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**Press release**

# Key principles for the use of electronic product information for EU medicines

EMA, the Heads of Medicines Agencies (HMA) of EU Member States and the European Commission (EC) have published today key principles outlining a harmonised approach to develop and use electronic product information (ePI) for human medicines across the European Union.

The product information (PI) of a medicine 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 prescribed and used. The package leaflet is provided in the medicine's box and can also be found, often as a pdf document, on the websites of EU regulators. However, digital platforms open additional possibilities to disseminate the PI electronically. This can address some of the current limitations (e.g. the current PI is not interoperable with other electronic health systems such as e-prescription and electronic health records) and better meet patients' and healthcare professionals' needs for accessible, trustworthy and up-to- date information on medicines available at the right time.

The ePI initiative was launched to support the digital transformation of healthcare across the EU, and the commitment laid out by the European Commission to prioritise innovations that will empower citizens and build a healthier society. It is also in line with EMA's current digitalisation efforts aiming to make best use of available resources and prepare for future challenges.

The key principles describe the benefits ePI can deliver for public health and the efficiencies it may introduce in regulatory procedures. They explain how ePI will comply with the existing legislative framework: it will be provided as open access information that complements the paper package leaflet. They also outline a flexible, harmonised approach to implementation across the EU, and describe how ePI will work in the EU's multilingual environment and will interact with other ongoing digital initiatives at EU and global level.

The key principles derive from extensive discussions and consultations carried out in 2018 and 2019 by EMA, HMA and the EC with representatives of all stakeholder groups concerned, from patients, healthcare professionals and regulators to the pharmaceutical industry. In particular, during a public consultation that took place from January to July 2019, 71 contributions from all stakeholder groups were received, including over 500 comments which were considered for the final version. A summary of the main points raised in the consultation and the submissions are also published today.
The key principles were endorsed at the end of 2019 by EMA's Management Board and by the HMA. They are now expected to be followed by all parties involved in the process of developing and implementing ePI for medicines across the EU.

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