EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

European Commission

Electronic product information for human medicines in the EU: key principles

A joint EMA–HMA–EC collaboration

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List of abbreviations

EC	European Commission
EEA	European Economic Area
EHR	Electronic health record
EMA	European Medicines Agency
ePI	Electronic product information
EU	European Union
HCP	Healthcare professional
HMA	Heads of Medicines Agencies
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
MAH	Marketing authorisation holder
NCA	National competent authority
PDF	Portable document format
PI	Product information
PL	Package leaflet
SME	Micro, small or medium-sized enterprises
SmPC	Summary of product characteristics
SPOR	Substance, product, organisation and referential (EMA implementation of ISO IDMP standards)

Background

In the European Union (EU), a medicine's product information (PI), which includes the summary of product characteristics (SmPC, intended for healthcare professionals [HCPs]), labelling (outer and inner packaging information) and package leaflet (PL, for patients / consumers and generally included as a printed copy in the medicines package[1]), is a pivotal source of regulated and scientifically validated information that assists HCPs in prescribing and dispensing the medicine and informs patients and consumers about its safe use.[2]

A report from the European Commission (EC) in March 2017, and a subsequent European Medicines Agency (EMA) action plan, identified areas where the SmPC and PL could be improved to meet the needs of patients and HCPs and proposed actions to address these shortcomings. These wide-ranging actions relate to enhancing readability, improving patient input in development and testing, promoting best practices and developing an electronic format. Throughout 2018 and 2019, a joint EMA-Heads of Medicines Agencies (HMA)-EC collaboration has worked on the latter: identifying stakeholder needs from a future electronic PI for medicines (ePI) and mapping ongoing initiatives in the field to create an overview of the current landscape. Developing an electronic format is the most pressing priority of the actions from a public-health perspective as it will facilitate timely access to up-to-date information and ensure coordination among the many initiatives ongoing in the EU. The current scope of this work is all human medicines authorised in the EU and EEA.[3]

A workshop held at EMA on 28 November 2018 brought together patients / consumers, HCPs, the pharmaceutical industry, academia, not-for-profit organisations and regulators to discuss stakeholder needs and concerns, give an overview of the main ePI initiatives ongoing in the EU and decide how to move forward with a common approach. The outcome of the workshop was a draft proposal for 'key principles' for ePI. These key principles were the subject of a 6-month public consultation (from January 31, 2019 until July 31, 2019). Following the consideration of submissions received during the public consultation, the key principles were updated. They now represent EMA-HMA-EC guidance on ePI and form the basis of follow-up implementation plans for ePI.

[1] The legal requirement to include the PL in the packaging is laid down in Article 58 of the Directive 2001/83/EC which states: "The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging."
[2] The content of the SmPC, labelling and PL is described in Articles 11, 54, 55 and 59 of Directive 2001/83/EC.
[3] Hereafter, when EU is mentioned in this document it should be understood to mean EU and EEA countries.

Key principles for ePI in the EU

The following key principles have been agreed by EMA, HMA, EC and representatives of patients, consumers, HCPs and the pharmaceutical industry. Users (and thereby also stakeholders) of ePI include patients, consumers, HCPs, pharmaceutical companies and regulatory agencies (EMA and national competent authorities [NCAs]). Future work on ePI will progress in alignment with these principles.

1. Definitions

Definitions of 'ePI' and 'common electronic standard' are intended to explain the meaning of these terms as they are used in this initiative.

1.1. ePI

Statement

The following definition of ePI is proposed:

ePI is authorised, statutory product information for medicines (i.e. SmPC, PL and labelling[4,5]) in a semi-structured format created using the common EU electronic standard.[6] ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms[7] and print. ePI fulfils the key principles.

Rationale

This ePI initiative refers to providing an electronic version of PI and not to any change in PI content. Changes to the PI content are outside the scope of this initiative.

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 product information in a format suitable for electronic handling as described in the definition above. ePI is semi-structured, which means that ePI contains some structured elements (e.g. consistent, fixed headings and controlled vocabularies), and some unstructured elements (e.g. free text and graphics). Formats such as PDF, Word or other free text files are not considered to be ePI because these do not deliver the benefits to stakeholders outlined in these principles.

[4] In certain procedures, Annex II of the marketing authorisation (manufacturer(s) responsible for batch release, conditions and requirements of the marketing authorisation, other conditions or restrictions as applicable) is provided electronically together with ePI.
[5] ePI does not include additional information specific to a Member State such as 'blue box' information (see: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/2018_packaging_guidelines_en.pdf) or artwork of the marketed medicine package. However, it will be possible for NCAs to add such additional information specific to the Member State in electronic format.
[6] See '1.2. Common EU electronic standard.'
[7] e-Platforms refer to methods that may be used to access ePI electronically, for example apps, software or websites and tools such as computers, mobile devices and wearables. Access may be online (via devices connected to the internet) or offline (via devices not connected to the internet).

Implication

By agreeing on an EU definition of ePI, there will be a harmonised understanding across the EU, which will guide collaborative work to create ePI that meets the definition.

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 and 3. Implementation of ePI does not imply any change to the legislation currently applicable to the PI. The development of ePI does not change the content of the PI (the information contained within the PI, headings, text or formatting) or create a new legal obligation to use ePI. In addition, this initiative does not change the interpretation of European pharmaceutical legislation. Nevertheless, implementation of ePI also aims to accommodate benefits brought by continuously evolving digital opportunities and should not exclude other changes to the PI that may be introduced in future (e.g. in the context of the EMA action plan).

1.2. Common EU electronic standard

Statement

ePI in the EU for all human medicines, including both centrally and nationally authorised medicines, will be created using a common electronic standard. The following definition of a common EU electronic standard for ePI is proposed:

A common standard for ePI in the EU refers to the technical features of ePI (including mark-up language, controlled vocabularies and interoperability specifications) agreed by EMA, HMA, NCAs, EC, and representatives of the pharmaceutical industry, patients and HCPs. The standard will be used to generate ePI that fulfils the agreed key principles.

Rationale

A common standard is necessary to provide consistent functionality of ePI for all medicines throughout the EU. This will reflect the reality of interlinked medicines regulatory systems within the European medicines regulatory network as well as meeting the expectations of patients and HCPs across the EU.

A common standard enables the generation and dissemination of electronic authorised information for HCPs, patients and consumers of medicines in the EU. It will not lead to a change in the interpretation of applicable European legislation nor will it create new requirements with regard to the content of the PI as described in EU legislation.

The aims of the common standard are:

- to create the technical foundation for the dissemination of trustworthy, regulator-authorised product information in the growing digital world, which will provide patients / consumers and HCPs with an additional and personalised approach for information on medicines (i.e. enabling more efficient retrieval of information the user is looking for in searches and facilitating the use of their preferred e-platforms);

- to offer possibilities to streamline, simplify and speed up the regulatory processes involved in the creation and updating (variation) of PI, using existing data, such as SPOR (substance, product, organisation and referential) data, both by regulators and the pharmaceutical industry.

Agreement of a common standard, together with acceptance and recognition of the common standard by all stakeholders, will avoid a situation where multiple different standards are developed and used in different parts of the EU, which would generate unnecessary complexity, impede access to information and require multiple interfaces between standards, restricting flow of data.

Implication

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, is compatible with use and exchange of ePI by all relevant stakeholders in the regulatory network, and fits the needs of these stakeholders.

The common standard will be established considering the available technologies and possible upcoming technical innovations, including those from EU Telematics projects.

2. Benefits for public health

Regulators and stakeholders wish to work towards ePI in the EU because of the benefits this format can offer for public health. While acknowledging that many future applications of ePI cannot currently be predicted, the following principles outline the key benefits which constitute the fundamental reasons underpinning this initiative.

2.1. Expanding access to information on medicines as a public health imperative

Statement

ePI is a public-health priority because it will expand the dissemination of unbiased, up-to-date, regulator-approved PI for all medicines in the EU. ePI will support, among other functions:

- provision of the latest information on a medicine's safety, benefits and conditions of use;
- better delivery of information so that the right information is available to the right HCP and patient / consumer at the point of need;
- informed decision-making by patients / consumers and HCPs.

Rationale

Unlike paper PLs contained in medicine packages, which are updated gradually as stocks of medicines turn over, it will be possible to rapidly update ePI with the latest authorised information. Patients / consumers and HCPs using ePI can be fully confident that they hold the latest information about benefits, risks and use.

In contrast to current PDF and unstructured text formats, ePI will enable wider availability on a range of platforms. ePI is thereby expected 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 better outcomes. ePI should also facilitate patient / consumer–HCP interactions and discussions about medicines.

The structured nature of ePI will offer new opportunities to better personalise PI to the needs of individual patients / consumers by enabling more efficient retrieval of information (e.g. in online multi-level searches) and facilitating the use of their preferred e-platforms. Although many future developments using ePI are outside the scope of this ePI initiative, structured ePI data will enable subsequent development of functionalities such as easier selection of information on medicines of interest, automatic update notifications, and access to authorised or supportive video or audio content or other interactive materials (in line with the appropriate guidance[8]) and online adverse-reaction reporting tools.

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, facilitating targeted delivery of the right information to the right patient / consumer at the point of need.

Availability of regulator-approved ePI will counterbalance unreliable and spurious claims about medicines, often widely spread through online and other forums, by providing an authoritative source of scientific and evidence-based information on EU medicines.

Implication

EMA and NCAs should work towards ePI to fulfil their mission to protect public health. Implementation, with a stepwise approach and clearly defined milestones, will have as a goal the creation of ePI for all authorised human medicines in the EU.

ePI will be rapidly and continually updated as soon as changes to the SmPC and PL are authorised by the regulatory authorities. The most up-to-date ePI version should be always easily available.

[8] EMA and CMDh guidance: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorised-medicinal-products_en.pdf and https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_313_2014_Rev8_12_2018_clean_Mobile_scanning_and_other_technologies.pdf

To achieve this principle, it is technically feasible to make ePI available through various technologies and applications, including mobile scanning technology on the medicine package (although this is not mandatory) and these options can be explored.[9] The use of the 2D barcode introduced via the Falsified Medicines Directive[10] may be explored for this purpose.[11] The need for the appropriate version of ePI to be supplied with each version of a medicine must be taken into consideration. For example, when a change happens to a medicine such as a change of excipient, both the medicine with the previous excipient and the medicine with the new excipient may be available on the market for an intermediate period, during which time the 2D barcode on each medicine package should link to the ePI version with the correct excipient information for the medicine contained in that package.

2.2. Accessibility to users with diverse abilities

Statement

ePI will facilitate creation of PI that is accessible to everyone, including users with print impairments, including physical impairments or learning difficulties, or for whom printed PI is difficult to access for other reasons.[12] ePI allows the use of large fonts or high screen contrast for partially sighted users and audible formats for blind users and those with low literacy levels. ePI on the web will be accessible to screen readers, web and mobile applications, convertible to large font and amenable to other accessible formats. Accessible formats will provide the full and balanced product information to users in formats suitable for their needs.

Rationale

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 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. ePI will make it easier to add authorised or supportive video or audio content or other interactive materials (in line with the appropriate guidance) to the PI. Accessible formats refer to format only, and will include the entire PI without any change to the content.

Implication

ePI will be 'accessible by design.' This means that accessibility to users with diverse abilities will be taken into account from the beginning and throughout the ePI initiative.

[9] EMA and CMDh guidance on use of barcodes is available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorised-medicinal-products_en.pdf and https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_313_2014_Rev8_12_2018_clean_Mobile_scanning_and_other_technologies.pdf

[10] More information on the Falsified Medicines Directive: https://ec.europa.eu/health/human-use/falsified_medicines_en

[11] See 'Safety features for medicinal products for human use Questions and answers,' question 2.16: https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

[12] Accessible ePI will comply with Directive (EU) 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies.

3. Efficiency gains for regulatory systems

Regulators and the pharmaceutical industry expect to be able to use ePI to create efficiencies in routine management of the PI during regulatory procedures and to facilitate analysis of information contained in the PI.

3.1. Enabling efficiencies in administration of regulatory procedures

Statement

ePI will enable increased efficiency in management of PI during regulatory procedures. By enabling PI changes to be made across all relevant PI annexes and products, ePI could eliminate many manually performed tasks and redundancies that are potential sources of error.

Rationale

Currently, PI for medicines contains the same information located in several places, each of which has to be changed individually in case of an update to the information. Following ePI implementation, automated systems could simultaneously change, or flag for change, all locations where the information occurs, leading to faster updates and reducing the risk of introducing errors (e.g. a change in the address of the marketing authorisation holder [MAH] could be implemented simultaneously and automatically).

Implication

ePI will improve the performance of regulatory procedures following implementation, delivering up-to-date, accurate PI to patients and HCPs more efficiently.

3.2. Enhancing knowledge of trends in medicines and their evolution

Statement

ePI will provide information on medicines that is amenable to analysis, and could be used to increase knowledge by facilitating study of characteristics of current EU medicines.

Rationale

Openly accessible, semi-structured ePI is a valuable resource for research. Academics, the pharmaceutical industry and other researchers will be able to access this resource more easily for studies of active substances, indications, target populations, adverse events and many other pieces of information contained in the PI. Regulators could more easily analyse the PI to assess the relevant evidence to contribute to Committee recommendations or future strategies and policies. Data on nationally authorised medicines could provide a source of information on medicines in countries across the EU. In the future, it could be possible to use ePI to analyse changes in the PI over time and to identify how medicines have evolved and predict future trends.

Implication

ePI will be a rich source of information on medicines for a wide variety of research, which may yield actionable insights for the benefit of public health.

4. Existing legislative framework

Implementation and use of ePI must comply with the legislation in force. These principles underline some of the legislation relevant to ePI.

4.1. Complementing paper package leaflet

Statement

ePI will not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of Directive 2001/83/EC[1]) 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.

Implication

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. Though not legally mandatory, the use of ePI will be a recommended digital source of information and EMA, HMA and NCAs shall commit to implementation.

The paper PL should include a statement directing to the ePI as the most up-to-date version of the PL. This statement (based on updated QRD [Working Group on Quality Review of Documents] product information templates) could be added to the PL as part of the next regulatory procedure affecting the PI.

4.2. Open access to regulator-approved information only

Statement

ePI is intended for the delivery of the full and complete regulator-approved medicine PI only. ePI will not be used for delivery of promotional information.

ePI should always be published as freely accessible open data.

Rationale

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 content — either for promotional or other purposes — can be included in the ePI.

The European Interoperability Framework (underlying principle 2: openness) describes the principle of openness as the idea that all public data should be freely available for use and reuse by others, unless restrictions apply.

Implication

In use of ePI, stakeholders must comply with the applicable EU legislation, which strictly regulates the content of PI and excludes any element of a promotional nature.

As is the case for the currently available PI, the full ePI shall be published without any amendments in the text or any extracts of the PI. It is the responsibility of the publisher to keep the PI that they publish up to date.[13]

The rights of patients and consumers to have access to validated, non-promotional information will be maintained.

4.3. Data protection

Statement

ePI itself will not include any personal data.

In any event where processing (e.g. collecting or handling) of personal data may occur in relation to the implementation and use of ePI, for example in the context of a mobile application developed for the use of patients to access ePI, personal data processing must be in accordance with applicable European data protection legislation. This includes, in particular Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725 applicable to EU institutions.

[13] 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.

Rationale

All parties involved in the development and use of ePI including EMA, NCAs, the pharmaceutical industry, other companies and HCPs are reminded of their obligation to comply with applicable European data protection legislation, which includes Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725.

Implication

All stakeholders processing personal data in relation to ePI must ensure full compliance with the applicable European data protection legislation.

5. Processes

The following principles relate to the implementation of ePI, including processes, roles and responsibilities.

5.1. High-level governance

Statement

It is envisaged that, eventually, ePI format will be used for the PI of all human medicines authorised in the EU through EMA and NCAs from the point of submission and throughout the evaluation process.

However, in the short and medium term, some regulatory authorities may decide to continue to perform assessment as is done currently, and that ePI should be created once the regulatory procedure is complete.

The ePI implementation process will depend on the findings of feasibility analyses and will be described in a future roadmap to guide implementation.

ePI will be made available to users (e.g. patients / consumers and HCPs) through websites at EMA level and if available, Member State level.

ePI data will be made available for use in other e-health systems, such as electronic health records and e-prescribing systems.

ePI will also be available for use by third-parties,[14] who can reproduce ePI and make it available to patients and HCPs (as is already the case for PI today).

[14] Any parties other than regulators and a medicine's MAH; third parties could include companies, not-for-profit organisations, academic institutions, and patient / consumer groups.

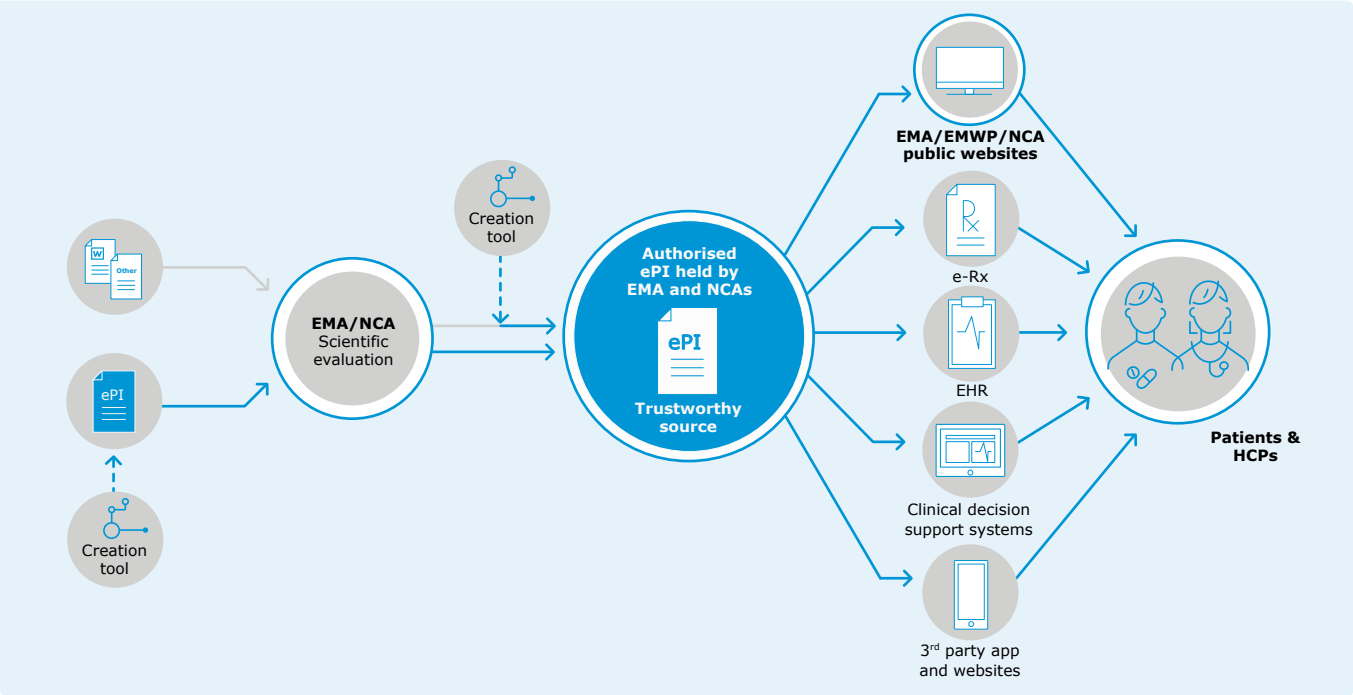

Figure 1. Proposed model for ePI process (subject to change following feasibility analysis once ePI project is started). A free, validated ePI creation tool is provided by the regulator. The tool could be used by the MAH to create ePI for submission in an application or to create ePI once an evaluation is complete. ePI for both nationally and centrally authorised products can be accessed from the European medicines web portal (EMWP) and NCA public websites. ePI can be used with systems for e-prescribing (e-Rx) and electronic health records (EHR). Data can be accessed by third-parties for example, for use in websites and patient / consumer apps.

Rationale

The most efficient implementation of ePI would involve submission of ePI in an application for a regulatory procedure, performance of the evaluation using ePI, and once the procedure is completed, making the appropriate ePI available via trusted sources.

Where authorities are not using ePI throughout the assessment, creation of ePI may take place once the evaluation is completed.

The regulator should hold ePI data, as a trustworthy source for reliable medicines information. The NCA in each country will store and handle ePI in their jurisdiction. In addition, it is envisaged that a pan-European medicines web portal could provide a central point for access of ePI for all centrally and nationally authorised medicines.

Implication

In the future, it is envisaged that the EMA and all NCAs will be able to use ePI from the point of submission, and ePI will be made available through EMA and NCA websites.

5.2. Flexibility in implementation

Statement

All stakeholders, including pharmaceutical companies and regulators, are expected to commit to implementation of the common electronic standard for creation of ePI for all EU medicines. However, timelines and processes for implementation will be flexible and amenable to the available resources and priorities at national level. A roadmap will be proposed by HMA and EMA to define the steps for development, which allows implementation in the EU on the basis of the key principles.

Rationale

The size and complexity of the task of creating ePI for European medicines is such that it is unrealistic to envisage implementation throughout the EU simultaneously.

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), companies producing generic medicines, orphan medicines or advanced therapies, and companies handling a high volume of PI.

Implication

Once a common standard and governance process are established, EMA and NCAs shall adopt it in their jurisdictions according to a roadmap, including timelines, determined at HMA and EMA level in collaboration with the pharmaceutical industry.

Some early-adopter Member States may begin using ePI for their authorised medicines, whereas other Member States may have different priorities for implementation.

Support and flexibility in implementation for stakeholders including NCAs and in consultation with pharmaceutical companies will also be considered.

Flexible implementation should also include planning for conversion of existing PIs of authorised medicines to the new ePI format. This could be incorporated into post-authorisation procedures.

Flexibility will allow for divergent timelines for implementation, as these will still ultimately allow a harmonised approach for ePI across the EU.

6. EU context

These principles describe how ePI fits into the multilingual EU environment and interacts with other ongoing initiatives.

6.1. Multilingual ePI

Statement

ePI shall support all official EU languages and Icelandic and Norwegian so that EU citizens will be able to read ePI in their preferred language when authorised ePI in that language is available.

Rationale

The PI for a centrally authorised medicine is available in all official EU languages (plus Norwegian and Icelandic) and the PI for a nationally authorised medicine is available in one or more official language(s) of the Member State where the medicine is placed on the market.

NCAs decide in which official language(s) PI will be provided in their countries for nationally authorised products. The ePI initiative does not imply any additional translations other than those that are already carried out for PI in the EU.

ePI should also be possible in these languages, as applicable. Availability of ePI in patients' / consumers' and HCPs' own language, where available, facilitates full understanding. However, this principle does not imply interchangeability of all language versions of a product that is authorised in individual Member States, as these may not necessarily be harmonised and differences may exist in the PIs in different countries.

PI may be needed in non-EU languages in some Member States, however additional non-EU languages are not currently in the scope of the ePI initiative.

Implication

ePI design and implementation must, from the start, ensure capability to provide PI in all official EU languages as well as Icelandic and Norwegian.

6.2. Interoperability with EU and global initiatives

Statement

ePI will interface and interact with many ongoing and foreseen eHealth initiatives. eHealth and related services should work together, within and across organisations or domains. ePI interoperability with cross-border prescription, electronic health records, the future European medicines web portal, pharmacovigilance systems, SPOR data management services, future ePI for veterinary medicines, a future European common data model, current electronic application procedures and national ePI systems must be considered in the design of EU ePI. Use of ePI in both an EU and global context should also be taken into account.

Rationale

This initiative takes place in the context of the ongoing digital transformation of healthcare. Digital tools and services such as electronic health records, e-prescribing, mobile platforms and wearables gather data and disseminate knowledge, yet maximising the benefits of digital technologies to public health will depend on ensuring the flow of data through interconnected health systems to deliver point-of-need access to the information that matters to patients / consumers and HCPs.

The EC policy on Transformation of Health and Care in the Digital Single Market anticipates that 'person-centred' approaches can ensure improved patient well-being and quality of care and contribute to sustainable health systems.[15] Patients / consumers and HCPs need information from the PI at various points in the treatment journey, including information on use and administration of the medicine, how to recognise possible side effects and how to act in the light of new safety data. Interoperability can ensure that this information can be delivered to patients / consumers at the time they need it through interaction of the ePI with electronic health records and e-prescriptions.

The European Interoperability Framework recommends (recommendation 9) ensuring data portability, namely that data is easily transferable between systems and applications supporting the implementation and evolution of European public services without unjustified restrictions, in accordance with the legal framework. In addition, the framework outlines (recommendation 7) that, unless privacy or confidentiality restrictions apply, information and data should be shared and reused when implementing European public services.

Implication

ePI will be interoperable by design with eHealth initiatives and EU Telematics projects, and will consider national infrastructures, NCA systems and global health standards.

[15] Communication on Digital Transformation of Health and Care in the Digital Single Market: https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

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