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Commentary Open Access

Readability of Package Leaflets – Update on Possible Improvements Using an Electronic Version Additionally

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Commentary

It was a major step forward when the European Commission added the requirements of some kind of user testing of package leaflets to the European Directive 2001/83 in 2004 as part of the entire review of the legislation for human medicinal products in Article 59:

- The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use. (Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004).

A couple of years later a report on still existing short-comings was required to be presented in 2013 according to Article 59:

- By 1 January 2013, the Commission shall present to the European Parliament and the Council an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals. The Commission shall, if appropriate, and on the basis of the report, and consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents. (Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010).

Proceeding to this report two studies have been published initiated by the European Commission: First one is "Study on the Package Leaflets and the Summaries of Product Characteristics of Medicinal Products for Human use. PIL-S study" [1]. Second report of EC gives more insight on "Feasibility and value of a possible "key information section" in patient information leaflets and summaries of product characteristics of medicinal products for human use. The PILS-BOX study" [2]. The general result was summarized in a way that readability (comprehension and layout) of package leaflets needs to be improved rather than in SmPC. It was recommended to consider to revise the existing guidelines (e.g. readability, content and layout related issues), to allow more flexibility among different medicines in QRD template (in the framework of the existing legislation) and to introduce guidance on translations in the existing guidelines. In parallel the input from patients should be improved and a more iterative assessment process may be introduced without impairment (delay) of the authorization process. In addition, an evaluation of an electronic format of the package leaflet in addition to the paper version (as legally required) should be undertaken. That could mean a better understanding on how to integrate the electronic version as a tool to inform patients and health care professionals on changes in the SmPC and PL. The final report from the Commission on the SmPC and PL for medicinal products for human use was adopted by the European Parliament and the Council on 22 March 2017 [3]. EMA took the leadership in generating an action plan on how to achieve the above-mentioned objectives. Unfortunately, all proposed activities with the exception of a workshop to be held in Q3 2018, with preparatory work (mapping and discussion with stakeholders) starting in Q4 2017 were put on hold due to missing resources [4]. This workshop has taken place on November 28, 2018 in London at EMA and was publicly broadcasted. Representatives of all national competent authorities and EMA including European Commission, of several pharmaceutical industry associations, patients and consumers' organizations, healthcare professionals' organizations and academia, Health Technology Assessment Bodies (HTAs) and payers took part in the information exchange. EMA presented an outline of potential future use cases and international standards to be employed in case an electronic package leaflet will be generated [5]. Representatives from several members' states as well as from pharmaceutical industry projects on electronic developments presented and run a live demonstration on how an electronic PL could look like and what the advantages would be. Up to now, it is a broad range of similar, but in details highly deviating proposals and developments underway [6]. However, for European purposes a harmonized and standardized approach is essential as marketing authorization holder and regulating agencies will not be able to assess each electronic publication in advance on a national or company specific solution. In addition, the publication process needs to be automated based on the authorization issued by the competent authority. In addition to several technical requirements, the features of an application presenting an electronic product information need to be evaluated against patients' requirements, whether they can and will use them and whether this approach supports the required improvement of comprehension and better use of package leaflets [7,8]. Whatever improvement of the design and lay-out of paper package leaflets has been achieved – the flexibility due to the legal framework is somewhat restricted –, the access to an electronic version might improve searching and tailoring for personal use of product information, offer options to explain technical terms as well as monitoring of updates of regularly used medicines, enlarging the font size on the screen, read-out the text and provide easy access to educational material and so on [9,10]. In the best case these developments are accompanied by scientific support, evaluation and assessment. Therefore, this short commentary should be understood as an invitation to undertake these activities and communicate this to EMA and on twitter @EMA_News #ePI4Medicines.

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