



EMA consultation on initiatives for electronic EU product information

Prescrire's contribution

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Access to, comparative, reliable and updated product information is essential for healthcare professionals and patients. Therefore, the current initiative should respect the previous EU decision to maintain the ban on direct-to-consumer advertising (DTCA) and not come up with new proposals allowing pharmaceutical companies to communicate directly to the patient/citizen about the products they sell.

Initiatives aiming to improve product information are welcome. However, the current EMA consultation is not primarily focused on the improvement of product information and the patient leaflet but rather on the exploration of how electronic or digital means can be used to improve access to medicines' information by patients and healthcare professionals. Access to the electronic version of the patient leaflet should always be considered as an additional option to the printed version provided within the product package. Even if electronic access to information is very popular it is not convenient for everybody.

Competent Authorities are already required to provide public access to official information (including the SmPC and the patient leaflet), notably through the European database on medicines Eudrapharm (article 57(2) of Regulation (EC) No 726/2004) and the Drug Regulatory Agencies' safety portals (article 106 of Directive 2010/84/EC). According to our experience, the use of these databases is rather cumbersome and efforts to make them more user-friendly would be very welcome.

Improvements of approved pharmaceutical product information and European access to relevant information are possible and needed through:

- permanent efforts to design approved leaflets that are more useful, user-friendly and accessible to patients (enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE);
- prioritisation of information, with the most frequent, positive and negative effects, given prominence;
- strengthening the content and user-friendliness of national and EU competent authorities' databases on medicines, and promoting their use among the public.

Access to updated patient leaflets (1)

Prescrire regularly finds that many product boxes contain outdated patient leaflets. Over the life-cycle of a pharmaceutical product, the SmPC and patient leaflet are updated following new information on adverse effects, changes of dosage, restrictions or extensions of indications, new contraindications, safety messages to prevent medication errors, etc. The SmPC and patient leaflets can be found on the websites of the national competent authorities and/or on the EU Commission and/or EMA websites, sometimes with different dates or without any date.

A single electronic access (regardless of marketing authorisation procedures) to the latest updated patient leaflets would represent a way to overcome the problem with replacement of outdated patient leaflets in product boxes. It would also be a solution when the product is exceptionally and regrettably delivered to patients without its packaging, for instance in hospital care. To overcome the problem of outdated leaflets, *Prescrire* suggests adding a message in the leaflet such as: "This leaflet might have been updated, you can find the most recent version at the following address".

All leaflets, including electronic versions, should clearly mention its date of validation.

Information for knowledge purpose, not for advertising

To prevent access to electronic leaflets being turned into disguised direct-to-consumer advertising, it has to be guaranteed that they are hosted on national competent authorities and/or on the European Commission and EMA websites.

Use of Quick Response (QR) codes (2)

The possible use of QR codes should be carefully designed, assessed and explained to end users. QR codes also may represent a useful support for visually impaired persons by providing access to online sound message leaflets (including INNs, dosage or alerts, for example "intake once a week"). Information provided through QR codes must be validated by a competent health authority to make sure that the content is non-promotional.

No DTCA in Europe

In order to protect public health, *Prescrire* invites EMA to make sure that any initiative resulting from the current consultation process is fully in line with and respects the EU agreement to uphold the ban on DTCA in Europe. The provision of public access to officially approved product information falls under the role of competent authorities, notably by their publication on national competent authorities and/or on the European Commission and EMA websites.

References :

- 1- Prescrire Rédaction "Savoir trouver une notice à jour sur internet et identifier la dernière version" *Rev Prescrire* 2017; 37 (401): 214-215.
- 2- ANSM "Avis aux titulaires d'AMM : soumission à l'ANSM des documents liés à un QR code sur le conditionnement primaire ou secondaire, ou dans la notice d'un médicament" October 2016: 4 pages
http://ansm.sante.fr/var/ansm_site/storage/original/application/ce27e5eccb149952ed344d916ff5dc16.pdf