17 December 2015
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Management Board meeting of 16-17 December 2015

An action plan to improve the perception and use of the Article 58 procedure

Issues for consideration

Article 58 was introduced in the 2004 revision of the Agency's founding regulation, and allows the Agency to give scientific opinions – in collaboration with the World Health Organization – on medicines for use outside of the European Union. The intention of the process is to increase access by low- and middle-income countries (LMICs) to medicines and improve public health. Use of the procedure during its first decade has been disappointing, with only 8 products having completed the process.

With the financial support of the Bill & Melinda Gates Foundation, a study was commissioned from McKinsey & Co in April 2015. The objectives of the study were to understand awareness, experience and views of stakeholders of Article 58 and its influence on manufacturers' decisions to use the procedure and the wider landscape of alternative regulatory tools and pathways. The final report from McKinsey & Co was delivered in September 2015, together with a series of recommendations and proposals for consideration by EMA and DG SANTE.

A number of major actions are included in EMA Work Programme 2016, and additional activities will be developed during the course of 2016. This revised version of document EMA/756676/2015 introduces some minor amendments to the text and removes the name of the consultancy firm that conducted the study. It also underlines the message relating to the importance of developing communication and awareness tools for Article 58 and also the support from the European Commission to discuss and clarify the regulatory options in association with the procedure.

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