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Reflection paper on linking to electronic product information (ePI) from EU medicine packages

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Table of contents

1. Executive summary

Electronic product information (ePI), generated as an outcome of EU regulatory procedures, is under development by the European Medicines Regulatory Network (EMRN). This paper outlines considerations for getting the up-to-date ePI into the hands of consumers at the time when it is needed. Only once ePI is delivered to patients and healthcare professionals can its benefits for public health be realised.

The scenario is outlined whereby consumers of medicines across Europe will be able to use their smart phone or other mobile device to scan the existing DataMatrix (two-dimensional code) on the medicine pack and display the electronic package leaflet, in addition to options to access the electronic summary of product characteristics and/or other relevant information.

The existing DataMatrix should be used for this purpose rather than printing additional codes on packaging, which can be hindered by space constraints and has the potential to cause confusion about which code should be scanned, impeding consumers' access to important information on their medicines.

The DataMatrix on the package contains a data carrier identifier (product code) for compliance with the falsified medicines legislation. This same identifier can allow the linking of the package to the ePI with no change needed to the DataMatrix printed on the package today, ensuring display of the correct, authorised ePI for the medicine in the consumer’s hands. The most widely used data carrier identifiers for anti-falsification purposes are the GTIN/NTIN (Global/National Trade Item Number). PPN (Pharmacy Product Number) is also used in Germany.

For solutions with patients as a target group, directing the user as easily as possible to the electronic package leaflet for the medicine should be the highest priority, as this is the up-to-date, regulator-authorised information specifically targeted to patients. Any additional information made available should not impede the patient being directed first and foremost to the package leaflet.

The electronic package leaflet displayed as html content should be presented in preference to pdf formats online. Unlike pdf, display of electronic information as html will maximise accessibility to provide an optimal user experience.

Information provided through mobile device technologies can not contain promotional elements.

Development of multiple apps for this purpose that have low coverage of medicines, such as apps that work for one product or only for the medicines of one company, is of questionable benefit to consumers, unless there is a specific justification. Solutions that enable access to ePI for as high a number of medicines as possible will reduce or avoid the need to use multiple apps. Having to use multiple ways to access ePI for different medicines will negatively impact the user experience, disadvantaging consumers with low digital literacy (low ability to use digital devices effectively) and potentially impeding access to information.

Involvement of patients, healthcare professionals and representative organisations in development and testing of solutions is advised to ensure that the needs of the end-user are met.

Regulators are encouraging and supportive of any future industry-led initiative to create a solution for medicines with EU-wide coverage. This could provide equality of access to ePI for all EU citizens, support consumers travelling across borders and facilitate provision of information when medicine stocks are reallocated to mitigate shortages.

Many existing health apps or solutions developed in future may adopt functionality of scanning and linking to ePI and developers are encouraged to follow the approaches mentioned in this paper.

2. Introduction

Development of electronic product information (ePI) for EU human medicines, compliant with a harmonised EU ePI Common Standard, is ongoing by the European Medicines Regulatory Network (EMRN) in collaboration with stakeholders. In the coming years, ePI will be created and updated for EU medicines as part of routine regulatory procedures.

The motivation for development of ePI, as outlined in the ePI key principles[1], is to benefit public health. One of the ways in which this will be achieved is by expanding the dissemination of up-to-date, accessible, regulator-authorised product information for EU medicines. ePI will support provision of the latest information on a medicine's safety, benefits and conditions of use and will enable availability of the right information at the point of need. This will support informed decision-making by patients and healthcare professionals and improve patient safety overall.

Realising these benefits requires a focus on how ePI, particularly but not exclusively the electronic package leaflet, can be accessed directly from the specific medicine in the hands of the consumer or practitioner using mobile scanning technology.

This reflection paper describes components to be put in place to realise an EU-wide solution in which ePI could be easily accessed by citizens wherever they are in Europe, in their preferred language when available. It calls on stakeholders to take action and invest in the development of such initiative at EU level, building on and complementing existing work to implement ePI in Europe. Opportunities, limitations and other relevant considerations are outlined. In addition, some existing EU and international examples are described.

Importantly, early action on an EU-wide solution will promote an optimised user experience for patients and healthcare professionals, with equality of access to ePI throughout Europe.

Harmonised EU-wide linking from the medicines package to ePI of EU medicines, irrespective of the marketing authorisation holder, will require cross-stakeholder collaboration to achieve development, integration and maintenance of several components, described below.

3. Components of a solution for ePI access

3.1. 2D code

Today in the EU, prescription medicines carry a DataMatrix (a type of 2D code) on the secondary medicine package to comply with anti-counterfeiting measures of the Falsified Medicines Directive (Directive 2011/62/EU) and Commission Delegated Regulation EU 2016/161 on safety features on packaging. The DataMatrix contains the following data:

1. the data carrier identifier (Global Trade Item Number [GTIN], National Trade Item Number [NTIN], or Pharmacy Product Number [PPN])
2. the serial number
3. the expiry date
4. the lot number/batch number
5. Optional: a national reimbursement number or other national number identifying the medicinal product

[1] See Electronic product information for human medicines in the European Union – key principles

The data carrier identifiers currently included in the DataMatrix are codes of the GS1 standards development organisation: GTIN/NTIN, or alternatively the Informationsstelle für Arzneispezialitäten (IFA) coding system: PPN. These identify the medicine package and they can be matched to a data carrier identifier in the correct ePI and used to retrieve and display that ePI to the patient.

During development of an EU-wide system, the data carrier identifier already contained in the DataMatrix could be leveraged also for the purpose of provision of medicines information. In order to build on the synergies offered by the DataMatrix, in future, all patients in the EU should be able to scan the same, existing DataMatrix on the medicine package that is used today for anti-counterfeit measures, to be shown the package leaflet for the medicine in their preferred language.

Printing an additional 2D code on the medicine package is undesirable. Firstly, space constraints may hinder the printing of more than one 2D code on the package. Secondly, the presence of more than one 2D code has significant potential to cause confusion regarding which code should be scanned.

3.2. Solution to scan and link to ePI

A solution, such as an app, browser, or smart phone, should have the following functions:

- **DataMatrix scanning** – most smartphone cameras cannot natively scan a DataMatrix, although this may change in the near future offering the possibility to scan the DataMatrix directly using a mobile device camera; currently software such as an app is needed.
- **Linking the data carrier identifier to the correct electronic information** – an ISO compliant[2] resolver could match the data carrier identifier retrieved from scanning the DataMatrix to the current, correct, regulator-authorised electronic information leading to display of the information with minimal intervention required by the user.

It is critical to ensure that any solution is simple to acquire and use and freely available, minimising friction in the flow of information to the consumer and taking into account varying levels of digital literacy. Aspects such as downloading and periodically updating an app from an app store or other source will present a significant barrier for many consumers. The use of a web-based solution that does not need to be downloaded or stored on the device could facilitate access by the widest number of consumers.

Should a solution involve collection of any personal data, applicable data protection legislation must be observed, including Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

3.3. Displayed content

The package leaflet provides important information for patients on the medicines safe and effective use. While mobile scanning can be used to display various types of medicines information, the highest priority is to show patients the medicine's package leaflet. Inclusion of barriers to accessing the information, such as log-in screens or excessive navigation, is strongly discouraged.

In addition to the package leaflet, options can be provided to also access the summary of product characteristics (SmPC), and additional relevant information such as instructional videos, educational material and side-effect reporting. The presence of the expiry date in the DataMatrix could also be

[2] ISO/IEC FDIS 18975 Information technology — Automatic identification and data capture techniques — Encoding and resolving identifiers over HTTP.

leveraged to alert patients when their medicine is expired. However, linking to additional information must not compromise ease of access of the patient to the package leaflet. All information must be consistent with the authorised product information and may not contain promotional elements.

Content should be derived from a reliable source of truth, such as generated using ePI sourced from the EMA-HMA-EC ePI FHIR repository.

Accessibility standards as outlined in the Web Accessibility Directive (Directive (EU) 2016/2102) should be implemented. Input from patients and healthcare professionals should be incorporated during design.

An important benefit of ePI is to enable EU citizens to read ePI in their preferred language when authorised ePI in that language is available. Browsing between languages should be enabled and it should be possible to easily choose, store and change language preferences, as well as other preferences such as for example preference for information targeted to the patient or to the healthcare professional.

Provision of content should take into account factors such as security and availability. Measures should be in place to ensure that the information provided cannot be compromised and that there is no interruption in service.

In case of the scenario where a user scans a package for which there is no ePI available with the scanned data carrier identifer, a 'not found' page should be displayed explaining why the ePI was not displayed and pointing to recommended sources of information, such as the national regulator website.

Information provided to users must comply with the requirements of existing guidance on mobile scanning: "Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products; General principles of acceptability and rules of procedure"[3] and with relevant national guidelines.

3.4. ePI annotated with data carrier identifiers

The fundamental data needed to underpin linkage to medicines information from the package is the ePI's package leaflet and summary of product characteristics associated with the relevant data carrier identifier(s) (e.g., GTIN(s)).

The Product Lifecycle Management (PLM) portal is a secure online portal of the EMRN where pharmaceutical companies and regulators can manage EU medicines data for centrally and nationally authorised medicines[4]. The PLM portal will offer the functionality for companies to enter data carrier identifiers and associate them with ePI documents.

Data carrier identifiers incorporated in the DataMatrix are allocated at package level (i.e. one data carrier identifier per presentation). The EU IDMP Implementation Guide, Product Management Service (PMS) foresees in chapter 2 section 5.9.6 that data carrier identifier(s) for all presentations may be specified in the ISO element: Data Carrier Identifier[5].

Package leaflet and summary of product characteristics documents are specific for the product strength and pharmaceutical form of a medicine. Combined package leaflets and summaries of product

[3] See Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products; General principles of acceptability and rules of procedure

[4] Product Lifecycle Management portal: A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.

[5] Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2: Data elements for the electronic submission of information on medicinal products for human use

characteristics are also available, covering several strengths of the same pharmaceutical form. Therefore, multiple data carrier identifiers covering all available presentations of the strength-pharmaceutical form need to be associated with the documents. It will be the responsibility of the marketing authorisation holder to ensure that the data carrier identifiers are entered at the PLM portal for all presentations and are correctly linked to the ePI documents.

The obligation to provide data carrier identifiers may necessitate changes to company processes to ensure that identifiers are generated and available in time, in advance of ePI publication.

Data carrier identifiers will be stored in PMS and in addition, directly included in the ePI data. The EU ePI Common Standard specifies how data carrier identifiers are to be included in the ePI data[6].

It will be essential that ePI available from the EMA-HMA-EC ePI FHIR repository via the ePI application programming interface[7] will offer an endpoint for querying by data carrier identifier.

3.5. Governance

Central to the reliable, secure and sustainable provision of medicines information will be well-defined responsibilities for development and ongoing maintenance of the above-mentioned resources, including putting into place service-level agreements, where necessary. Roles for regulators, industry and potentially dedicated bodies should be described and agreed and processes put in place for rigorous oversight.

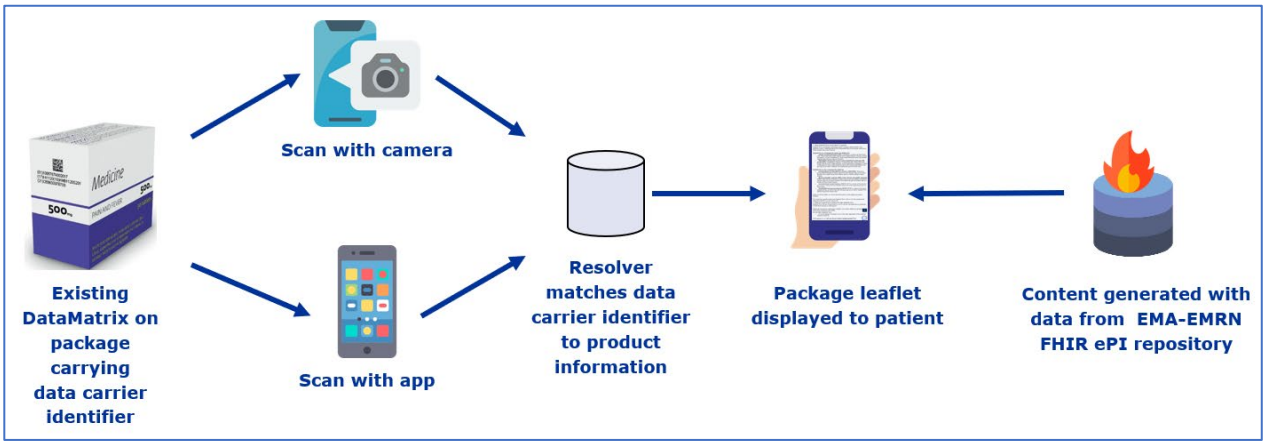

Figure 1. Potential scenario linking electronic information for consumers to the medicine package.

4. Opportunities, limitations and other considerations

4.1. Established, existing solutions

Existing solutions for access to electronic package leaflets by scanning are already established for several years, notably in Nordic countries (see 5.4. Nordic countries). Wide acceptance and use of these solutions nationally provides encouraging evidence of the value of a coherent, cross-company process for provision of information to users. An EU-wide solution should build on and utilise synergies with these proven systems.

[6] EU ePI Common Standard is described in the EMRN ePI Implementation Guide.
[7] ePI consuming API: https://epi.developer.ema.europa.eu/api-details#api=ema-epi-consuming&operation=get-api-retrieval-bundlebyid

4.2. Over-the-counter medicines

The DataMatrix compliant with the Falsified Medicines Directive is currently placed on prescription medicines and is not required for over-the-counter (OTC)/non-prescription medicines. This means that any solution involving scanning the currently available DataMatrix would be limited to prescription medicines. Manufacturers of OTC medicines should investigate potential pathways for linking ePI, including assessment of data carrier identifiers and barcodes. If required, scanning functionality could be extended to incorporate scanning of linear barcodes in addition to the DataMatrix.

4.3. Parallel trade medicines

In the same way as for medicines from the original manufacturers, prescription parallel traded medicines carry a DataMatrix on the medicine package which can be utilised to link to medicines information.

Currently, the EMA-HMA-EC ePI initiative does not have in scope ePI for parallel distributed/imported medicines. However, business processes could be extended to include implementation of ePI for these medicines in future. This would allow extension of a mobile scanning solution to cover parallel trade medicines in addition to medicines from the original manufacturer.

4.4. Primary and secondary packaging

The DataMatrix compliant with the falsified medicines legislation is currently placed on secondary packaging (outer packaging, such as boxes) of medicines in the EU. However, on establishment of systems for linking from packaging to ePI, use cases for inclusion of the DataMatrix on primary packaging (packaging in direct contact with the medicine, such as blisters) could be considered. Presence of the DataMatrix on primary packaging could enable point-of-need provision of information for medicines in cases where secondary packaging is generally discarded, such as for some hospital-use medicines. Depending on the public health need, inclusion of the DataMatrix on primary packaging, as already implemented in other regions (see 5.1. Japan), may be considered for future development.

4.5. Change of excipients

An important benefit of ePI available via mobile scanning is the provision of the most up-to-date information. Unlike paper package leaflets provided inside the package that can take many months to be updated, electronically available information can be made available to users soon after authorisation.

Under certain circumstances, the need to supply more than one version of ePI concurrently may arise. This could occur when a change happens to a medicine such as, for example, a change of excipient, and where both the medicine with the previous excipient and the medicine with the new excipient are available on the market for an intermediate period. When such a change occurs, it can warrant a new data carrier identifier for the product. The GTIN Management Standard states that a new GTIN can be required when a consumer is expected to distinguish the changed or new product from previous/current products (see GTIN Management Standard section 1.1).

In order to facilitate the need to provide previous ePI versions, the EMA-HMA-EC ePI FHIR repository will include current ('Published') and previous ('Archived') ePI versions, which can be managed via the PLM portal and can be linked to the respective data carrier identifiers.

Additionally in such situations, the importance of any other information in the updated ePI since the change of excipient must be considered. For example, if new safety information has been added and 2

ePIs are supplied concurrently, the consumer should be alerted to the most up-to-date safety information.

The requirement to provide 2 concurrent ePI, accessible from the appropriate packages by means of different data carrier identifiers and/or to provide information to the user regarding the change of excipient in another way, can be managed in consultation with the regulator.

4.6. Human readable URL

Mechanisms should be in place to ensure that patients who do not have a smart phone/mobile device can access the information by typing a URL (web address) in an internet browser. The URL should be short and human readable. It is recognised that, for a solution covering a large number of EU medicines, it could be impractical to include the name of the medicine in the URL and it may instead be necessary for users to visit a website and find the correct information by manually entering the data carrier identifier or the medicine name. Consideration should be given to facilitating users to access the information as easily as possible and providing a good user experience.

4.7. Printed package leaflets

The paper package leaflet is particularly important for consumers with low digital literacy or limited internet access. The components mentioned above (3. Components of a solution for ePI access) can facilitate scan and print services that can guarantee that the patient can have access to a paper package leaflet, if this is the preferred format.

4.8. Veterinary medicines

Use of electronic product information for veterinary medicines is accommodated in article 14.3 of the new veterinary regulation (Regulation 2019/6), which states that Member States may decide that the package leaflet shall be made available on paper or electronically, or both.

Use of electronic information and linking to the package of veterinary medicines will be informed by the relevant stakeholders and expected benefits. Accordingly, aspects of ePI for human medicines can be leveraged, extended and adapted in future for application to veterinary medicines, including the harmonised EU ePI Common Standard, as well as processes, tooling and systems for ePI creation, management and dissemination. Although veterinary medicine packages do not currently require a DataMatrix, future developments linking packages of veterinary medicines to ePI can take into consideration systems used for human medicines.

5. Real-world examples

Implementation of access to ePI from the medicines package is not only technically feasible, it has already been successfully achieved in several regions. It is critical to harness existing knowledge and experience, utilise synergies and reuse existing infrastructure where practicable. Examples (non-exhaustive) of regions providing access to electronic medicines information are described below.

5.1. Japan

Prior to 2021, all medicine packages in Japan contained paper package inserts. Of note, the package inserts contain information targeted to healthcare professionals, not to patients, and therefore are not the equivalent of EU package leaflets. The pharmacist removes the medicine from the package and

prepares it for the patient by adding a leaflet prepared at the pharmacy, which includes directions for the patient on how to take the medicine and precautions.

In August 2021, an amendment to the PMD Act[8] came into effect, with a transition period ending in July 2023, after which it is no longer necessary to include paper package inserts for healthcare professionals in the medicine package for most prescription medicines.

All medicines in Japan carry barcodes incorporating GS1 standards on many levels of packaging, including on primary packages, for labelling and traceability purposes. This has allowed the barcode to be additionally leveraged to link to medicines information.

Today, a GTIN-containing GS1 code on the package can be scanned using a smartphone app which directs to the product information on the Japanese Pharmaceutical and Medical Devices Agency (PMDA) website[9]. An app, called "Tenbun-Navi", has been developed by Japanese pharmaceutical industry associations (Federation of Pharmaceutical Manufacturer's Association of Japan [FPMAJ] and the Japan Federation of Medical Devices Association [JFMDA]) in collaboration with GS1 Japan for this purpose. Depending on the preference of the user, the app directs to information for healthcare professionals or for patients. The app uses the GTIN read from the GS1 code to generate a URL. The URL then redirects to the page on the PMDA website displaying the latest leaflet for that GTIN[10].

Companies are responsible for linking the GTIN in the GS1 barcode to the product's leaflets on the PMDA website.

In Japan, primary and secondary packages have GS1 barcodes, which means that leaflets can be accessed at the point of dispensing, even once medicine is removed from its secondary, outer package.

5.2. Spain

The Spanish medicines regulatory agency (AEMPS) has provided an electronic HTML version of package leaflets and summaries of product characteristics on their website CIMA for many years. CIMA also provides patients and healthcare professions with important information about medicines authorised in Spain such as active ingredients, excipients, ATC codes, etc. Recently, AEMPS has developed a web app that allows users to scan the DataMatrix found on the packages of prescription medicines. The web app can scan the DataMatrix to obtain the NTIN and direct the user to the medicine's URL on CIMA.

5.3. Germany

Gebrauchsinformationen GI 4.0 is an app created and maintained by a consortium of pharmaceutical industry partners to provide electronic information to patients for medicines marketed in Germany. For medicines of participating pharmaceutical companies, the DataMatrix on prescription medicines or the linear barcode on non-prescription medicines can be scanned using the app. Participating companies have uploaded package leaflets and the corresponding GTIN/NTIN, PPN or PZN to the GI 4.0 platform. (In Germany, non-prescription medicines carry a barcode on the package which contains a nationally used identification number called PZN [Pharma-Zentral-Nummer]).

The app queries the database for a match to the scanned GTIN/NTIN, PPN or PZN, and sends the corresponding electronic package leaflet to the app where it is displayed for the patient.

[8] Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act):
[9] PMDA website: https://www.pmda.go.jp/english/
[10] See GS1 Digital Link helps deliver valuable e-leaflet information to healthcare providers and patients: https://www.gs1.org/sites/gs1/files/case_study_library_item/referencebook-2021-2022-final-pandemic_japan.pdf

5.4. Nordic countries

Medicines information providers in the Nordic countries are companies supported by the national pharmaceutical industry associations, who collaborate with the National Competent Authorities. They have led the way in provision of electronic information on medicines in the EU for many years.

Medicin.dk (Denmark) provide the Indlægssedler app enabling scanning of the DataMatrix or linear barcode (both of which contain GTIN(s)) to display the electronic package leaflet on the medicin.dk website. The app covers all prescription, non-prescription and parallel trade medicines on the market in Denmark.

Felleskatalogen (Norway) provide the Finn Pakningsvedlegg app enabling scanning of the DataMatrix or linear barcode (both of which contain GTIN(s)) to display the electronic package leaflet on the felleskatalogen.no website. This app provides full coverage to information on all medicines on the Norwegian market.

FASS (Sweden) provides the Fass Allmänhet app enabling scanning of the DataMatrix or linear barcode (both of which contain GTIN(s)) to display the electronic package leaflet on the fass.se website. This app provides full coverage to information on all medicines on the Swedish market.

5.5. Ukraine initiative in Poland

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and member companies have developed an app for use by Ukrainian refugees living in Poland. The app can be used to scan the existing DataMatrix of prescription medicines authorised in Poland[11].

Participating companies have created websites hosting electronic package leaflets in Ukrainian and the corresponding GTIN/NTIN. The app reads the GTIN/NTIN from the scanned DataMatrix and delivers this to the ISO-compliant GS1 resolver, which provides the link to the webpage to be displayed for the patient.

6. Conclusion

Progress towards availability of harmonised EU ePI will require solutions for accessing medicines information from packages. The proposal of this paper is that ePI, in particular the package leaflet, displayed in html format, should be available via straightforward scanning of the medicine package. In this way, users should have direct access to information on the medicine they are holding in their hands, without any unnecessary impediments.

In order to support meaningful, patient-friendly solutions, the pharmaceutical industry is encouraged to lead and maintain a cross-company initiative providing access to information with wide coverage of a large number of EU medicines. Such an initiative will serve citizens across Europe working, living and travelling between countries to access medicines information wherever they are, using one solution. It can also provide information when medicine supplies are re-allocated between countries to mitigate or reduce shortages.

The highest priority is the best interests of patients, including aspects such as protection of personal data, user-friendly provision of non-promotional, up-to-date information, provision of information in the preferred format and language, and optimisation of the user experience, thereby promoting the safe and effective use of medicines and benefiting public health.

[11] See GS1 contribution to EFPIA initiative: Product information available to Ukrainian refugees through ePIL: https://efpia.app.box.com/s/7viqxzpyzpq2lqh4wklh86zajmf747b3