any): ePI will not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of Directive 2001/83/EC1) to include a PL in the packaging of all medicines or directly convey all information required (by Articles 59 and 62 of the Directive) on the outer or immediate packaging. **However, there are situations where patients do not receive a medicine package (e.g. medicinal products administered in hospitals / administered by a Health Care Professional, e.g. IV injectables), under these circumstances an ePI could negate paper PL.**	
270 – 271		Comment: The conversion tool should be provided free of charge by EMA to assure consistent validation and standards. Proposed change (if any): Following regulatory evaluation, if final PI is not already in ePI format, it is converted to ePI by the MAH using a	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		validated conversion tool **provided by EMA**.	
		Comment: Proposed change (if any):	

Industry Comments: Consultation on Electronic Product Information for Human Medicines in the EU – Draft Key Principles

Version: 30-07-2019

Preface

The Inter-Association Task Force (IATF) on Product Information welcomes the opportunity to provide comments on the draft ePI principles. The IATF is a collaboration between AESGP, EFPIA and Medicines for Europe. For the consultation comments, the IATF co-operated with the following associations: EBE, EuropaBIO and Vaccines Europe, and therefore the attached comments should be considered to be broadly illustrative of the EEA human pharmaceuticals sector in general.

The IATF aims to provide a representative cross-EEA industry forum, which can partner with stakeholders to focus on:

- Creating proposals for improved product information content, layout and readability within current legislation
- Applying (digital) health literacy principles
- Developing standardised electronic product information formats
- Enabling a single trusted portal or network to facilitate dissemination of electronic product information

In the remainder of this document, more detailed comments and suggestions are included. In general, the main highlights of the comments are outlined below (please note that these may go beyond the scope of this public consultation but reflect aspects that the IATF consider to be important).

General

The draft EU Telematics Strategy 2020-2025 Concept Paper (October 2018) strives for optimising use of digital technology and to manage ePI ensuring timely implementation and meeting functional/non-functional requirements, timelines and budget. By doing so, two of the top three business priorities; i.e. tackling a better and more effective regulatory decision making and building trust in medicines by empowering patients and healthcare professionals will be addressed.

ePI functions

In line with the business priorities and building up to the functions of ePI as outlined in the consultation document, further functions have been identified by IATF for consideration in future roadmap iterations:

- Optimisation of the process for variations impacting the PI.
- Easier implementation of safety variations/referrals (reducing the urgency to provide updated printed information to EU citizens, which are currently managed through the appropriate transition/grace periods).
- Supply chain management: ePI may support further solutions for availability/shortage in one country by providing product from another country (based on same dossier) without the requirement for repacking (provided that the outer package is the same).

- Waste / environmental; reduction of old PLs that can no longer be used, or even removal of paper from products where the PL is not provided to patient.

Content improvement

It is clear that ePI will make it easier for patients/consumers to have access to up-to-date product information, and to search and retrieve information in a more suitable and intuitive ways. However, it will not solve issues encountered due to poor compliance or low literacy *per se*. To address these latter aspects, work on the content and other related information such as instruction videos and risk minimisation materials will need to take place in parallel. In addition, considerations need to be given on how user testing may need to be adapted to take account of new formats.

Legislation

The current regulatory/legislation framework is considered a limitation for the allowance of patient-relevant (digital) innovative developments. Industry acknowledges the importance of not losing sight of patients/consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access. However, it is necessary for the EU network to set out an ambitious plan considering the needs of mentioned patient/consumers-groups and the fast pace of technology (ePI principles should already consider opportunities in highly digitalized markets). Additionally, in cases where patient information has been incorporated into the information present on outer packaging it is assumed that the requirement for an ePI will not become mandatory.

It is realistic to think that in the long term the paper leaflet will be replaced by the ePI and the IATF believes this evolution needs to be accompanied by a stepwise approach with all stakeholders involved to ensure suitable implementation and to safe-guard patient needs. Therefore, it is important to consider current practices of hospital- / healthcare professional-administered products where patients rarely receive the package leaflet. In these cases, changing to ePI could potentially increase patient access, and healthcare professionals could refer to ePI as the primary source of information.

The IATF proposes an EEA-wide pilot study to investigate the current practices and possible exemptions to replace paper package leaflets with ePI (or other alternatives, such as printing at pharmacy level). Such a pilot could be expanded to products directly dispensed to (and used by) patients in highly digitalised markets.

Implementation

Member state implementation

The consultation paper suggests that a broad margin of flexibility is given for national implementation. The industry IATF supports submission of the ePI at the time of application, but not as an extra step after authorisation, as of the full benefits of ePI would then be lost While certain NCAs could choose to go ahead and start early at their discretion, MAHs would need to implement all necessary systems and processes even if only one NCA starts requiring ePI. For MAHs this could mean running parallel processes (with and without ePI) for the same submission in different markets. Therefore, if flexibility is not being accompanied by a clear and binding phased roadmap and value-added milestones, based on defined user requirements, and without further national requirements - the consequence will be a fragmented and cost intensive implementation and loss of the opportunity to impose optimal practice across the EU Regulatory Network.

Resources for retrospective implementation

While being supportive to the implementation of ePI, one significant challenge for industry will be the "conversion" of the existing PIs (Word, PDF) into the ePI. For this to occur, the creation of legacy PIs in ePI format will most probably cause a major logistical burden. For companies with many MAs, this will require significant resources, while also for SMEs the implementation of ePI compliant systems will be a constraint. Essential incentives for regulators and industry would be:

- Efficient process/guidance for having the current PI changed to ePI.
- Process optimisation for changes to the PI; easier process for variations where PI is impacted. The ePI should not lead to increase of workload on maintenance of PI, it should in fact give opportunity to decrease the workload.
- Free creation tool and open application programming interface (API) for all stakeholders with a wish to have machine-to-machine communication.
- Implementation should be without any regulatory submission/approval process.

Batch specific implementation

We agree that some parts of the ePI may be applicable to all batches and some only to specific batches (e.g. when excipients change). The need for batch-specific product information is not a new one and industry has established processes with sufficient control to ensure the right paper version associated with the appropriate batch of the medicine e.g. to reflect changes in the composition of a product. This ensures that any information for which the patient needs to be aware in relation to a particular batch of the medicine, is available when they receive their medicine. However, already today we see situations with divergent sets of product information such as in online compendia. Online compendia always show the latest electronic version of PI which is released by the responsible MAH in sync with the market implementation of a change. Thus, always the newest information is available via the trusted electronic source, but unexpired older goods bearing out-dated product information will remain in the market. Discussion on the batch specific changes and ePI needs to take place as part of the implementation roadmap (including for new classes of medicinal product such as ATMP – in cases of device or batch specific information) but shouldn't hinder the implementation of ePI.

Data-stewardship: accountability/liability

Industry recommends having a transparent and open discussion regarding the "data stewardship" of the content of the Product Information. A clear responsibility assignment needs to clarify the accountability and liability for each step, in particular for the final content that is publicly available. We believe this openness will facilitate a collaborative and efficient regulatory evaluation between Industry and Authority and improve the governance aspect.

Collaborative roadmap

With the vast experience from industry and agencies to implement existing telematics programmes, lessons learnt from the eCTD and CESP programmes are welcomed (phased approach and the mandated milestones) to build a successful ePI implementation roadmap, with reliable timelines and supportive requirements (financial/resource) for all stakeholders. The level of acceptable flexibility for an ePI approach can be tested in a proof of concept phase, which forms part of the Roadmap.
Controlled timelines, content-structuring approaches, standards and sources of information will bolster the main objective of providing updated and trustworthy product information to patients and HCPs from one authoritative source and to one standard. Therefore, industry welcomes collaboration with the regulator network to define the success criteria by utilising the agile approach into a phased meaningful EEA-wide ePI implementation.

Technical

Lessons learnt from other projects

Historically, telematic projects within the EU regulatory network have been slow to evolve and under-resourced. This should be avoided, and clear timelines should be developed in the Roadmap. We support a coordinated and 'phased' approach across member states in the development of ePI harmonised with the current infrastructure and priorities of member states (ensuring sustainability and interoperability1). At the same time, we call for a reasonable application of flexibility principle that can to help guarantee the success of the ePI Programme: while maintaining the same standards across all member states. This means that countries and (smaller) companies which can move swiftly should be allowed to do so, but support (resource/financial/ expertise) should be provided by the EU Commission to any countries requiring it, to ensure no-one is left significantly behind and that parity of opportunity across European patients is achieved as soon as possible.

The Importance of high data quality for a successful ePI implementation

High quality SPOR data is crucial to support upstream and downstream activities of ePI life-cycle.

Our assumption is that the full potential of ePI will be leveraged by high quality data from a TOM-facilitated SPOR system. This will guarantee that data will be more reliable and re-usable, while reducing the number of verification and checking steps.

Harmonisation of standards

As previously mentioned, since ePI is part of the future Telematic Strategy, a common electronic standard and Process Governance should encompass success criteria such as high quality of data, and its re-use, inter-dependency and connection to all EU telematics projects, including SPOR and TOM. The common standard and design of the system should create a digital and agile infrastructure with an integrated process to facilitate the submission, review and authorisation of structured electronic product information, which will be continuously enriched via dissemination to key stakeholders (i.e. patients, HCPs and information consumers). It is recommended that the review and approval of ePI content should be carried out in the format that will best facilitate the downstream uses of that information. This means to avoid manual transfer of approved information in one format to another format for re-use; i.e. ePI format should be easily transferrable/converted into the other required formats: Word, PDF, artwork CAD to avoid manual interaction, which may lead to errors and thereby reduce PI content quality.

The choice for the Common Electronic Standard for ePI should also take into consideration the Regulatory dialogue and co-operation between EMA and FDA. The Common Electronic Standard for the ePI system should be designed with the aim to build a framework that facilitates a collaborative cross-stakeholder (EMA, NCAs, Notified Bodies and Industry) management of product information. The output should be high-quality structured product information, which can be disseminated to patients, HCPs and information consumers as well as EMA, NCAs and MAHs. The IATF considers it positive to consider co-operation with the European Common Data Model and European Interoperability Framework (EIF). In addition, it is recommended to design the ePI to take into consideration the core recommendations of EIF to achieve efficient sharing and re-use of structured and semi-structured data. Principle 4 (recommendation of re-usability of data for processes optimisation) should be also included.

The IATF positively acknowledges that the common standard will be agreed not only amongst Regulators but with all stakeholders, particularly including Industry who will be the main player in providing information in the pre-defined standard. More clarity on how this constructive dialogue will be handled and how Industry can positively contribute would be appreciated.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0233&from=EN

Funding model

Future funding models of EU telematics projects are under discussion within the Telematic Management Board; accordingly, an integrated approach using common building blocks would help to assure cost-efficiency between projects and sustainability of the system. Funding for any project that develops ePI based on the principles in this draft document should be clearly established and discussed among all stakeholders.

Please refer to the remaining document for further detailed comments and suggestions*

The Association of the European Self-Medication Industry (AESGP) is the official representation of manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe.
Contact: [redacted]
Email: [redacted]
Website: www.aesgp.eu

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research-based pharmaceutical industry operating in Europe.
Contact: [redacted]
Email: [redacted]
Website: www.efpia.eu

The Medicines for Europe is the official representative body of the European generic, biosimilar and value-added pharmaceutical industry.
Contact: [redacted]
Email: [redacted]
Website: www.medicinesforeurope.com

List of technical abbreviations

API	Application Programming Interface
CESP	Common European Submission Portal.
CRO	Contract Research Organisation
CTIS	Clinical Trial Information System[2]
eCTD	Electronic Common Technical Document
EHR	Electronic Health Record
GDPR	EU General Data Protection Regulation[3]
IDMP	Identification of Medicinal Products
IFU	Instructions for Use
ISO	International Organization for Standardization
PIM	Product Information Management[4]
QR Code	Quick Response Code[5]
SPOR	Substance, Product, Organisation And Referential (EMA implementation of master data management system based on ISO IDMP standards)
TOM	Target Operating Mode[6]l
xEVMPD	Extended EudraVigilance Medicinal Product Dictionary

[2] An EMA-led programme to develop the Clinical Trial Portal and the Union Database mandated under Clinical Trial Regulation EU No. 536/2014 to facilitate a harmonised assessment and supervision process for clinical trials throughout the EU

[3] Regulation (EU) 2016/679 designed to protect the personal data of EEA citizens.

[4] An EMA-led project to increase the efficiency of the management and exchange of product information through the structuring of the information and its exchange by electronic means. The project was closed in March 2011 pending a review on IT strategy, technologies and priorities.

[5] Two-dimensional barcode, first designed in 1994 and which comprises black squares arranged in a square grid on a white background. It has faster readability and greater storage capacity compared to standard barcodes.

[6] An NCA-led project, started in 2018, which has the intent to optimise the exchange of regulatory ISO IDMP-compliant product data between regulators and applicants during new marketing authorisation and post-authorisation activities. Still a concept, it is considered to be a rational means by which data quality will continue to be improved by means of in-built checks.

Section 1: Definitions			
1	Lines 83 ff	Comment: The definition of ePI encompasses more than information for the prescriber and patients, it also includes labelling, blue box requirements and Annex II information. This seemed to be based on the current PL as PDF provided by EMA; which contains all annexes to the Commission Decision. The priority for delivering ePI should be the freely-accessible provision of trusted (regulator-approved) information to patients, consumers and HCPs. For this reason, we propose a phased approach, which starts with the creation, regulatory processing and dissemination of digitised PLs and SmPCs; and with the addition of other value-adding aspects of Product Information plus corrective modifications (from post implementation learning) in later phases according to a mutually agreed roadmap. This phased approach should include an analysis with relevant stakeholders, for whom additional information, including from Annex II, are considered an added value for patients and HCPs. Therefore, it is proposed to focus on regulatory communications which have an impact on patient care, e.g. risk minimisation materials. Proposed change: Replace labelling and footnote by "**risk minimisation material relevant for patients and HCPs**".	
2	Lines 86 - 91ff	Comment: It is important for all members of the broader audience to understand the concept of ePI and the underlying principles fully, and we, therefore, propose to establish and maintain a 'Glossary of Terms' providing important definitions throughout the text, e.g. what is to be understood by structured elements and unstructured elements.	

		The concept of ePI including the aspects of structured and unstructured and re-usable elements should be further explained in a (future) EU implementation guideline for ePI. In our opinion, an ePI adapted QRD Guidance document provides a good opportunity to align content, technical and design requirements for both PI and ePI. However, to make use of the full potential that ePI can offer to all stakeholders, the specific features of ePI and its re-usable data elements need to be explained in the adapted QRD guidance and the respective xml schema. Line 87 mentions ePI in an "organized format". Line 91 mentions "ePI refers to a semi-structured format" and a definition is also included. Organized and semi-structured don't have the exact same meaning but both are used to qualify the format of the ePI. <u>Proposed change:</u> <u>Line 86</u> ePI is authorised, statutory product information for medicines (i.e. SmPC, PL and labelling) in a **structured** ~~organised~~ format created using the common EU electronic standard. <u>Lines 90-95</u> There are many different interpretations of 'electronic product information.' Therefore, it is important to clarify that for the purposes of this collaboration, ePI refers to a ~~semi-structured~~ format suitable for electronic handling of product information **as specified above**. ~~Semi-structured means that~~ ePI contains structured elements (e.g. fixed headings and vocabularies), and some unstructured elements (i.e. free text) ~~which are re-usable throughout the lifetime of a medicinal product~~. Unstructured formats such as PDF, Word or other unstructured text are not considered to be ePI because these do not deliver the benefits to stakeholders outlined in these principles.	

3	Line 108	Comment: While section 1.2 of the Key Principle document talks only about creation, we feel the objective of process efficiencies and its full potential can only be achieved when all stakeholders work with a common standard. Throughout all steps of the regulatory process (including creation, submission, review, authorisation and dissemination) it is important that all stakeholders work with a common electronic standard throughout the life-cycle of ePI to realise the full potential. In addition, we propose to stress the need for a common transmission standard for the harmonised exchange of ePI between all stakeholders. The programme for developing ePI must be aligned with all complimentary EU telematics projects including eCTD, SPOR, CES(S)P Dataset Module, and Regulatory Optimisation of Variations, and be strongly positioned in the EU Telematics Strategy for 2020-2025. Proposed change: "ePI in the EEA for all human medicines, including both centrally and nationally authorised medicines, will be created, **submitted, technically validated, reviewed, authorised and disseminated** using a common electronic standard"	
4	Lines 118-19	Comment: "*A common standard enables the generation and dissemination of electronic authorised information for patients and consumers of medicines in the EU/EEA*." Suggestion to add healthcare providers as well. Proposed change: "A common standard enables the generation and dissemination of electronic authorised information for **healthcare providers,** patients and consumers of medicines in the EU/EEA."	

5	Lines 123-124	Proposed change to create the technical foundation for the dissemination of trusted **and regulatory-approved product** information in ~~the~~ today's ~~electronic~~ **digital** world	
6	Lines 124-125	Comment: Clarification on what is meant by 'tailored' would be welcome, to avoid confusion and/or wrong expectations (link with glossary lines 86-91ff)	
7	Lines 127-129	Comment: ePI should also have as secondary objective the optimisation of the regulatory process: "avoid complexity, offer possibilities to streamline, simplify, reduce administrative burden to manage paper versioning vs ePI. Ultimately speed up system should refer to ePI. Regulatory process in the creation and updating process (variation) of PI by using existing data of the TOM facilitated SPOR system, both for regulators and the pharmaceutical industry". **Proposed change** to streamline, simplify and speed up the regulatory process in the creation and updating (variation) of PI by using existing data of the SPOR System, both for regulators and the pharmaceutical industry. **As SPOR Data should be validated and of high quality, there should be no further need to verify common data under variation procedures, although the affected PI documents would still need to undergo a formal up-versioning and promotion to authorised status. Furthermore, the existence of a pan-EU/ EEA system for the management of ePI should obviate the need to submit full PI content in support of variations**.	
8	Lines 130-133	**Proposed change** Agreement **and acceptance / recognition of the standard by all stakeholders, especially NCAs and national association or already established providers will avoid [...]**	
9	Lines 135-137	Comment:	

		We propose to clarify the following statement: […] is compatible with use at centralised and national (through national competent authorities [NCA]) levels <u>Proposed change (if any):</u> The first step and pre-requisite for ePI implementation is the agreement of a common standard that fulfils the requirements outlined in the key principles and is compatible with use **and exchange of ePI with all relevant stakeholders in the regulatory network** ~~at centralized and national (through national competent authorities [NCA]) levels~~.	
10	Lines 138-140	<u>Comment:</u> Features such as vocabularies and interoperability specifications are considered important for ePI and should be added at inception because they are key for the specification of ePI. The impact of the statement "later releases" on progressing ePI and the Common Technical Standard creates uncertainty for the implementation and may lead to an unnecessary revamp of existing ePI and underlying technology and is therefore to be further explained. Lessons learned from previous telematics projects such as eCTD, xEVMPD, CESP, should be considered and extensive reworking and hybrid solutions should be avoided wherever possible while transitioning to the stakeholder agreed ePI model. In this context a robust milestone driven roadmap that is aligned with the different stakeholders and which is based on agreed use cases and takes into account user acceptance testing and post milestone learning would provide the assurance to plan for rapid and agile implementation of ePI and its future enhancement. <u>Proposed change</u> The common standard will be established considering available **technologies and possible upcoming** technical **innovations** including those from EU	

		Telematics projects. ~~Further features, such as vocabularies and interoperability specifications yet to be developed, may be added in later releases.~~	

Section 2: Benefits for public health			
11	Lines 151 156 – 159 202 – 204 217 220 – 222	Comment: Due to its electronic nature ePI can be much more easily kept up-to-date (i.e. updates can be implemented immediately where no conversion is required) whereas the printed packaging materials, e.g. PL and IFU, may still be the previous version. As long as the paper PL is required to be available, it should be taken into consideration that during a certain period of time, there might be an "inconsistency" between the paper PL and the ePI, with potential increased amount of patient/consumer requests due to discrepancies. Therefore, as soon as ePI is introduced, the corresponding paper PL should carry a standardised sentence advising patients/consumers that the most current version of the product information is provided by ePI with a link to the source, i.e. as done in Spain with the possibility for the patient/consumer to identify easily whether the available paper PI is the same or an older version than the ePI (versioning or PI/ePI should be defined). The link to the ePI (URL, QR code, other etc) should be further elaborated so that it is clear that the code or URL is intended for the patient to scan/type and use.	
12	Lines 152-153	Comment: (1) The content of the PI for national authorised medicines may significantly differ from one EU member state to another. Also within one country, the PI may be different for various MAHs, as their products may have different excipients that may for example result in different warnings. Therefore, it is important that the architecture of the web portal (and any other access point) in structured in a way that patients are smoothly and unequivocally guided and directed to the	

		right ePI, without risk to access to an ePI that is authorised in another regulatory procedure. The ePI/System must have the functionality to only link to translations of products that are approved in the same regulatory procedure, to make sure the PI is identical in the provided languages. (2) Suggestion to add healthcare providers since we are talking about product information: "• better delivery of information so that the right information is available **to healthcare providers**, to the right patient/consumer at the point of need" (3) It is not entirely clear how country-specific information is integrated within the ePI. Further guidance would be welcomed.	
13	Lines 170-172	Comment: It is a priority for the involved stakeholders to provide an environment with better and easier access to trusted information. Having ePI in place is one (important) step; however, education and raising awareness by regulators on this (new) source of information is key. An informative and educational campaign for patients/consumers and HCPs should be planned. If ePIs are available from multiple-sources, possibilities to implement a trusted source stamp and/or explore use of available technologies to ensure an audit trail, and an associated awareness campaign to patients/consumers should be explored.	

14	Line 171	Comment: Proposal to rephrase the scope to cover patients/consumers beyond "EU citizens" and for medicines authorised in the EU/EEA. Proposed change: [...] by giving citizens an authoritative source of information for medicinal products authorized in the **EU/EEA** [...]	
15	Line 175	Comment: Industry welcomes and supports the goal of implementing ePI for all authorised human medicines in the EU/EEA. The objective of implementation should follow a clear roadmap based on agreed use cases, that is discussed and created with relevant stakeholders, leaves nobody behind and works for everybody. Proposed change to add: **...with a stepwise approach, with clearly defined milestones.**	
16	Line 177	Comment: (1) It is important that patients/consumers and HCPs have access to updated product as soon as those updates are authorized by the regulators and ePI is a valuable tool here. To gain an efficient regulatory network it is important that communication of ePI to regulators and to patients/consumers and HCPs is as simple as possible. Industry agrees to the importance of having one source for delivering of ePI (e.g. similar to CES(S)P) to achieve an efficient communication on ePI within the regulatory network. When it comes to dissemination of information to patients/consumers and HCPs it is of importance that trusted information is provided. In the future, further considerations are needed on how existing providers such as FASS, Rote Liste, etc. should be linked.	

		(2) "The most up-to-date ePI version should be always easily available." Timelines and responsibilities should be defined, in order to ensure that a smooth and timely update of the electronic version of the PI is carried out.	
17	Lines 178-179	Comment: While the benefits of ePI can only be achieved when it is made available to patients, the statement '*ePI should be made available …*' creates uncertainty towards the owner of such an objective. In our understanding several stakeholders can play an important role here, e.g. EMA/NCAs, MAHs, third party providers, etc. Further expectations can be discussed as part of the roadmap creation. A single repository should be used from a common point of access for use by all. "*To achieve this principle, ePI should be made available through various technologies and applications, including mobile scanning technology (such as a 2D barcode) on the medicine package*". The ePI principles and roadmap will have to be aligned to the mobile scanning technology guidelines. Proposed change: To achieve this principle, ePI should be ~~made~~ available through various technologies and applications.	
18	Line 185-187	Proposed change: ePI will facilitate creation of PI that is accessible to everyone, including patients/consumers with ~~print~~ **visual** impairments such as blind and partially sighted people (e.g. use of audio, large font size) and those with low literacy levels (e.g. audible formats).	

19	Line 196	Comment: "ePI will be accessible by design." Suggestion to elaborate more on the meaning of this since might not be clear to everyone	

Section 3: Legislative framework			
20	Lines 202-212	Comment: As stated in the general comments, it is realistic to think that in the long term the paper leaflet will be gradually replaced by the ePI. Today there are **situations where** according to current legal requirement and when patients' needs, and interests are respected**, the paper PL could be removed and substituted by ePI.** As an example, a scenario where only ePI could be provided to patients is the case of medicinal products administered in hospitals or directly by a Health Care Professional, e.g. injectables. In most of these cases, the patient does not have access to the paper leaflet and ePI will improve the way in which the right information reaches the appropriate patient. For vaccines the use of multilingual packs/package leaflets is strongly limited by logistical constraints. Indeed, since the vast majority of vaccines have to be stored in refrigerated conditions, it is critical to reduce as much as possible the size of the packs to facilitate storage. Multilingual packs are therefore limited to a maximum of three different languages. The replacement of the paper package leaflet by ePI available in all 24 EU languages would be a key measure to facilitate the transfer of doses within EU/EEA and ultimately vaccine supply. In addition, a pilot for products directly dispensed to and used by patients in highly digitalised markets should be considered. Further lessons should be taken from various national initiatives to consider rolling this out on a European	

		level, such as, i) the Italian practice of printing at pharmacies of the most up-to-date package leaflet, ii) Belgium / Luxembourg pilot project at hospitals. Additional use cases will need to be discussed and developed, considering: i) faster dissemination of relevant regulatory approved changes of products, (operational excellence) ii) decreases risk of drug shortages (opportunity of redistribution of packages in different languages) iii) less cost related to implementation of safety changes and recalls of batches (improved transitional period for replacing the paper as long as required). <u>Proposed change for line 202 -204:</u> **It is not foreseen that** ePI will ~~not~~ supersede ~~or negate~~ the requirement of the pharmaceutical legislation (Article 58 of Directive 2001/83/EC) to ~~include a~~ **have** PL **accompanying** all medicines or **directly conveying** all information required (by Articles 59 and 62 of the Directive) on the outer or immediate packaging. **However, there are situations where patients the patient does not have access to the paper leaflet (e.g. medicinal products administered in hospitals / directly administered by a Health Care Professional, e.g. injectables). Under these circumstances the provision of an ePI would substitute for the need of a paper PL and ensure supply to patients.** <u>Proposed change for line 208 - 212:</u> The ePI is intended to expand the formats in which PL is available and not to remove or substitute the currently available paper format **entirely**. **However, in situations where according to current legal requirement and when patients' needs and interests are respected, the paper PL could be removed and substituted by ePI.** **If a medicines package is provided directly to patients without HCP interaction**, PLs are a valuable tool presented directly in the medicines	

		package and therefore provided to all patients/consumers when they open their medicine. The paper PL is particularly important for patients/consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access. **The paper leaflet should make reference to the ePI, but only when the ePI is available. (**see also comment 31**)**	
21	Lines 207-212	<u>Proposed change:</u> An additional line to be added specific to non-prescription medicines: "**Non-prescription medicinal products need to be regarded separately. As the patient may have no or little interaction with a HCP, information provided directly with the pack will continue to be required but could possibly be complemented by more user-friendly electronic information. In this case, electronic availability of the leaflet may help people to get information before buying a non-prescription medicine and, therefore, help them in choosing the appropriate product or addressing questions to a healthcare professional."**	
22	Lines 213-216	<u>Comment:</u> 'Generation of ePI does not involve any change to the content of the PI. ePI generation will be performed in addition to the current inclusion of the PL in the medicine package. The use of ePI will be a recommended innovation; however, it is not mandatory. This statement seems in contradiction with that, lines 298-299: "All stakeholders, including pharmaceutical companies and regulators, will commit to implementation of the common electronic standard for creation of ePI for all EU medicines."	

		Proposed change: "The use of ePI will be a recommended innovation; however, it is not **legally** mandatory."	
23	Line 217	Comment: 'The paper PL should include a statement directing patients to the ePI as the most up-to-date version of the PL.' The paper PL should only include a statement directing patients to the ePI, if there is an ePI available. Otherwise it may cause confusion. The inclusions of such a statement may lead to a significant number of updates to the PL, which should not require any regulatory procedure (no review and/or assessment). Proposed change: The paper PL should include a statement directing patients to the ePI as the most up-to-date version of the PL**, but only if the ePI is available**. **Adding this statement does not require any regulatory submission or approval.**	
24	Line 223	Comment: The term "reuse" can be interpreted in various ways, and therefore the change as proposed below is preferred. Proposed change: "ePI should always be published as open data, freely accessible for use **directly from the single repository** ~~and reuse~~"	
25	Lines 224-235	Comment: There should be flexibility to allow for validated (regulator approved), complementary materials in support of patients' needs and health literacy, e.g. educational materials, additional instructions, dictionaries etc. Proposed change:	

		The development and implementation of ePI will be carried out in accordance with applicable EU legislation; therefore, the content of ePI will be approved as a result of regulatory procedures currently prescribed in the legislation (or as will be amended by any future legislation). ~~Accordingly, no additional information — either for promotional or other purposes — can be included in the ePI.~~	
26	Lines 236-251	Comment: No further comments on this section. Industry considers that the GDPR covers relevant scenarios / future features.	

Section 4: Process			
27	Lines 255-262	Comment: The Principle paper suggests that a broad margin of flexibility is given for national implementation. However, if flexibility is not being accompanied by a clear and binding phased roadmap and value-add milestones, based on the user requirements, the consequence will be fragmented and cost intensive implementation and loss of the opportunity to impose optimal practice across the EU Regulatory Network. With the vast experience from industry and agencies of telematics-facilitated regulation, industry endorses the key learnings of eCTD, CESP and XEVMPD programmes (phased approach and the mandated milestones) to build a successful ePI implementation roadmap, with reliable timelines for all stakeholders. The level of acceptable flexibility for an ePI approach should be tested in a proof of concept phase, which forms part of the phased-approach roadmap. Industry welcomes collaboration with the regulator network to define the success criteria by utilising the agile approach into a phased meaningful EU/ EEA-wide ePI implementation. Variable timelines, together with multiple standards and sources of information will undermine the main objective of	

		providing updated and trustworthy product information to patients and HCPs based on one authoritative source and to one EEA-wide standard.	
28	Lines 255ff	Comment: Our proposal would be to enrich the governance model by segmenting it into relevant sections impacted by ePI with corresponding workflows, and by considering the agreed use cases and stakeholder requirements, respecting the lifecycle of ePI as: - Creation - Internal approval - Submission - Review - Authorisation - Dissemination - Superseding - Archiving Industry welcomes an open dialogue to build an effective governance model. The latter would be greatly facilitated by the adoption of common terminology and definitions to assure a common understanding across the EU/EEA regulatory network.	
29	Lines 267-268 276-277	Comment: Industry recommends having a transparent and open discussion, with the goal of confirming "data stewardship(s) and data ownership(s)" of the content of ePI. Clear assignment of responsibility is required to clarify the accountability and liability for each step; in particular for the final content that is publicly available. We believe this openness will facilitate a collaborative and efficient regulatory evaluation between Industry and Authority and improve the governance aspect.	

		Industry is convinced that besides the data stewardship, also the data ownership should also be discussed. Dissemination of trusted information via ePI to patients and HCPs is the primary objective and due to its digital nature and accessibility ePI might be reproduced in various ways. While patients and HCPs are expected to benefit from well-controlled ePI services, less controlled reuse of data always comes with the risk that the reproduced data set is not kept accurate e.g. when the data in the original source changes. Therefore, it needs to be clarified that such a scenario is beyond the control of MAHs. Proposed change: The purpose of the reuse by third party is in accordance with the intent of ePI. As such we propose to add *ePI will also be made available for use by third-parties,* ***who can make ePI available*** *to patients and healthcare professionals following agreed terms of use.* ***Reproduction of ePI should only be allowed when it is for the benefit of patients and HCPs and respects the rights of the data owner. After reproduction, the MAH is no longer liable in cases of misuse of the information or incorrect dissemination of PI"***	
30	Lines 269-271	Comment: A free ePI Creation tool should be provided by Regulators. Proposed change: Following regulatory evaluation, if final PI is not already in ePI format, it is converted to ePI by the MAH **using a GxP validated regulator-provided creation tool.**	
31	Line 284	Comment: Data-stewardship/accountability/liability Industry recommends having a transparent and open discussion regarding the "data stewardship and ownership" of the content of the Product Information.	

		Clear assignment of responsibility is needed to clarify the accountability and liability for each step; in particular for the final content that is publicly available. We believe this openness will facilitate a collaborative and efficient regulatory evaluation between Industry and Authority and improve the governance aspect.	
32	Line 286	Comment: "A pan-European web portal could provide a central point for access of ePI for all centrally and nationally authorized medicines". We support the concept to have a single access-point to ePI on the World-wide Web, because this will guarantee a better trust of ePI source. However, as highlighted in comment to lines 152-153, it is important that the architecture of the web portal (and any other access point) is structured in a way that patients are smoothly and unequivocally guided and directed to the right ePI, without risk to access an ePI that is authorised in another regulatory procedure. The ePI/System must have the functionality to only link to translations of products that are approved in the same regulatory procedure, to make sure the PI is identical in the provided languages.	
33	Line 304-308	Comment: Pragmatic solutions should be available where ePI implementation would place an undue burden on MAHs of orphan medicinal products, e.g. low volume products, and where ePI implementation/maintenance requirements may result in products not being brought to the EU market. Further use cases and appropriate pragmatic solutions should be explored during the roadmap development in collaboration with the relevant MAHs / stakeholders, also in light of current exemptions rules to paper labelling and package leaflet obligations (incl. translations).	
35	Line 306	Comment: We propose to consider any company with a high volume of legacy information irrespective of size.	

		Proposed change: as well as certain companies such as micro, small or medium-sized enterprises (SMEs), **ATMP / orphan manufacturers and companies with a high volume of product information**.	
36	Line 310	Proposed change: "Once a common standard and governance process are established, stakeholders must plan for their implementation in their jurisdictions according to a roadmap, which includies timelines, determined at HMA and EMA level **in collaboration with industry".**	

Section 5: EU Context			
37	Line 331-340	Comment: IATF welcome the multilanguage principle, according to which the availability of different official languages is accomplished by translations accomplished as part of the applicable EU procedure. We support that PI will be available by default only in the official language(s) of the Member States where the medicines are placed on the market. Links to available translations should only be made for MAs approved in the same regulatory procedure, see also comments to line 152-153 and line 286. It is appreciated that the use of structured authoring, which in turn employs standard and validated language constructs (i.e. according to QRD) and ISO Standard data, will enable translation processes to become optimised and translated output to be more reliable. Consequently, EEA citizens may in the long run benefit through having access to accredited PI in more languages than the official national defaults.	

Submission of comments on 'Consultation on Electronic Product Information of EU medicines' (EMA/849614/2018)

Comments from:

Name of organisation or individual
Krka d.d., Novo mesto

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	We support idea that ePI is not obligatory.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
127-129		Comment: It will be crucial to integrate SPOR data in to ePI. If connection is not made between ePI and SPOR data this will inevitably, create new data silos independent of all other EU telematics project. For example: If ePI will have no connection to SPOR we will have to build new database for substances and maintain it as well. The same is true for products, Organizations and Referential. Delivery method of this ePI should be further defined. In that expect connections to CESSP and TOM should be strongly considered. Bearing in mind large amount of changes (some of them parallel) on these documents. Proposed change (if any):	
179-182		Comment: We support implementation of ePI, but in connection with FMD (serialisation; ePI corresponds to specific batch, we need to ensure that right shelf life, composition, storage conditions ect will be in line with printed packaging materials). For some safety variations, it's possible to be updated in ePI before printed PI, but we need to define which types and content of variations. ePI shouldn't cause double work and costs for company in order to ensure right PI in production and connection to the right approved ePI. Deadlines needs to be clearly defined (implementation, transition period,…).	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Proposed change (if any):	
217		Comment: Additional sentence in PIL will lead to update of QRD version. No separate variation should be required for this change. Proposed change (if any):	
271		Comment: We find it necessary that conversion tool (and not only creation tool) is provided by regulators. Both tools should be free of charge. In key principles document (section 10. Process governance) it is proposed that "if final PI is not already in ePI format, it is converted to ePI by the MAH using a conversion tool". Our concern is that especially national PI documents within MRP/DCP which are handled in national phase outside of eCTD lifecycle are subject to uncontrolled changes which potently would make conversion of such documents problematic. In case creation tool only would be used, NCA's should do assessment/corrections/comments in the tool directly and not via other documents. Proposed change (if any):	