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Electronic Product Information ("ePI"): Industry Views on Regulatory Issues

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The key principles for electronic Product Information ("ePI")[1] issued by the European Medicines Agency ("EMA"), the Heads of Medicines Agencies ("HMA") and the European Commission ("EC") aims to support the digital transformation of healthcare across the EU. Indeed, digital platforms open additional possibilities to disseminate the PI electronically, thus addressing some of the current limitations on interoperability with other electronic health systems (such as e-prescription and electronic health records) and better responding to patients' and healthcare professionals' needs for accessible, trustworthy and up-to-date information on medicines. Recently, the Voice of European Self-Care Industry ("AESGP"), the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and Medicines for Europe published their position on the key principles for ePI, aiming to highlight the industry views on key aspects of those principles and to summarize the drivers for ePI and the benefits for all stakeholders. The aim of the present is to outline a couple of regulatory issues on ePI, further to this development:

Definition

Pursuant to the provisions of the Directive 2001/83/EC, medicines' product information ("PI") include: (a) the summary of the product's characteristics intended for healthcare professionals, (b) the labeling (outer and inner packaging information) and (c) the package leaflet which is included as a printed copy inside the package.

In an effort to contribute to the European initiative to cover patients' and healthcare professionals' need for an electronic format of PI, EMA, HMA and EC proposed a common EU ePI definition, according to which "*ePi is authorised, statutory product information for medicines (i.e. SmPC, PL and labeling) in a semi-structured format created using the common EU electronic standard. ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print*."

[1] https://www.ema.europa.eu/en/news/key-principles-use-electronic-product-information-eu-medicines

According to AESGP's, EFPIA's and Medicines for Europe opinion, the aforementioned ePI's definition should also include blue box requirements and Annex II information. Since ePI should be freely-accessible by patients, consumers and healthcare professionals, they even propose a phased approach, starting with the creation, regulatory processing and dissemination of electronic Summaries of Product Characteristics and Package Leaflets. In later phases, other Product Information will be added along with further corrective modifications.

Legislative Framework

Despite the new digital developments, the current applicable legislation on medicinal products, namely the Directive 2001/83/EC as amended and in force, provides only for PI and not ePI. That being the case, ePI does not replace the information requirements of the Directive 2001/83/EC and does not affect and/or alter the content of PI. *A contrario*, the purpose of ePI is to expand the formats in which product leaflets are available and to become a freely accessible multilingual information tool to the general public and healthcare professionals in addition to product leaflets inside medicines' packages.

Even though the Pharmaceutical Industry acknowledges that printed PI are important for patients with low digital literacy/low ability to use digital devices effectively and in general for patients with limited access to internet, the establishment of an ePI regulatory framework is considered to be of paramount importance; so as for ePI to have the same value as paper product leaflet. For that reason, an EEA-wide pilot study is proposed to be conducted in order to investigate and assess the current practices for the provision of information to patients and the possible future alternative options.

In light of the above, it is apparent that ePI is intended to improve the access to up-to-date medicines information. Since the regulatory framework of ePI is yet to be established, further clarifications issued by the competent EU authorities are expected.

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