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Development of the European medicines web portal

Reflection paper

[*] Correction on page 21. Article 75(2) replaced to read 57(2).

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1. Introduction and purpose

The 2010 pharmacovigilance legislation, which came into effect in 2012, gave the European Medicines Agency (EMA) the responsibility of launching a European medicines web portal for human medicines in collaboration with the European Union (EU) Member States[1] and the European Commission. It also gave the Member States the obligation to launch similar national medicines web portals. These new legislative provisions set out a clear mandate for EMA and its partners to provide information online on medicines to the EU public, as a major part of their role in protecting public health.

> *The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised in the Union.*
>
> Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)

In addition, the European Union Medicines Agencies Network Strategy to 2020[2], published in December 2015, refers in theme 3, objective 3, to the fact that the network will seek improvements in dissemination of medicinal product information in particular through access to state-of-the-art databases.

In the EU, 385 million citizens have access to the internet at home[3], with many using it to source medical and health information. As such, the European authorities can support citizens in finding high-quality, validated information on medicines and their efficacy and safety in order to ensure better public-health outcomes.

It is clear that the legislation requires EMA and Member States to provide access to the information it holds within their databases and systems in an intelligent, helpful way, by not only complying with the legislation per se, but also by going beyond the legislation to ensure that:

- user needs are taken into account;
- EMA and its partners expect positive reputational gains;
- there is increased visibility of the work of the EU medicines regulatory network;
- consideration is given to wider use of the data in order to provide more functionality to the EU medicines regulatory network.

As an initiative of the EU medicines regulatory network, the development of the European medicines web portal has been endorsed by the EU Telematics Management Board within the EU Telematics Strategy 2014-2016[4] and the EU Telematics strategy and implementation roadmap 2015-2017[5].

This reflection paper discusses the provision of information on human medicines through the European medicines web portal and the opportunities this presents for EMA and its partners within the EU medicines regulatory network.

[1] The provisions also apply to the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf
[3] In 2014, 81% of the EU population of 507 million had internet access at home: http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&plugin=1&language=en&pcode=tin00088
[4] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/09/WC500172949.pdf
[5] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/08/WC500191875.pdf

Disclaimer: This paper sets out a vision for how the European medicines web portal will be developed, managed and designed. All decisions on how this will be achieved in practice will be dependent upon agreement across the EU medicines regulatory network and the availability of financial and information-technology resources.

2. Vision

2.1. What we want to achieve

The vision for the European medicines web portal is to launch a multilingual website for patients and healthcare professionals, as well as other groups or individuals looking for information and data on medicines, such as academic researchers, providing access to information on nationally and centrally authorised medicines for human use in the EU. It will provide a unique source of information on all medicines authorised in the EU, providing a helpful and up-to-date resource for target audiences as well as other interested parties including industry and national competent authorities (NCAs).

The website will help to position the EU medicines regulatory network as a core provider of free[6], unbiased, up-to-date, trustworthy, scientifically sound and validated online information on medicines, and will provide access to nationally authorised product information in a phased approach, initially via national web portal and then transitioning to data delivered through the EMA's Data Integration Programme. This will increase the visibility of information on medicines held by the NCAs and EMA, strengthening the network's reputation as a champion of public health within the EU.

The website should be a high-quality example of how public bodies should make information available online to citizens and will be accessible on mobile devices and desktop monitors. It will also comply with the HONcode[7] standard for trustworthy health information. The European medicines web portal will also be a clear example of the network's commitment to the EU open data agenda[8] which aims to enable distribution and re-use of data in order to foster economic activity, enhance evidence based decision making and demonstrate transparency by EU public bodies. As such, one of the principal drivers of the project will be to make the data available so it can be consumed and repackaged by other information providers. This would include patient and healthcare-professional organisations, electronic patient journals and online applications aimed at these target audiences.

Furthermore it will support the Digital Agenda for Europe[9] including patient empowerment through improved access to information. While not a primary driver, the European medicines web portal could also support the European eHealth action plan 2012-2020[10] over the long term, including the development on the cross-border exchange of ePrescription as part of the eHealth Digital Service Infrastructure where the first exchanges will take place at the earliest in 2018.

The website will replace EudraPharm[11], the online interface developed by EMA and its partners in 2006 that aimed to provide access to information on medicines authorised in the EU.

The vision for the development of the European medicines web portal is to progress following a stepwise approach, taking into account the data initiatives within the EU Telematics programme, i.e. the implementation of the International Organization for Standardization (ISO) Standards on Identification of Medicinal Products (IDMP) via the master data management services for Substances, Products, Organisations and Referentials (SPOR) within EMA's Data Integration Programme.

[6] A Health Online survey by the US-based Pew Institute shows 26% of internet users who look online for health information say they have been asked to pay for access to something they wanted to see online: http://pewinternet.org/Reports/2013/Health-online/Summary-of-Findings.aspx

[7] HON was founded to encourage the dissemination of quality health information for patients and professionals and the general public, and to facilitate access to the latest and most relevant medical data through the use of the internet. The HONcode certification is an ethical standard aimed at offering quality health information. It demonstrates the intent of a website to publish transparent information. The transparency of the website will improve the usefulness and objectivity of the information and the publishing of correct data. DG-SANCO Health-EU portal complies with the HONcode standard for trustworthy health information: http://www.hon.ch/HONcode/Conduct.html

[8] https://open-data.europa.eu/en/about

[9] http://ec.europa.eu/digital-agenda/

[10] https://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

[11] http://www.eudrapharm.eu/eudrapharm/selectLanguage.do?NOCOOKIE=NOCOOKIE&NEW_SESSION=true

Specifically, as a precursor to the implementation of the European medicines web portal, a set of data currently registered in the database established under Article 57(2) of Regulation 726/2004 will be published online. This initiative would help improve overall data quality and completeness by encouraging pharmaceutical companies to review data and update as required.

The first iteration of the portal would use structured Article 57 data and would provide access to the medicines search page on NCA websites. In a second phase, additional content and functionality will be published as these become available from SPOR master data management services. This would in effect progressively realise the full list of benefits and the strategic vision described in this reflection paper.

Publishing Article 57 data before the official launch of the European medicines web portal is likely to:

- further improve the quality and completeness of submissions from the pharmaceutical industry;
- introduce the terminology that will be used for the implementation of the ISO IDMP standards in the EU;
- ensure that shortcomings identified in the EudraPharm project are addressed, guaranteeing the usability and effectiveness of the future portal.

The European medicines web portal will also incorporate the European Database of Adverse Drug Reaction Reports (ADR)[12] and the EU Clinical Trials Register[13], websites currently maintained by EMA, as well as the new clinical data website, a platform to make clinical study reports available to external parties, which is being launched in October 2016 in line with EMA policy 0070[14].

It will be critical that Member States recognise the need to invest in reliable provision and maintenance of the data on national products in national databases in order to keep the data current.

2.2. Expected benefits

The European medicines web portal is not only required by EU legislation, but also has the potential to bring benefits to EU citizens and to the EU regulatory network. These benefits are outlined below.

2.2.1. Reliable information on medicines for patients and healthcare professionals

Patients and healthcare professionals use the internet to find information on medicines and want to locate information they can trust. The internet contains millions of pages about medicines, but users often struggle to find reliable content. In 2012, a Eurobarometer survey on patient involvement in healthcare[15] found that both patients and healthcare professionals questioned the validity of online information resulting from searches and were aware of the need for high-quality, trustworthy sources of information.

The European medicines web portal will be an opportunity for the EU medicines regulatory network to provide an authoritative, single and validated source of online information on medicines for EU citizens complementing, and linking to information that is already published on NCA websites.

[12] http://www.adrreports.eu/
[13] https://www.clinicaltrialsregister.eu/
[14] http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp
[15] http://ec.europa.eu/public_opinion/archives/quali/ql_5937_patient_en.pdf

2.2.2. Comprehensive pan-European information

NCAs and EMA currently hold a large amount of data and information on medicines in several national and pan-European systems, some of which are already available to the public on a range of websites. Having access to this breadth of information puts EMA and its partners in the unique position of being able to provide an EU-wide view of all medicines authorised in the region. By providing access to all of the data from the relevant repositories through a single website, users will be able to carry out a wide range of searches across the entire EU dataset in one place.

Furthermore, as the network moves closer to a standardised identification system for medicines in the European Union through the use of ISO IDMP[16], the European medicines web portal could ultimately allow users to query unique product identifiers stored against medicine data in the information-technology (IT) systems supporting the website. This would allow users to find medicines containing the same active substance but in different Member States as illustrated in annex 7.1, enabling the website to support the delivery of cross-border prescription services.

The European medicines web portal will support provisions in the EU Clinical Trial Regulation[17] on information to stakeholders, as this states that data must be made available in easily searchable formats and include links to other related content and documents held by the Agency. However, there is no dependency between these two initiatives, and the European medicines web portal does not need to be available in advance of the Clinical Trial Portal and Database.

2.2.3. Enhanced cooperation and visibility within the EU regulatory network

The collaborative ownership of the European medicines web portal is expected to benefit the EU medicines regulatory network as a whole. Through interlinking between the European and national medicines web portals and surfacing of product information owned by NCAs, the European medicines web portal is expected to raise the visibility of NCAs and the documents they hold.

The portal will also provide key information to the public in all EU official languages that showcases and explains the EU's medicines regulatory processes. This will help to increase public knowledge of and confidence in the EU regulatory system.

2.2.4. Improved data-sharing

One key feature of the European medicines web portal will be to make certain data on medicines available for re-use, not only by human users such as academics looking for data on clinical trials, but also by other websites and data stores that collect, analyse and re-use data on medicines. By providing data on medicines in a single place in formats that can be re-used and recycled (i.e. the ability to download datasets), EMA and its partners would be supporting the open-data agenda. Content on the portal would be further disseminated through multipliers such as patient and healthcare-professional organisations, electronic patient journals, applications and other media used by the target audiences.

Establishing a legal framework for the open-data agenda has been gathering momentum within EU institutions in recent years, with considerable emphasis on the importance of making data available as a resource for new knowledge and the development of applications, products and services. Legal references include Directive 2013/37/EU of 26 June 2013 amending Directive 2003/98/EC on the re-use of public sector information and the Commission Decision of 12 December 2011 on the re-use of

[16] More information on ISO IDMP:
http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55034
[17] Art.81(2), EU Clinical Trial Regulation No. 536/2014

Commission documents (2011/833/EU). In May 2013, the G8 adopted the open-data agenda[18] and Member States are developing their own open-data strategies as a consequence.

3. Principles

The following principles are relevant in order to ensure a successful implementation of the vision for the European medicines web portal:

- Ownership, including roles and responsibilities
- Content
- Visibility and awareness

3.1. Ownership, including roles and responsibilities

The European medicines web portal will be owned by the entire EU medicines regulatory network, including NCAs, the European Commission and EMA. A close collaboration between all partners is critical to ensure that decisions concerning the European medicines web portal are made after considering the viewpoints of all parties concerned. This will take place in two main arenas: the EMA Management Board and the Heads of Medicines Agencies (HMA), following consultation with the EU Telematics Management Board.

The website will be developed and maintained by EMA.

An important aspect to be considered is obtaining a clear understanding of how the European medicines web portal will complement the national portals, with the aim of creating a coherent online network of websites supporting the safe and effective use of medicines in the EU. EMA is supporting discussions among NCAs on development and maintenance of national web portals within the context of the ongoing work within the SCOPE initiative[19] of HMA and this will also be taken into account.

3.2. Content

The range of content available on the European medicines web portal will be driven by:

- legislative requirements;
- expectations identified by NCAs, the European Commission and EMA;
- stakeholders' expectations and needs.

During the interface design project for the portal, EMA will work directly with the main target audiences of patients and healthcare professionals from across the EU in order to understand design and functionality needs based on typical user tasks identified by these groups.

Expectations of the NCAs for the European medicines web portal have already been gathered in a survey that ran between October 2014 and January 2015. Although the feedback was varied with some differing views expressed, many of the expectations were in line with EMA's original proposals. Further discussion will take place on NCAs' expectations as the project progresses and once the appropriate governance structure is established to guide project roll-out.

[18] http://ec.europa.eu/digital-agenda/en/non-legislative-measures-facilitate-re-use

[19] The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators are collaborating to improve skills and capability in the network which will help safeguard public health in both national territories and the EU as a whole.

3.3. Visibility and awareness

Once launched, the European medicines web portal will be competing with many other online sources of information on medicines. Therefore, simply launching the website online is not sufficient to ensure findability and use. As a consequence, the success of the European medicines web portal will also heavily depend on the development and implementation of a multi-annual promotion strategy aimed at increasing awareness and visibility. It will also be important to ensure that dissemination of content is maximised through other information providers.

4. Achieving the vision

4.1. Aspects to be considered

The following aspects need to be taken into account when implementing the aforementioned principles.

4.1.1. Article 57 database and data quality and completeness

The Article 57 database will be published online as a precursor to the initial launch of the European medicines web portal. EMA will continue to work closely with NCAs and the pharmaceutical industry to maximise data quality and completeness within the Article 57 database and support the transition to ISO IDMP.

Once launched, Article 57 data will be used on the portal to enable search and browse functionality. EMA will ensure that on pages throughout the portal, there are clear statements about the source and quality of the data. High data quality will rely on a number of factors, including coordinated implementation of the ISO IDMP standards, and correct and timely submission of data from marketing authorisation holders. A statement should also be included advising patients and consumers to never stop or change medication without prior consultation with their healthcare professional.

4.1.2. Source of product-information documents

EMA holds the full range of documents on centrally authorised medicines, because it captures and maintains these documents as part of its core regulatory remit. As these documents are currently already published on the Agency's corporate website, they can also be published on the European medicines web portal.

In contrast, EMA has few product-information documents on nationally authorised medicines at its disposal. EMA and its partners need to find a common agreement on how nationally authorised product information, including summaries of product characteristics (SmPCs), package leaflets and labelling should be made available.

As an initial stage in finding a solution for this challenge, EMA and HMA considered a number of options for the sourcing of these documents[20], two of which have been further considered by EMA and HMA[21]:

1. Marketing Authorisation Holders (MAHs) include the Uniform Resource Locators (URLs) for the product information on national web portals in their Article 57 data submissions.

[20] Discussions between EMA and HMA took place in Rome on 16 July and 27 November 2014 and in Riga on 4 February 2015.

[21] Two other options were considered but rejected at this stage:

- MAHs provide patient information from their own internal databases through the Article 57 data submission process
- A web service/aggregator parses national web portals for product information on nationally authorised products.

2. The European medicines web portal, using Article 57 data, provides access to the medicines search page on national web portals.

An analysis of the strengths and weaknesses of these two options (see 7.4) has taken place, including the outcomes of a survey of NCAs that ran between October 2014 and January 2015. This survey set out to gain a clearer picture on the current provision of product information on national web portals and to gather NCAs' needs with respect to the European medicines web portal. It revealed that eight of the 23 national web portals[22] changed the URL for product information when the documents were updated. Of these eight, only two respondents stated that it would be possible to change the code of their national web portal in order to achieve stable URLs for these documents.

On the basis of this analysis, a two-stage launch of the European medicines web portal was agreed upon by HMA at its February 2015 meeting. This will involve an initial launch of the website in line with option 2, with the European medicines web portal providing access to the main medicines search page on national web portals. This will be followed by an exploration of new solutions to explore searchability and parsing of information from the national web portals, once a standardised medicine identification system has been introduced in the EU and in line with the legal obligations set out in Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012. These require the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines (i.e. the ISO IDMP standards).

EMA, in close cooperation with the EU regulatory network and European pharmaceutical-industry associations, is moving forward with the implementation of the ISO IDMP standards via regulatory master data management services for Substances, Products, Organisations and Referentials (SPOR). As part of the implementation of the product and substance management system, the Agency will replace the current Article 57 format with the formats, terminologies and standards defined by the ISO IDMP standards and as agreed within the EU medicines regulatory network. Once this management system is fully functional and the proposed target operating model for the data governance has been implemented in the EU, the product information as released by the NCAs will be consistently available in the product management system as well as in the Member States' websites for integration and consumption by the EU medicines web portal.

The European Commission, the EU Network Data Board and the EU ISO IDMP Task Force have endorsed a phased implementation[23] of the ISO IDMP standards. This foresees the kick-off of electronic submission into the product and substance management system from 2018/19, following the release of the referential and organisation management system in 2016.

[22] There were 29 respondents to the survey representing 20 EU Member States (Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain, the United Kingdom) plus Iceland, Liechtenstein and Norway.

[23] See EMA page (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp&mid=WC0b01ac058078fbe2) for the phased implementation agreed

4.1.3. Lessons from EudraPharm

In 2006, EMA and its partners developed EudraPharm, an online interface providing access to information on medicines authorised in the EU. Despite long-term investment and stakeholder involvement, the website was unable to achieve its main objectives and today has low visitor rates[24]. The development of the European medicines web portal needs to take into account the recommendations of a 2010 audit of EudraPharm[25]. These recommendations include:

- the importance of identifying a clear business case;
- ensuring quick delivery of national data; ensuring sufficient technical support and documentation for NCAs;
- introducing a focus on users to lead interface design;
- making the website more visible on the internet;
- developing a comprehensive communication strategy;
- thinking beyond legal requirements.

This reflection paper takes these recommendations into account to ensure that the lessons from this experience are used and that the objectives missed during the EudraPharm project are achieved in the development of the European medicines web portal.

With respect to the consultation with Member States, the goal of showing content on nationally authorised medicines on national web portals through the European portal should not require large-scale technology investments on the part of Member States, but should be achieved by finding cost-effective technical solutions.

4.1.4. Re-use of content

For the information to be considered useful and valued by patients and healthcare professionals, the solution should take into account better dissemination of the product information to other information providers such as patient and healthcare-professional organisations, electronic patient journals, and applications developed for the needs of the target audiences. Data should be made available in such a way that they can be consumed easily and repackaged by other information providers.

We would also consider the need to enable additional functionality for the EU regulatory network over the course of time.

4.2. Implementing the principles

4.2.1. Ownership, including roles and responsibilities

In order to reflect its joint ownership, the European medicines web portal should be cobranded with:

- a specific visual identity that reflects the joint ownership;
- the logos of the HMA and EMA on every page;
- a statement explaining the fact that EMA maintains the website on behalf of the EU medicines regulatory network.

[24] According to AWStats, the website had 421 unique visitors in 2013
[25] MBTC-2011-09-025 Prognos Final report on Eudrapharm (EXT/757793/2011): https://docs.eudra.org/webtop/drl/objectId/090142b281930091 (link only accessible within EMA)

Since the European medicines web portal will be developed and maintained by EMA, development, build and launch will be dependent on the availability of the necessary human and financial resources.

4.2.2. Content

As stated previously, the content on the European medicines web portal will primarily be driven by the 2010 legislative requirements under the pharmacovigilance legislation, expectations identified within the network, and stakeholders' expectations and needs. Other aspects to be considered relate to how to make best use of the available data, how to best search for the data and how to ensure that EU citizens can search in their national language as far as possible.

This area is likely to present the biggest challenge, namely how best to integrate the medicine data and document sources feeding the web portal, while providing users with a meaningful, usable and useful experience. Until a full analysis of the technical aspects of this challenge has been undertaken, the extent to which the vision can be achieved, in particular with respect to timelines for finalisation, is difficult to assess with certainty.

4.2.3. Expectations identified within the network

During the course of 2016, HMA, the EMA Management Board, and Telematics governance have provided comments and this reflection paper has been updated accordingly.

The survey conducted between October 2014 and January 2015 gathered information on the expectations of NCAs for the European medicines web portal and technical aspects related to the publication of information on national websites. Continued constructive collaboration among the joint owners of the portal will be necessary to allow the website to become the comprehensive reference source for the most accurate information on medicines across the EU.

Further discussion will take place on NCAs' expectations as the project progresses.

The European medicines web portal will link to relevant content on national web portals in order to create an online network of websites supporting the safe and effective use of medicines in the EU. For initial launch, there will be links to the national portal homepages and the medicines search page on these websites in in order to access product information for nationally authorised medicines hosted there (see 4.1.1.). The responsibility for the completeness and accuracy of the documents relating to nationally authorised medicines will therefore lie with the NCAs themselves and not EMA. In a second phase, additional content and functionality will be published as these become available from the new master data management services.

The reliability and searchability of content on the European medicines web portal will be critical to its trustworthiness and success. Poor-quality and unreliable information will undermine confidence in the product and impact the network's reputation. The issue of poor-data quality was identified during the 2010 audit of EudraPharm as one of the interface's main failings. EMA and NCAs will need to take measures to guarantee the quality of the information they supply to the website in order for the vision to be reached.

4.2.4. Stakeholders' expectations and needs

In order to ensure that the European medicines web portal is seen as a resource of value in the existing range of tools providing information on medicines to the various stakeholders, it is important that stakeholders' expectations and needs are recognised and met.

The primary target user groups for the European medicines web portal will be:

- patients, consumers and carers;
- healthcare professionals;
- others looking for information and data on medicines, such as academic researchers.

The pharmaceutical industry and NCAs are considered secondary user groups and their needs will be investigated in a second phase of development. They already have good knowledge of the regulatory process and outcomes and have established channels of communications with (other) regulators. These groups, however, will still be able to access and use the website as it is public and not password-protected[26].

Therefore the focus will be on the primary user groups' expectations and needs.

EMA will ensure that crosslinks are in place between the European medicines web portal and its other websites, particularly the corporate website, to allow all users to find the information they need as simply as possible.

Poor usability of a website is the main reason for low user traffic and high bounce rates (when users only stay on a website for a few seconds before leaving). To ensure that the European medicines web portal is as user-friendly as possible, EMA will work closely with the primary target user groups across the EU to understand their needs. All aspects of the website, including interface design, search functionality, download functionality, navigation and web texts will be developed to meet the specific needs of these groups. The range of content and the quality of written content will also be researched. Marketing and communications activities required to ensure the website's success after launch will also be developed with these users' profiles taken into account.

4.2.5. Making best use of the available data

A key principle of the vision for the website is that it will bring together the data and documents already available to EMA and the NCAs within its respective databases and systems, but will present them in a usable and helpful manner for the benefit of its users. A sample list of some content elements (non-exhaustive) that could be made available is in the table below[27].

[26] It is noted that the pharmacovigilance legislation provides that companies will keep their product information up to date with information from the EMA committees placed on the EU medicines web portal. And this provision will be considered during the interface design stage.

[27] A full analysis of the content for the web portal is available in 'Content analysis of the EU medicines webportal - Excel document' (EMA/151288/2013): https://docs.eudra.org/webtop/drl/objectId/090142b2821ed3fa (link only accessible within EMA).

Content element	Nationally authorised medicines	Centrally authorised medicines	Medicines in development	Source
Medicine data: • Invented name • Active substance(s) • Status (authorised / withdrawn / suspended) • Therapeutic indication[28] • Country where authorised / available	✓	✓		Article 57 database
Summary of product characteristics	✓	✓		EMA document repository / NCA web portals
Package leaflet	✓	✓		
Labelling	✓	✓		
Adverse-drug-reaction reports	✓	✓		EudraVigilance database[29]
EU clinical-trial information	✓	✓	✓	EU clinical trials register
EU clinical-trial result summaries	✓	✓	✓	
Ongoing and completed referral procedures	✓	✓		EMA document repository
Safety announcements	✓	✓		
Clinical-trial data (clinical study reports for example)		✓		Clinical data website (to be launched in October 2016 in line with EMA policy 0070[30])
Regulatory background information		✓		EMA document repository

The 2010 pharmacovigilance legislation lists further pieces of content that need to be published on the European medicines web portal, including the minutes of the Pharmacovigilance Risk Assessment Committee and the name of the Qualified Person for Pharmacovigilance of the marketing authorisation holder.

[28] The indication will indicate if the medicine is authorised for use in children.
[29] Currently published on the European database of adverse drug reaction reports.
[30] http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b0

4.2.6. Search engine

EMA holds a complete database of data on medicines authorised in the EU both centrally and nationally as supplied by marketing authorisation holders through the Article 57 database submission process (EVWEB). These data will form the backbone for the information on medicines to be displayed and searched for on the European medicines web portal, including active substance, strength, invented name, status (authorised, withdrawn or suspended) and therapeutic indication. Information in the database will also allow the web portal to display the countries where the medicines are authorised. The database's controlled vocabularies include translations of all of these data elements in all official EU languages, allowing multilingual searches and publication of data.

4.2.7. Multilingualism

One of the unique selling points for the European medicines web portal is that users from across the Members States can search in their national language and read content in their national language.

To be useful to patients and health professionals, it is important that information is provided in all official EU languages when available. This will be complex to achieve. Success will rely heavily on resolving issues relating to the development of controlled lists and data structure as part of EMA's ongoing Data Integration Programme.

A number of hurdles will need to be overcome, including:

- dealing with controlled terminology in all EU languages to ensure accurate search results;
- coping with 'holes' in language provision for some data elements;
- maintenance of static translated texts;
- dealing with queries in any language.

The European medicines web portal should be available in all official EU languages. In particular, all static texts should be translated, including static text webpages, navigation, error messages and search interfaces.

As far as possible, the website should return results based on search terms submitted by the user in all EU languages. This, however, has a dependency on how much information is available on a medicine in each language, and may only be possible for some languages for search results relating to nationally authorised medicines.

The project will examine lessons learned from the audit of EudraPharm to understand how to best develop search specifications related to multilingualism, taking user needs and expectations into account.

4.2.8. Marketing and visibility

The network will develop strategies to increase awareness of the European medicines web portal in the EU before its launch. These should include an overarching communication strategy, with an emphasis on digital marketing and use of social media. This strategy should focus on the unique attributes of the website, including its provision of validated information that covers all medicines authorised in the EU. Tactics will be based on information gathered on user needs and behaviour from the user research phase.

It is important to ensure that the website's content returns as highly as possible in search engine result lists by implementing a robust search engine optimisation (SEO) strategy covering all aspects of

the website's technical and editorial development and maintenance. This is important because search engines are the main route into most content on the internet[31] and it will increase the visibility of the website as a reliable and trustworthy source of information on medicines.

5. Launch of the European medicines web portal

In line with the principle of incremental delivery laid out in EMA's information management strategy[32], the European medicines web portal will be developed in stages, with an initial launch of a website containing a limited set of data and with limited minimum functionality. Then, through incremental releases, the portal will be continuously improved to provide increased functionality over time. Therefore:

- for the first phase of launch, the portal will use structured Article 57 data and provide access through links to the medicines search pages on the NCA national web portals;
- for the second phase, population of the portal will be with validated data based on the migration of the Article 57 database to the proposed target operating model for product information within the EMA's Data Integration Programme, with an optional link to NCA websites.

This staged approach takes account of the following constraints in particular:

- Around a third of the national medicines web portals are publishing product information documents with URLs that change with each update. This renders simple cross-linking from the European medicines web portal to medicine information on national web portals impossible without substantial manual intervention.
- There is currently no standard to allow the identification of individual medicinal products and the automatic collection of product-information documents on nationally authorised medicines in a cost-effective manner from the national web portals. This will improve as new international standards for the identification of medicines will begin to come into effect over the next five years.

The roll-out of the project is dependent upon agreement across the EU medicines regulatory network and the availability of financial and information-technology resources.

[31] According to a US study, 77% of online health seekers say they began their last session at a search engine such as Google, Bing, or Yahoo: http://pewinternet.org/Reports/2013/Health-online/Summary-of-Findings.aspx
[32] EMA's Information Management Strategy: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199073.pdf

6. About this document

6.1. Document location

The document is located in the following folder in DREAM

Reflection_paper_european_portal
EMA/353162/2013
https://docs.eudra.org/webtop/drl/objectId/090142b2822a2a45

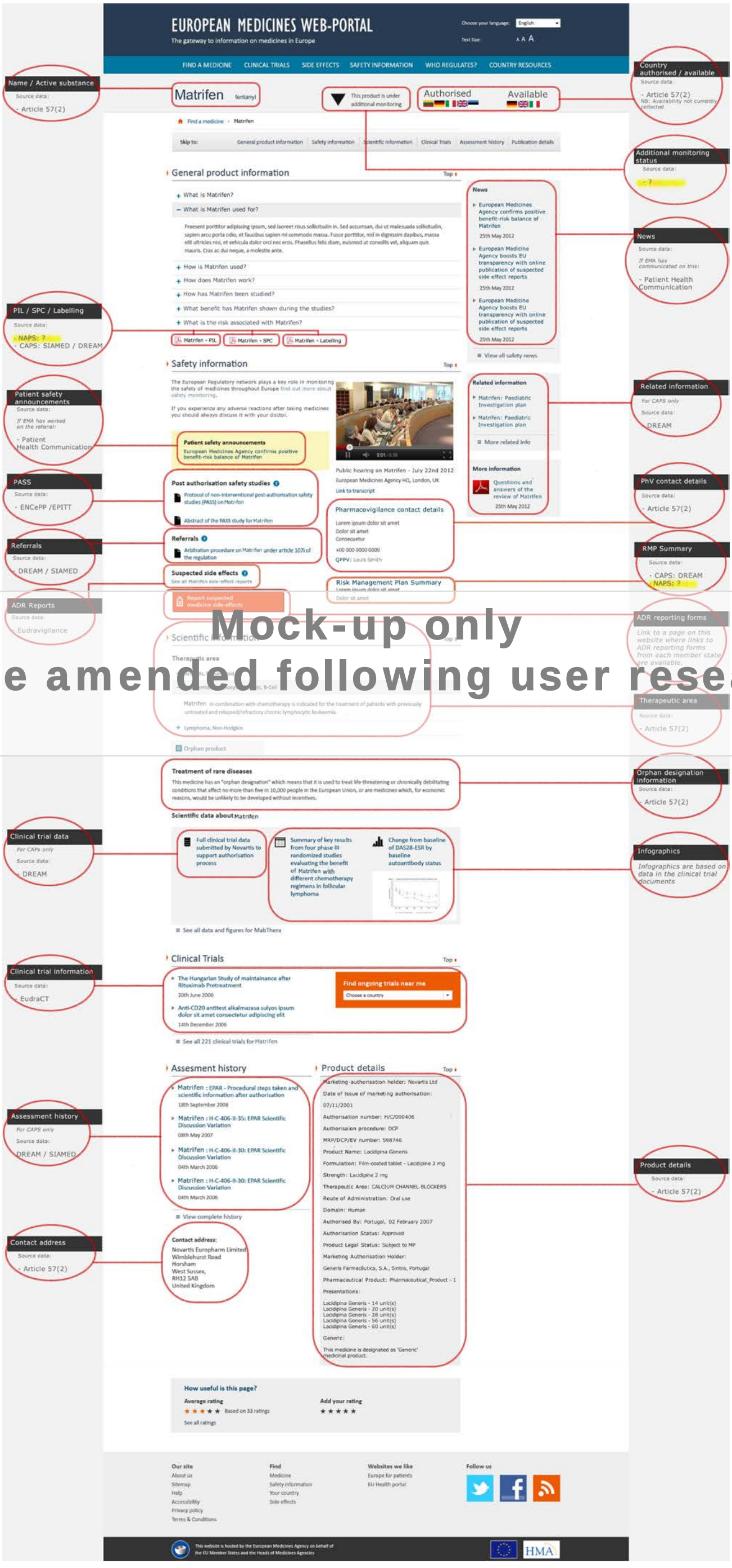
7. Annexes

7.1. Additional information on interface design

Example of a mock-up medicine webpage

The image on the following page shows how information on medicines could appear on the European medicines web portal. The way the content on the portal will be organised will be based on needs identified during user research.

The mock-up includes examples of all of the possible content elements for a medicine displayed on the portal and is annotated to show their source. Since not every medicine will have all of the possible content elements available, the page will be designed in a manner that enables display of the available content elements in a clear and usable manner.



7.2. Eurobarometer survey on patient involvement[33]

Almost all of the 150 patients interviewed for the study said that they use the internet to access healthcare information. Usage varied by type of patient with a general feeling that younger patients and those with chronic conditions referred to the Internet most. A few older patients asked relatives and friends to help them[34].

Healthcare professionals were generally negative about patients' use of the internet with concerns around misinformation and unauthorised advice leading to additional time spent on persuading patients to change their minds, or correct them.

Healthcare professionals did concede however that the Internet could be useful for patients.

"Some practitioners said that they hoped patients would visit **official and reliable websites**, containing correct information about their illnesses and treatments. **These sites could be selected and recommended by practitioners**. Some practitioners suggested that an authoritative website, providing comprehensive answers to patients' questions, be established."

Predictably, patients interviewed for the survey were highly positive about their use of the Internet describing the Internet as very useful as a quick, easy way to gather information and opinions about any medical condition and also about medications and treatments proposed by practitioners. Patients rated their ability to be discerning and responsible about information found on the Internet more highly than practitioners did.

"Patients generally felt they were able to use the Internet in a responsible and constructive way whereas practitioners were much more sceptical. However some patients also recognised that the information to be found online was not always reliable. **Some patients were aware that they had to exercise some discernment when it came to trust in the source of information** - for instance, scientific texts and articles were seen as more reliable than information posted on online message boards."

7.3. Legislative requirements

Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Specific references to be taken into account by the European medicines web portal include:

Pharmacovigilance legislation

New pharmacovigilance legislation (a Directive and a Regulation) amending existing legislation was adopted in the European Union (EU) in December 2010. One major component of the legislation

[33] Extracted from http://ec.europa.eu/public_opinion/archives/quali/ql_5937_patient_en.pdf
[34] A Health Online survey by the US-based Pew Institute shows that 39% of those surveyed said that the last time they looked online for health information, they were looking for information related to someone else's health or medical situation: http://pewinternet.org/Reports/2013/Health-online/Summary-of-Findings.aspx

relates to improved communication with EU citizens. Following a review of the Directive and Regulation, the legal requirements regarding online communications focus on the following:

- to increase transparency as regards pharmacovigilance issues and support the new legislation in the protection of public health by publishing online content relevant to the safety of medicines as detailed in the legislation;
- to support the Agency's ability to comply with Article 57 (l) of the regulation which requires it to create a public database on authorised medicines[35] in the EU accessible to the general public by requiring marketing authorisation holders to submit data on authorised medicines to EMA;
- to ensure close liaison with Member States, the European Commission, patients and other stakeholder groups in the development and maintenance of the European medicines web portal;
- to host, on behalf of the Member States and the European Commission, a European medicines web portal.

Clinical trial legislation

EMA is required to publish summarised information on ongoing and completed trials and summaries of clinical trial results.

Article 81(2) of Regulation (EU) No 536/2014:

"… To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency."

Article 57(2) of Regulation (EC) No 726/2004:

"Where appropriate, the database [*described under Art. 1(l) (currently EudraPharm)*] shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC [*EudraCT database*]. The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public."

Article 41 of Regulation (EC) No 1901/ 2006:

"The European database created by Article 11 of Directive 2001/20/EC shall include clinical trials carried out in third countries which are contained in an agreed paediatric investigation plan (PIP), in addition to the clinical trials referred to in Articles 1 and 2 of that Directive … By way of derogation from the provisions of Article 11 of Directive 2001/20/EC, the Agency shall make public part of the information on paediatric clinical trials entered in the European database."

As this information was not included in Eudrapharm as described in the legislation, as an interim measure for publishing clinical trial information, the European Union Clinical Trial Register (EU-CTR) was launched in 2010 by EMA: https://www.clinicaltrialsregister.eu/.

EudraVigilance access policy

By law, EMA is required to publish Adverse Drug Reaction (ADR) reports. In accordance with the provisions of Article 26, paragraph (3) and Article 57, paragraph (1)(d) of Regulation (EC) No 726/2004 and Article 102 of Directive 2001/83/EC as amended, access to EudraVigilance data is provided to the public as described in the EudraVigilance Access Policy in the following ways:

[35] Currently conceived as Eudrapharm.

- In accordance with the provisions of Article 24, paragraph (2) of Regulation (EC) No 726/2004 as amended, access to EudraVigilance data is provided to the public as described in the EudraVigilance access policy.
- A subset of data from spontaneous reports as described in Annex 1 of the EudraVigilance Access Policy are released, taking into account the need to comply with Regulation (EC) No 45/2001 on personal data protection. This applies to all types of medicines, independent of the authorisation procedure and the source of the report (e.g. healthcare professional, patient). Spontaneous reports are unsolicited reports by healthcare professionals or patients that do not derive from a study or any organised data-collection scheme. For centrally authorised medicines, access to reports is granted both by the name of the medicine or the name of the active substance or combination thereof. For non-centrally authorised medicines, access will be granted based on the name of the active substance.

The ADR website was launched for centrally authorised medicines in 2012 by EMA. This was expanded to cover nationally authorised medicines in October 2014: http://www.adrreports.eu/EN/index.html

7.4. Strengths and weaknesses of options for sourcing product information on nationally authorised products

7.4.1. Option 1: MAHs include the product information URLs on national web portals in their Article 57 data submissions

Source of information

An MAH includes the product information URLs on the appropriate NCA websites in its Article 57 data submission for a nationally authorised product, for subsequent publication on the European medicines web portal.

User journey

The user:

- searches on the portal;
- finds product details;
- clicks on product information link;
- is directed to product information on the appropriate NCA website.

Strengths

- Access to all information about medicines authorised in the EU and related information; viewable through one single entry point.
- Information on product information is not coming from MAH but is provided and validated by NCAs.
- No additional investment for most NCAs is required (European medicines web portal will link directly to product information on relevant NCA website).
- Content will not be duplicated and this results in medicines information having higher search engine listing positions.
- Visibility of NCAs is maintained and traffic to NCA websites will increase.

Weaknesses

- Finalised version of the URLs is needed, not clear whether it would be available on time.
- Need to agree on process of quality assurance of information.
- Need agreement from industry to include URLs in Article 57 data submission process.
- For a number of NCA websites (8 out of 23), the URL changes when the product information is updated, which results in complications.

7.4.2. Option 2: The European medicines web portal, using Article 57 data, provides access to the medicines search page on national web portals

Source of information

Search pages on national web portals.

User journey

The user:

- searches on portal;
- finds product details;
- is able to see the Member States where the product is authorised;
- clicks on the Member State name or flag;
- is directed to the search page of the national web portal where a new search takes place.

Strengths

- Easy to set up as no data integration necessary
- All medicines authorised in the EU are listed and searchable; for NCA information the user however exits the EMWP
- Visibility of NCAs is maintained and increased
- Information on SPCs and PILs is not coming from MAH but is provided and validated by NCAs

Weaknesses

- Less user-friendly solution (searching twice to find NAP product information)
- Poor user experience – users cannot see CAP and NAP information on one single page
- Users have to search twice, once on the portal for CAP information and a second time for NAP information on the NCA national medicine web portal
- Whether users can find information on NCA portals depends on each NCA portal