EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

First electronic product information (ePI) published for selected human medicines

News 08/11/2023

The Heads of Medicines Agencies (HMA), the European Commission (EC) and EMA have published for the first time electronic product information (ePI) for selected human medicines harmonised across the European Union (EU).

The product information of a medicine includes its summary of product characteristics, labelling and package leaflet. These documents accompany every medicine authorised in the EU and explain how they should be prescribed and used. They can all be found, often as a PDF document, on the websites of EU regulators, with a printed package leaflet also provided in the medicine's box. Digital platforms open new possibilities to share this information electronically, keep it constantly updated and make it more accessible to end users such as healthcare professionals and patients.

The creation and testing of ePIs in real regulatory procedures is being explored through a one-year pilot initiative by HMA, EMA and the EC to enable the transition to the electronic system for medicines evaluated both nationally and at European level. The ePI initiative is an action under the Pharmaceutical Strategy for Europe supported by the EU funding programme EU4Health.

The published ePIs are for medicines evaluated by EMA or by national authorities in Denmark, the Netherlands, Spain and Sweden. Companies participating in the pilot create and submit the ePI as part of their regulatory application. The pilot, which involves 25 medicines, will conclude in July 2024, and the outcomes will inform how to integrate the ePIs into common practice and expand their use across the EU.

The ePIs can be viewed at the Product Lifecycle Management Portal in English for centrally approved medicines and in the local language for nationally approved ones. Testing is ongoing to allow access to ePIs in all EU languages.

In addition, ePI data can be accessed via a public application programming interface where developers can explore the potential of this new format within existing digital platforms.

These ePIs were created following the EU ePI Common Standard adopted by the European medicines regulatory network to provide a consistent structure throughout all Member States and ensure the information works across different e-health platforms. This should facilitate the

use of product information to meet individual needs and access requirements. Future developments could include functionalities such as automatic update notifications, access to supportive videos or audio content and online adverse-reaction reporting tools.

Related content

- Electronic product information (ePI)

External links

- Product Lifecycle Management Portal
- Application programming interface for ePI
- EU4Health

Contact point

Media enquiries
Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

All other enquiries
Please submit your request via the online form
Follow us on X @EMA_News

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000

How to find us

Postal address and deliveries

Business hours and holidays

European Union agencies network

An agency of the European Union