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Press release

Towards electronic product information for EU medicines

EMA, the Heads of Medicines Agencies (HMA) and the European Commission (EC) are organising a workshop on 28 November 2018 in London to agree with various stakeholders on common European Union key principles to pave the way for implementing electronic product information (ePI) in the EU.

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 workshop follows up on an EC report highlighting that, despite efforts to make the PI easy to read and useful, there is still a need to improve how information on medicines is conveyed to patients and healthcare professionals.

One of the key areas of this report is to explore how electronic formats can be used to improve citizens' access to medicines' information. 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, novel digital platforms open additional possibilities to disseminate the package leaflet electronically. This can enhance access to up-to-date information and offer new opportunities to better tailor this information to the needs of patients. In addition, ePI will support patients with visual impairments and citizens with low literacy levels.

The workshop offers a platform for healthcare professionals, patients and consumers, academics, non-profit organisations, regulators and the pharmaceutical industry to discuss:

- opportunities, needs and concerns identified by different stakeholder groups;
- ongoing initiatives in the EU;
- how ePI fits into other EU and global initiatives.

The outcome of the workshop will serve as a basis to draft key principles for the use of ePI in the EU, which will be released for a six-month public consultation in January 2019.

The workshop will be live streamed on EMA's website. No registration or password is required. Participants interested in tweeting about this event are invited to use the hashtag **#ePI4Medicines.**

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

Progress on using electronic means for a better dissemination of product information in Europe is one of the key priorities of the action plan that EMA published in 2017 to address the shortcomings identified in the EC report and to improve the PI for EU medicines. In addition to electronic formats for the PI, other initiatives focus on:

- how to make the package leaflet easier to understand for EU citizens;
- strengthening patients' input during the preparation of the package leaflet;
- updating EU guidance and sharing best practices on preparing the package leaflet.

The timelines of these activities may need to be adjusted in view of EMA's business continuity plan in the context of Brexit and the Agency's upcoming relocation to the Netherlands. EMA and the EC are committed to working together with EU Member States to successfully implement the action plan. All relevant stakeholders will be involved as their input is crucial to ensure that their needs are addressed.

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