Key Principles for EU Electronic Product Information on Medicines

EPF Response to the EMA Consultation

Principle 1.1 Definition of "ePI" ("electronic product information")

Proposed definition: "*ePI is authorised, statutory product information for medicines (i.e. SmPC, PL and labelling[1]) in an organised 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*."

EPF agrees with the definition.

Principle 1.2 Common EU electronic standard:

EPF supports the definition of a common EU electronic standard for ePI. As stated in the key principles (line 130-131), a common technical standard is necessary to avoid multiple different standards being developed and used in different parts of the EU.

Principle 2.1 Expanding access to information:

EPF supports the ePI initiative as part of a comprehensive strategy to ensure all patients across the EU have access to comprehensive, high-quality, up-to-date, understandable information on medicines. Information is a cornerstone of *patient empowerment* that enables health literacy, shared decision-making and effective self-management. (EMPATHIE, 2014) More and more people look for health information online, with medicines information a top search topic. According to the 2014 Eurobarometer, 6 in 10 Europeans look for health information online and whilst most people *think* they can distinguish high from low-quality information online, 17% think they cannot.

Statutory product information – particularly the package leaflet – is a key and sometimes only source of information available to patients on the medicines they take. It is particularly important to improve the availability of up-to-date information on any changes, whether regarding safety, benefit/risk, dosing or other factors that patients need to know and, possibly, act upon.

Information on medicines must be unbiased and available through an authoritative, public source, such as the EMA and the national competent authorities. We agree that the development of ePI by public authorities is an urgent task, as lack of action will simply result in industry and other, possibly unreliable, actors filling this need. Action led by EMA and national authorities should ensure that ePI will be developed with public health and patient safety as the primary goals, and is critical to ensure patients' and public trust.

Please also see below, under "other comments".

[1] 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.

Principle 2.2 Accessibility:

Accessibility of ePI to everyone, including people with various impairments, is critical to ensure equity and inclusivity. EPF agrees that ePI offers different possibilities to address the needs of those who have, for example, visual impairments by using large fonts or audible formats. We agree on the principle of accessibility by design.

We stress, however, that in order to be accessible for people with limited or low health literacy, the easy understandability of the product information needs to be ensured, and this will require further work on content. People from the target populations should be involved in testing the content and user interfaces, to ensure these are fit for purpose and truly accessible to all.

Principle 3.1 Complementing paper package leaflet:

EPF agrees with this principle. ePI should not be a substitute for the paper leaflet, but instead seen as an opportunity to expand the formats available. Paper information will remain necessary for people who do not have online access or have limited digital literacy.

Principle 3.2 Open access to regulator-approved information only:

EPF agrees with this principle. ePI should only include the regulator-approved information. Furthermore, it should not include links to information provided by third parties, which could be promotional in nature, such as industry websites accessed through barcodes on medicines packaging.

Principle 3.3 Data protection:

EPF agrees with the principle that ePI does not include personal data, and its processing must be in accordance with the EU data protection legislation.

We would add that any mobile applications developed for the use of patients to access ePI should ensure that personal data, e.g. on what information a given patient has accessed, or information the patient has submitted (e.g. reporting a possible side effect), will not be collected inappropriately or passed to third parties without consent. Any informed consent provisions must be explicit, clear, and understandable. Application by third parties of the EU data protection legislation must be monitored and enforced.

Principle 4.1 Governance:

EPF believes that the *European-level medicines portal*, maintained by the EMA, should be developed as an urgent priority. The EMA information portal is critical to pull together all existing resources and ensure unbiased, up-to-date medicines information is truly accessible to patients across the EU in a coherent way.

National competent bodies should ensure their own medicines portals link to the EMA portal. The information portal should also be comprehensively linked, in an understandable way, with other relevant information resources, such as the EU clinical trials portal and the EU database on adverse reactions. The interfaces need to be designed with users' needs as priority, and with user involvement, to ensure they are user-friendly, understandable and intuitively easy to navigate.

We also call for a role for patients and patient organisations in the governance of ePI, to ensure that the actions and steps foreseen meet patients' needs and address any concerns.

Principle 4.2 Flexibility in implementation:

EPF agrees that some countries may be able to progress faster than others. However, to avoid too much divergence leading to a "multi-speed" implementation that is detrimental to the patients' right to information wherever in the EU they live, we believe *sufficient resources should be allocated* to the implementation of ePI by all countries. EU funding possibilities could be explored to support those countries that need it.

The roadmap mentioned on lines 302 and 311 should include the *involvement of patients* in implementation, describing concrete elements and specific activities where patients' involvement is needed. The Patient and Consumer Working Party should be a natural discussion partner in elaborating the roadmap and should have opportunity for meaningful input at development stage.

Principle 5.1 Multilingual ePI:

EPF agrees that the ePI must support all official EU languages, plus Norwegian and Icelandic. This applies only to product information for centrally-authorised products. For national authorised products, we would highly recommend that Member States also make PI available in English in addition to the country's official languages, as well as linking to all other available language versions. This is because people are increasingly mobile, living and working in different EU countries, and they need information on medicines in their own language. Access to information in one's own language is an important support to patients' medication safety and self-management. Electronic systems should make it easy to include additional languages.

Principle 5.2 Interoperability:

EPF agrees with the principle that ePI should be integrated with other eHealth initiatives, including cross-border prescriptions and electronic health records. We would add to this: tools for patients reporting of suspected adverse events. We repeat our call to prioritise the development of the European medicines portal, mentioned on line 348, and the allocation of appropriate resources to the EMA for this. When considering interoperability of information, a person-centred approach implies the *meaningful involvement of patients in designing systems and processes* to ensure they really are well-coordinated and connected from the user perspective. Relevant information mentioned on line 362-3 should include also safety notifications, DHCP communications and other updates.

Additional comments:

EPF believes *electronic product information needs to be seen as one part of a more comprehensive strategy on information on medicines*, which should also include a focus on health literacy and actions to address the critical areas identified in the studies commissioned by the European Commission studies, "PIL-S" and "PILS-BOX" (2014): enhancing readability and understanding, i.e. improving the *content* of product information to ensure it is really "fit for purpose" for health literacy and informed decision-making; and improving patient involvement both in the development and the testing of product information – not currently prioritised in the EMA strategy.

The shortcomings of the package leaflet have been known for a long time. According to the European health literacy survey (HLS-EU, 2012) almost a third of respondents found understanding package

leaflets “fairly” or “very” difficult, whilst there was significant variance per country. Side effects listings and the causal relation between the listed side effects and the medicine often confuse both patients and health professionals (Mühlbauer et al. (2018); Herber et al. (2014); Mühlbauer and Mühlhauser (2015). Patient review of package leaflets comes too late in the process, is limited to one or two reviewers, and constrained by the legal requirements; patients’ comments can often not be considered because of the constrained format. There is no systematic approach to user-testing by the EMA.

EPF calls for the EMA and national medicines agencies to prioritise the above issues and to allocate the appropriate resources to the EMA from the EU budget in order for it to take action in this long-overdue area.