**ePI: Saving lives with personalised healthcare information**

When it comes to disseminating up-to-date regulated product information to patients and healthcare professionals, electronic product information is the future. But how can the European pharmaceutical industry rise to this challenge?

**Executive Summary**

After years of talk, regulatory bodies worldwide are taking a significant interest in paperless processes and documentation such as electronic product information (ePI) for pharmaceutical companies. In addition to increased efficiency for regulatory systems, ePI will also transform how patients and healthcare professionals interact with the industry.

Faced with this growing interest, organisations should evaluate how ready they are for the paperless transformation ahead of them and how they can turn these regulatory requirements into a win-win situation for all stakeholders.

This white paper explores the market drivers for ePI, the competitive advantages it can deliver if properly implemented and a tried and true approach to convert lofty concepts into beneficial reality.
Time’s up for printed product information

In an increasingly digital world, the use of printed product information for patients and healthcare professionals looks out of place. While older generations or people without a reliable internet connection often prefer to receive information detailing scientifically validated information on how and when to prescribe and use the medicine or medical device alongside advice on safety considerations in a printed format, it has some clear disadvantages for the dissemination of information for the wider public.

From a design point of view, the main disadvantages include the difficulty in reading small font sizes, the length of the text due to all the legally required details, and the multiple language versions. All of which make it difficult for a patient or healthcare professional to find and read the parts that are relevant for their situation.

From an information dissemination point of view, it is possible that the printed information has changed between when the medicine or medical device was produced and the date that it is actually used by a patient. Some of the reasons include the possibility of identifying new safety signals or the medicine or medical device expiring in a patient’s medicine cupboard or a medical facility’s storage room.

Depending on the pharmaceutical company’s cycle times and the stock already available, it can take months or even years to get updated product information into the market. All of this relies on the
patient’s or healthcare professional’s ability to find the printed product information when they plan to use the medicine or medical device. Compared to this, digital product information ensures leaner and faster information flows and processes.

Digital sources of information enable pharmaceutical companies to deliver a wider range of content, including disease awareness materials. ePI, with rapid safety updates, ensures a higher level of information accuracy for patients and healthcare professionals, while simultaneously gathering data and generating insights for the pharmaceutical companies about what these stakeholders are actually interested in.

Lastly, from an environmental point of view, digital product information results in less waste and requires fewer scarce resources compared to printed product information.

The beginnings of ePI

Starting in March 2017, a European Commission (EC) report and a European Medical Association (EMA) action plan identified ways to improve the summary of product characteristics (SmPC) and product leaflet for patients and healthcare professionals. In addition to enhancing readability and ensuring improved accessibility to users with diverse disabilities, the new ePI will give better access to the latest product information for medicines and medical devices, aligning with the EU’s existing legislative framework.
Quick Take

ePI at a glance

ePI includes the medicine or medical device's product information, summary of product characteristics (SmPC – used by healthcare professionals), labelling (outer and inner packaging information) and package leaflet (used by patients).

According to the EMA, ePI refers to sharing the authorised, statutory product information for medicines using common EU electronic standards and presented in a semi-structured format. The interest in ePI does not impact the actual content of the product information required for a medicine or medical device.
Simply put, ePI will ensure that the latest details and advice for all medicines and medical devices are available online via a weblink or by scanning a QR code or barcode printed on a product label.

Putting ePI into practice

Simply put, ePI will ensure that the latest details and advice for all medicines and medical devices are available online via a weblink or by scanning a QR code or barcode printed on a product label. As well as significantly reducing the time-to-market for the latest safety advice, it will also improve cost efficiency of information dissemination to patients and healthcare professionals, potentially improving patient experiences and outcomes through safer application, improved adherence, increased awareness for early signs of symptoms from disease and adverse drug reactions.

Anatomy of a new-age ePI

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 marketing authorisation holder (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 national competent authority (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.

Figure 1
Turning ePI to a competitive advantage

When implementing ePI, there are a number of elements that pharmaceutical companies must consider:

- The ePI process needs to be embedded with the existing way of working, including the production of the printed product information to ensure a seamless transition as pharmaceutical companies move from producing just a printed version to both printed and electronic versions.

- Content management is more important than ever before. To be able to scale globally, it is vital that the pharmaceutical company has clear processes that connect content from across the entire organisation to ensure that core data assets are approved and available in an easy-to-use format. The easiest solution is to ensure that all content is integrated in one system, such as on a dedicated platform or in the cloud.

- Pharmaceutical companies need to unify and structure their information flows in accordance with regulatory requirements to ensure one source of truth for all information and content for ePI.

- Artificial intelligence (AI) can play an important role in simplifying processes and ensuring compliance. While most of the content of the ePI will need to be handled manually due to its complex nature, the conversion into different formats such as PDF or HTML can be done automatically. Additionally, when there are new regulations from the EMA or the U.S. Food and Drug Administration (FDA), then AI can inform staff about what this means for the organisation, what needs to change, what is relevant, who needs to be informed and when it needs to happen.

Furthermore, pharmaceutical companies should take into account the requirements of all external and internal stakeholders: for example, assisting the medical, marketing and sales teams by connecting regulatory requirements to the CRM/CMS system, or by finding new ways to keep external stakeholders updated.

Keeping the comms channels clear

Figure 2
Instead of a one-step implementation, pharmaceutical companies may find it easier to utilise a step approach where each element is implemented in a logical order, building on the existing foundation to add value to the organisation.

The digital edge

The digitisation of product information offers many advantages to pharmaceutical companies. This digitisation will also help streamline procedures for showing compliance with local regulatory requirements for faster market approvals.

However, without the internal processes and technology to update this information frequently across global markets, digitisation is doomed. For example, with printed product information it is often easier for pharmaceutical companies to outsource labelling management requirements and merely check the print-ready files a few times a year. With digitisation, the company needs the right internal processes and technology to frequently adjust content and information that is both approved and easy-to-assemble.

Instead of a one-step implementation, pharmaceutical companies may find it easier to utilise a step approach where each element is implemented in a logical order, building on the existing foundation to add value to the organisation. This added value could be in the form of higher accuracy of information, faster regulatory procedures, swift safety updates and easier content validation. Furthermore, as printed materials are phased out, there will be less waste every time information changes (see Figure 3).

A phased approach

<table>
<thead>
<tr>
<th>Now</th>
<th>Next steps</th>
<th>Later</th>
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<tbody>
<tr>
<td>One platform solution to cover e-leaflets in multiple languages &amp; according to local regulatory requirements</td>
<td>Reconstitution videos</td>
<td>Personalisation (e.g., chatbots)</td>
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<tr>
<td></td>
<td>Disease awareness materials</td>
<td>Data integration into CRM systems</td>
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<td></td>
<td>Live data collection</td>
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(Figure 3)
However, it’s important to keep potential risks in mind at every step as they could cause a challenge in the routine workflow. For example:

- How can your organisation ensure that the ePI lifecycle is robust enough to support all markets?
- How can your organisation guarantee data security and integrity when working with external partners in a regulatory environment?
- What is the added value of each element when considering the global platform for ePI?

### Intimacy and industrialisation

Another consideration is the amount of personalisation, data and content to be shared at each step. In this case, personalisation could be aimed at different niches of the target audience rather than individuals. To put it into perspective, healthcare professionals have different requirements to busy parents of small children suffering from a curable illness or an older person who has had the same medical condition for a long period of time.

This means that instead of producing stand-alone content assets, the pharmaceutical company must design and develop content that meets the needs of each of these niche target segments. A collaborative approach to content strategy, structure and development to create modular content “fragments” can be combined to align with the generated insights on the requirements of each target segment. These combinations should be continuously refined based on the response from patients and healthcare professionals.

Achieving personalisation on a global scale requires a combination of intimacy (i.e., a deep understanding of how to engage different audiences) and industrialisation (i.e., the ability to cost efficiently create and deliver multiple content variants through the automation of decision-making and execution processes).

We have worked with numerous international brands to design both the strategic and operational models required to achieve this delicate blend.

- For example, we are working with a leading global automotive brand to harness their vast bank of customer data to create highly personalised marketing campaigns at a geographic level.
- Similarly, we are working with a German pharma business to map patient and healthcare professional (HCP) journeys, and identify specific motivations and behaviour at each touchpoint.
- In both of these examples, we have also built a scaled delivery engine that utilises automation and collaboration technologies to industrialise the delivery of content in line with the specific audience needs identified. Combining these capabilities will be critical as pharma companies aim to maximise the value of ePI.
Looking Forward

ePI is a critical component of the complete patient journey transformation, improving safety, disease awareness and access to reliable medical information. But implementing it means more than adding new technology. A change in mindset is required to accelerate the transition of patient-sensitive information into digital experiences.

Working processes – involving regulatory standards and packaging – must be revamped as the first step. Such global level orchestrations require long-term supervision, involvement and ownership by the leadership for successful execution. Only when the orchestration of business and patient needs are combined with the ability to deliver efficiently and effectively at scale will the full benefits of ePI be realised.

Getting there from here

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<tr>
<th>Organisational structure</th>
<th>Cultural attributes</th>
<th>Business processes</th>
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<tbody>
<tr>
<td>• Clear ownership and leadership, guidance and governance for digital transformation</td>
<td>• Shift mindset: Think beyond package inserts in regulatory affairs — patient centricity around disease awareness and handling</td>
<td>• Synchronisation of the new digital regulatory and packaging processes</td>
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<tr>
<td>• Create, adopt and spread digital expertise in regulatory and legal terms</td>
<td>• Increased schedule flexibility integrating new information/data to speed up information distribution</td>
<td>• Content modularisation and management</td>
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<td>• Deeper integration of content producing partners into the new ecosystem</td>
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ePI: Challenges managing the transformation alongside the implementation of digital technology
Endnotes


About the authors

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