AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

efpia
European Federation of Pharmaceutical Industries and Associations

medicines for europe
better access. better health.

ELECTRONIC PRODUCT INFORMATION: FROM PRINCIPLES TO ACTIONS

AESGP, EFPIA and Medicines for Europe reflections on EMA-HMA – EC Key principles for electronic product information

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The document is structured with an opening 'executive summary' which summarises the drivers for ePI and the benefits for all Stakeholders, the way forward to move from principles to action and the key asks.

The following paper includes the content and key points from the individual sections which relate to the EMA Key Principles guidance document.

In addition to the paper, there are a series of seven stand-alone annexes, that provide more in-depth detail that can be used separately in discussion or as an integrated document about the ePI Key Principles. At the end of each section is a 'Call for Action' which is a practical list of recommended actions to be initiated.

Executive summary

Electronic product information: from Principles to actions

The European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) of EU Member States and the European Commission (EC) have published in 2020 the **key principles paper outlining a common approach to develop and use electronic product information (ePI)** for human medicines across the European Union[1].

The pharmaceutical industry fully supports the provision of comprehensive, accurate and up-to-date regulator-approved information on medicinal products, both for patients and healthcare professionals (HCPs) and EMA/HMA's conclusion that there is a need to explore alternative innovative pathways of disseminating information in electronic format.

The value of ePI has been clearly recognised in the **European Medicines Regulatory Network Strategy**[2] **(EMRN)** where multiple benefits for patients' empowerment, operational excellence and sustainability of the Regulatory Network have been envisaged for the healthcare and pharmaceutical environment.

Also, the European Parliament (EP) has called for the urgent implementation of ePI *"in order to facilitate the moving and sales of medicines within the single market and thus mitigate shortages"* in the **EP Report on shortages**[3].

Moreover, the recent **European Pharmaceutical strategy**[4] has highlighted how the *"better use of product information in electronic format (ePI) could facilitate the delivery of information on the medicine to healthcare professionals and patients in the EU's multilingual environment and support wider availability of medicines across Member States". In the next years, the European Commission (EC) will collaborate with Member States and industry "to develop and implement electronic product information (ePI) for all EU medicines"* and *"evaluate and revise relevant provisions in the legislation by 2022".*

Moreover, the need for flexibility by using ePI was recognized in the context of the preparedness work of COVID-19 vaccine development and the associated logistics of early printing packaging activities.[5]

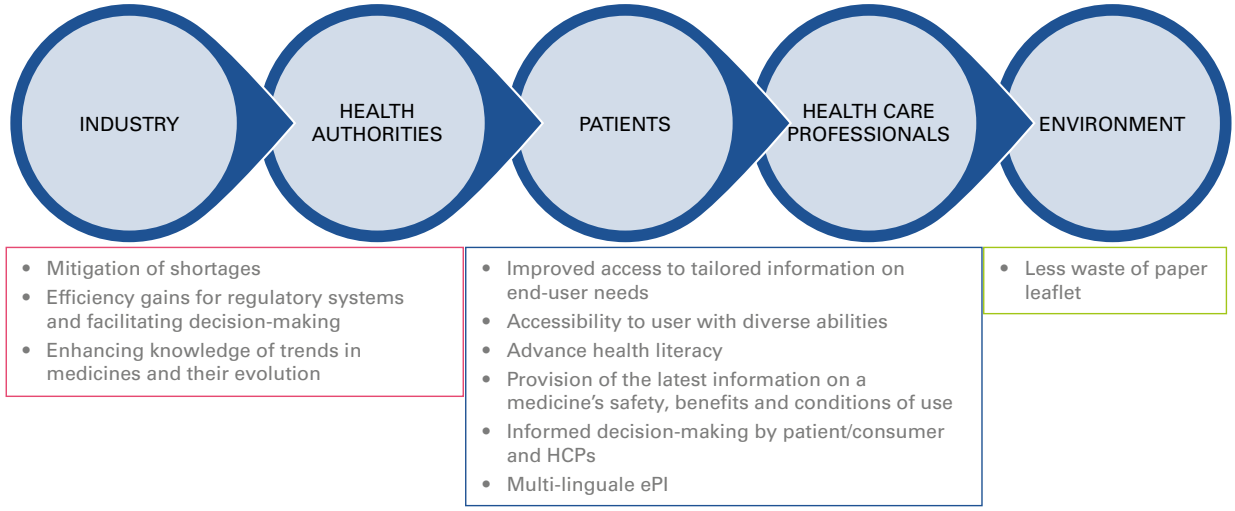
This paper provides the industry views on the 'Key Principles' document but also provides a holistic vision of what is needed to deliver timely and easily accessible and up-to-date medicinal product information to patients and HCPs, contributing to the overall health literacy of EU Citizens.

1 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
2 EP REPORT on the shortage of medicines – how to address an emerging problem (2020/2071(INI)), para 75.
3 https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmastrategy_com2020-761_en.pdf
4 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
5 https://www.ema.europa.eu/en/documents/other/questions-answers-labelling-flexibilities-covid19-vaccines_en.pdf

ePI: Drivers and benefits for all stakeholders

All stakeholders (patients, healthcare professionals, caregivers, regulators and industry) can benefit from ePI implementation.

The needs of the patient and HCPs (the ultimate end-users) must be at the forefront of the EC/EMA/HMA ePI implementation strategy and approach.



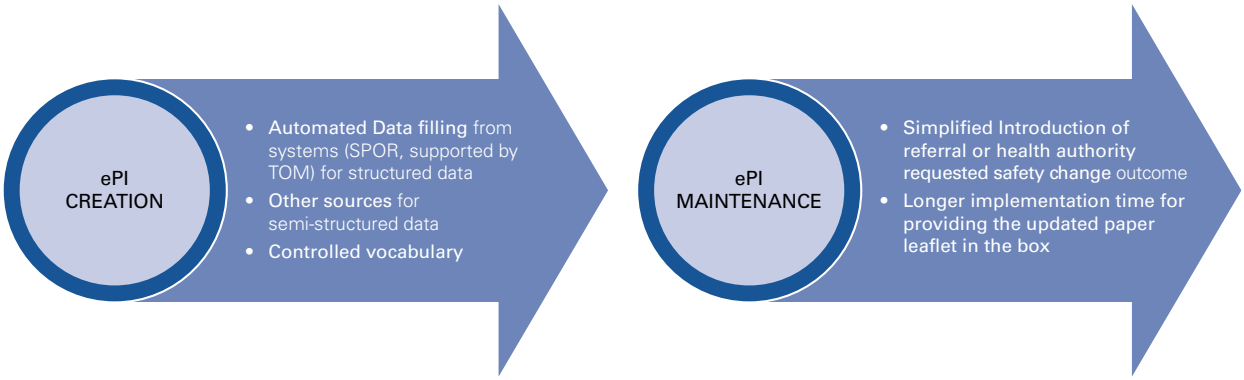
Industry believes that public health could benefit enormously from a coherent and consistent ePI implementation across the EU. Considering new advanced technologies, we could and must go beyond the current scope proposed by the EMA key principles.

Some examples of benefits and functionality that ePI could bring:

- Immediate access to the most recently regulator-approved product information.
- Attractive, presentable and user-friendly interface with other potential supportive features (e.g. user font modification) would motivate patients to take a more active interest in their health status.
- Availability of additional materials to the statutory information: video and audio facilities[6] accessible to support and improve health literacy and safe use of the product.
- Alerts for major updates to the leaflet.

However, ePI will not solve issues encountered due to poor compliance or low literacy per se, so work on the content (readability, user testing, QRD template, etc) and other related information such as instruction videos, audio content, additional materials and risk minimisation materials will need to take place in parallel.

Efficiency for the Regulatory Network



HOW

Maintenance of text should be easier: as ePI is structured, only the update of the relevant section of the PI needs to be changed. In case information needs to be changed in several places of the PI (e.g. product name), this could be done automatically.

Changes made directly into systems: will speed up the process for update and approval of any change to the PI

Update of the QRD requirements should be reflected in the system, leading to automatic update of the ePI in accordance with the new version of the QRD

Regulatory efficiencies and operational excellence will be achieved for the benefit of regulators and industry via a harmonised implementation of ePI across Europe. There are excellent opportunities for efficiencies with ePI in the regulatory system

6 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/mobile-scanning-other-technologies-labelling-package-leaflet-centrally-authorised-medicinal-products_en.pdf

through improved interoperability, ensuring better accessibility and a high level of regulatory compliance, by using structured and semi-structured data. These regulatory processes should leverage existing data of the TOM facilitated SPOR system.

The Environment

The **Green deal and the EU Commission agenda to improve the environment:** we see a huge potential upside of the ePI by successively replacing the paper leaflet, starting in the hospital setting and outside of the hospital setting with products that are directly administered by HCPs (e.g. vaccines), to reduce the volume of paper and ink (and all associated industrial activities) that are currently used. This will also contribute to the decrease of the Carbon footprint.

The way forward to move from principles to action

1. Need to collaborate at different levels of the pharmaceutical network to establish Governance model and balance flexibility with patients and stakeholders needs

Industry has reached out for a strong collaboration with regulators and other stakeholders including the Telematics Management Board, to ensure we gain the efficiencies in the processes while being conscious of the priority to improve health information.

The programme for developing **ePI must be aligned with all complementary EU telematics projects** including eCTD, SPOR, TOM, CESP Dataset Module, and Regulatory Optimisation of Variations, and be strongly positioned in the EU Network Strategy. The ePI programme needs to be based on a **solid governance structure** and attribution of roles and responsibilities in the ePI implementation.

There is a need for a **robust milestone-driven roadmap that is aligned with the different stakeholders and which is based on agreed use cases**. The roadmap should be drafted with high priority given to the benefits of the patients; for that reason, both **new and existing products** should be considered as part of the first milestone.

- To achieve these key objectives and meet these expectations, **urgent and adequate funding** is required to underpin the project work.
- For a successful implementation of ePI across EU/EEA in the interest of the patients, **technology and process have a crucial role to play in achieving the goals**.
- It would also be important to start urgently an open dialogue with industry and regulators to agree on **how ePI will fit into the future telematics ecosystem** to ensure benefits for all end-users (such as patients, HCPs and carers).
- The ePI Key Principles paper suggests that a broad margin of **flexibility** is given for national implementation of ePI across EU/EEA. However, this flexibility should be accompanied by a **clear and binding phased roadmap and value-added milestones** that include a **proof-of-concept phase** in which the level of acceptable flexibility for an ePI approach can be tested and improved accordingly.

2. ePI definition and common standard

The definition of ePI encompasses more than information for the prescriber and patients, it also includes labelling, blue box requirements and Annex II information[7].

The priority for delivering ePI should be the freely accessible provision of trusted (regulator-approved) information to patients, consumers and HCPs. Therefore, we propose a phased approach, which starts with the creation, regulatory processing and dissemination of **electronic Package Leaflets (PL) and Summary of Product Characteristics (SmPCs); a mutually agreed roadmap** defines the subsequent addition of other value-adding aspects of ePI, plus corrective modifications (from post-implementation learning).

One of the first key enablers for the adoption of ePI is a **common standard** that allows the generation and dissemination of authorised information in the EU/EEA. Features such as **vocabularies and interoperability specifications** are considered important for ePI.

3. Existing legislative framework to coexist with digital innovation

The EC Pharmaceutical Strategy[8] formulates as an action to *"develop and implement ePI for all EU medicines with involvements of member states and industry".* In addition, it recognised the need to *"evaluate and revise provisions in the legislation".* Industry believes that the **ePI shall have the same value as paper PL**, however this evolution requires further practical experience following the implementation of ePI and should be considered as part of the evaluation of the legislation.

There are situations where the paper PL could be removed from the pack and substituted by **ePI while still ensuring patients' needs** and interests are respected (e.g. by providing printed leaflet at point of dispensing).

Current practices with hospital / healthcare professional-administered products where patients rarely receive the package leaflet, show there is no reason not to remove the paper leaflet from the pack. By directing patients toward the ePI, it will fill the gap of information that is a reality in today scenarios.

Therefore, industry proposes to expand current national pilot[9] into an **EEA-wide pilot study to investigate the current practices** and benefits **of replacing paper with ePI for hospital/HCP administered products**. Such a pilot could be expanded to products directly dispensed to (and used by) patients in highly digitalised markets **to investigate the current**

7 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf , page 4.
8 https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmastrategy_com2020-761_en.pdf, pages 15 and 16.
9 More information available at the following links: https://www.afmps.be/fr/news/projet_pilote_e_pil_la_notice_papier_fait_place_a_la_notice_electronique; The Ministère de la Santé in Luxembourg website https://sante.public.lu/fr/actualites/2020/08/e-pil-call-for-candidates/index.html

practices for provision of information to patients and possible future alternatives such as the replacement of paper package leaflets with ePI (or other alternatives, such as printing at pharmacy level).

Industry welcomes further discussion on additional **'use cases'** that explore broader benefits of ePI considering:

- faster dissemination of relevant regulatory approved changes to product information
- mitigation of medicines shortages (by redistribution of packages in different languages)
- reduced packaging/distribution and wastage costs (arising from changes and recall of batches)
- immediate access to the latest information via ePI following approval, enabling a more flexible transitional period for the provision of up-to-date paper leaflets
- possible removal of the paper leaflet to reduce the volume of packaging and use of paper and ink and decreased carbon footprint
- efficiencies in the size of outer packaging materials thereby reducing transport and storage space, (especially important for products requiring controlled temperature storage)

4. ePI as main source of product information

The availability of ePI in multiple languages will facilitate the **mitigation of product shortages** by enabling easier supply **without the need for relabelling**. This is especially important in times of increased risk of medicinal shortages as observed with the COVID19 pandemic. As recognised in the EU Pharmaceutical strategy ePI can *"support wider availability of medicines across Member States".*

Broader use of multilingual packages could increase availability of medicines and improve management of the supply chain. However, due to the challenges in providing printed paper leaflets in all languages in the final packaged product this is complex. ePI represents a game-changer tool to address this, if individual EU and EEA states will agree to accept packaging potentially with one language only and have the other official approved language versions available electronically. This would also facilitate the supply to small markets.

5. Access to ePI: intuitive and friendly for an informed decision-making by patients / consumers and HCPs

In the ePI key principles document, it is envisaged that *"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, who can reproduce ePI and make it available to patients and HCPs (as is already the case for PI today)".* This is the reason why *"ePI should always be published as freely accessible open data"* and will be accessible by third parties for example, for use in websites and patient/consumer apps.

Industry understands the value of ePI being available on a range of platforms throughout the EU but most importantly each Member State must follow a **coherent and consistent approach to develop and use ePI** (from the point of submission). In addition, it is critical to have a **safe and secure access to the correct ePI from the medicinal pack**. This process should be intuitive and as simple as possible.

We support the concept to have **a single access-point to extract and re-use ePI as described in the Key principles – process chart**.

- **Outer package:** further discussion is needed in light of current and evolving technologies and standards, to facilitate **one code**[10] **only on the (secondary) packaging** to ensure clarity to patients, HCP and pharmacists and to avoid the risk of mistakes and/or misunderstanding.
- **The architecture of the web portal**[11] must be structured in a way that patients are smoothly and unequivocally directed to the correct regulatory ePI, for that specific product.
- Patients who cannot access their product information electronically should have the **same opportunity as those who have** (e.g. by providing printed leaflet at point of dispensing).
- **An educational campaign to raise** awareness on this new way of accessing information is key to its widespread adoption as part of the informed decision-making process.

6. Interoperability by design

Industry welcomes the ePI principle of **interoperability by design** employed in other ongoing initiatives in the digital environment such as eHealth initiatives and EU Telematics projects and recommends including it as a criterion the design and implementation of ePI from the start. This will be **essential to achieve significant objectives for patients and HCPs**, such as alert of significant changes in the PI content or specific, like safety measures, but also to achieve efficiencies in the regulatory systems. **SPOR data management service, current electronic application procedures and national ePI systems represent the foundation of ePI for its effective implementation**.

10 A code can be achieved using different technology including but not limited to QR codes, 2D data matrix codes, linear barcodes.
11 A pan-European medicines web portal providing a central point for access of ePI for all centrally and nationally authorised medicines (see EMA/HMA/EC paper 'Electronic product information for human medicines in the EU: key principles').

Key Asks

Launch the ePI project

Governance/Guidance/Regulatory

- Identify a clear Governance structure and ownership of the ePI project, that will take care of ensuring the appropriate funding, which is required to accelerate the ePI development
- An agreed binding Roadmap for a consistent and coherent ePI implementation in all EU member States, covering all pharmaceutical products
- Establish a central coordination of all "ePI like" initiatives
- Start an open dialogue between regulators and industry in early 2021, to fit ePI into the future telematics ecosystem
- Active involvement of the telematics network, to ensure processes are more efficient and linked to other relevant telematics projects
- A future EU Implementation guideline elaborating on the concept of ePI, structured and unstructured and re-usable elements should be provided by EMA
- Develop a Common standard in collaboration between the Industry, Regulators and impacted stakeholders
- ePI interoperable by design should be a successful criterion for its coherent implementation
- Stronger collaboration between regulators and industry to establish the needs of both in the Regulatory processes
- Pragmatic way to include a standardised sentence in the paper leaflet, highlighting the existence of an ePI on reference websites, and avoid any regulatory or administrative burden to the system.
- Architecture of the web portal (and any other access point) should be structured in a way that patients are smoothly and unequivocally guided and directed to the right ePI
- Supporting stakeholder discussions on additional 'use cases' and the positive benefits
- Discussion between Industry and regulators must be undertaken on how to link ePI with only one code on the (secondary) package

Policy and legal aspects

- A transparent and open discussion, confirming "data stewardship(s) and data ownership(s)" of the content of ePI
- Expansion of Pilot projects investigating the benefit of replacing paper with ePI for hospital/HCP administered products
- Dialogue between industry and regulators on recognition of ePI as main source in scenarios where it can mitigate shortages or increase availability of medicines in small markets.
- In future, removal of the paper on voluntary basis and ePI as single source will facilitate multi-country packs
- Conduct legal framework analysis, for the development of an ambitious ePI roadmap

Patients and HCPs

- Educational campaign to raise awareness on ePI
- Discussion on how to secure safe and easy access to ePI for patients
- Collaboration of all stakeholders (patients, HCP, Industry, regulators) to define how the content of the PI can be improved.
- Recognise ePI as a part of the eHealth strategy