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Summary of Product Characteristics Advisory Group (SmPC AG) 6-year activity report (2016)

Quality assurance of SmPCs

The SmPC Advisory Group has been established in 2010, following the last revision of the SmPC guideline, to promote and facilitate the application of the SmPC guideline. The SmPC Advisory Group has developed into a platform of training, experience-sharing and support for any SmPC issues arising within the EU regulatory network.

Its 2015 activity report has summarised the first 5-year experience of the group and analysed the impact of the SmPC guideline implementation plan within the framework of SmPC. This report noted that the overall quality of SmPC is satisfactory and in line with the primary objective of the SmPC guideline to support provision of information to healthcare professionals for safe and effective use of medicine. At the same time, it recognises that continuous supervision is necessary to ensure that this objective is maintained according to users' new demand for information, scientific progress and evolution of healthcare practice stemming, for example, from Health Technology Assessment or IT development.

In 2016, the SmPC AG group has continued to provide training and advices on SmPC, in cooperation with Committees, working parties and working groups. On top of communicating principles for presenting efficacy and safety information, 2015 SmPC webinars put emphasis on readability for clinical practice. Attendance and satisfaction to webinars remain very high. Overtime the number of product-specific advices has increased. In order to improve the searchability of such documents, which vary in term of scopes, the SmPC AG will work towards incorporating advices given in thematic Q&As. For example, it could be the opportunity to underline the general principles for selecting and presenting safety information and how to integrate new safety information when it emerges after marketing authorisation. The value of grouping related adverse reactions (i.e. adverse reactions deriving from the same mechanism or part of the same phenomenon) was noted to facilitate readability and update of safety information after marketing authorisation. No major gaps in the recommendations of the SmPC guideline were identified. However, information on drug interactions is often described as an area for improvement; lengthy and piecemealed information on investigation of drug interaction potential does not always result in clear advice for clinical practice. The new product information review process is seen as very successful in facilitating review of SmPC within the regulatory network.

An EMA survey on information on medicines among healthcare professionals in Europe in 2016 has confirmed that SmPC stands out as the regulatory document of reference on a medicine and is used by all Healthcare Professionals. At its September 2016 meeting, the Healthcare Professional Working Party has recommended optimising the ease of use of regulatory information. In line with this objective, the SmPC AG proposes to maintain its activities as described in 2015, including acting on any recommendations of the upcoming Commission report on "Shortcomings in the SmPCs and the package leaflet".