Medicinal products for human use: Community code. Codification

1999/0134(COD) - 22/03/2017 - Follow-up document

In accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use, the Commission presented 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 Directive requires that a summary of product characteristics and a package leaflet be included in the application for authorisation to place medicinal products on the market in the Union.

Based on two studies by external experts and a European-wide stakeholder survey, the report concluded that the current EU legislation on medicinal products for human use allows for **enhancement of the statutory medicines information** to support the safe and effective use of medicinal products.

The following recommendations were made:

- more focus on **improving the package leaflet** rather than the summary of product characteristics. The clarity of the notice and its readability could be improved. The language used is often too complex and the presentation is not always practical. The elderly and those who have low literate skills are particularly disadvantaged;

- revise the **existing guidelines**, in particular, the readability guideline, the packaging information guideline and, where appropriate, the summary of product characteristics guideline. These revisions should also include the introduction of guidance on **translations** that go beyond the principle of faithful translation to ensure that the lay language introduced through user testing in the original language version is not lost during translation;

- **the input from patients during the process and the related methodology** should be further improved, for example, by considering the requirement to make the user testing process more iterative and to ensure that a sufficiently mature version of the package leaflet is user-tested. This iterative user-testing would be coordinated by regulatory authorities in parallel to the assessment in a way that does not disrupt the whole marketing authorisation process. It should focus on the content of the package leaflet rather than on format and layout;

- **best practice examples** of aspects of the package leaflet and the summary of product characteristics design could be made available for pharmaceutical companies on a platform that would be suitable for that purpose and that could be regularly updated;

- explore how **electronic formats** can be used to provide the information to individual EU-citizens in accordance with the existing legislation (e.g. in terms of presentation, format or use of multiple languages). For example, developing mechanisms through electronic tools to inform patients and healthcare professionals on changes in the SmPC and PL should be considered. The exploratory work in this area should be based on and further develop the existing work done by the European Medicines Agency in this area and should follow a multi-stakeholder approach involving also the

pharmaceutical industry, patients, consumers, healthcare professionals, the Member States and the Commission. The aim will be to develop the key principles for the use of electronic summary of product characteristics and package leaflet formats;

- the **potential introduction of the "key information" section** in the summary of product characteristics and package leaflet with the objective to allow patients and healthcare professionals to rapidly identify key safety messages, balanced with information on the benefits of medicines, has been also subject to the assessment. It is suggested to continue further exploratory work on the use of such key information in the package leaflet.

Lastly, the Commission and the European Medicines Agency will work towards implementation of the above-mentioned recommendations in close collaboration with the Member States. It will be ensured that the key stakeholders will be duly consulted and involved as appropriate with regards to the respective proposed possible actions.