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Press release

Public consultation on key principles for the electronic product information of EU medicines

EMA, the Heads of Medicines Agencies (HMA) and the European Commission (EC) are launching today a six-month public consultation on draft key principles which will form the basis on which the electronic product information (ePI) for human medicines will be developed and used in the European Union.

Stakeholders and members of the public are invited to submit comments on these key principles via an online form **until 31 July 2019**.

The product information (PI) of a medicine in the EU includes the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals. These documents accompany every single medicine authorised in the EU and explain how it should be used and prescribed. The package leaflet is currently provided in the medicine's box and can also be found, mainly as a pdf document, on the regulators' websites. However, digital platforms open additional possibilities to disseminate the PI electronically. This can address some of the current limitations and better meet patients' and healthcare professionals' needs for accessible, up-to-date information on medicines at the point of need.

The draft key principles derive from extensive discussions and consultations carried out by EMA, HMA and the EC throughout 2018, with representatives of all stakeholder groups concerned, from patients, healthcare professionals, regulators to the pharmaceutical industry. This includes a workshop which took place on 28 November 2018 at EMA's premises in London. A report and the video from this workshop are also published today; the presentations are available on the EMA website.

The key principles define an EU-wide approach to support harmonised development and implementation of ePI. They define the various concepts, give examples of the expected benefits of ePI for public health and explain how ePI can be seen in the context of the existing legislative framework, as a complement to the paper package leaflet. They also outline the processes, roles and responsibilities in this approach, describe how ePI can be supported in all official EU languages and explain how it would interact with other ongoing initiatives at EU and global level. The ePI initiative takes place in the context of digital transformation of healthcare across the EU, and the commitment laid out by the EC to prioritise digitalisation that will empower citizens and build a healthier society.

See websites for contact details

European Commission www.ec.europa.eu/commission
European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

Following the consultation, the final version of the key principles will be agreed. They will then form the basis to support a harmonised approach to ePI across the EU.

Contact our press officers

European Commission
Anca Paduraru, Spokesperson public health and food safety
Tel. +32 2 299 12 69
E-mail: anca.paduraru@ec.europa.eu

EMA press office
Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu

Heads of Medicines Agencies Permanent Secretariat
c/o Paul-Ehrlich-Institute
Paul-Ehrlich-Straße 51-59
63225 Langen
Germany
E-mail:hma-ps@pei.de