PRESS RELEASE

European Commission focuses on 'lessons learnt' from Paediatric Legislation

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Stakeholders ranging from industry to clinicians have had an opportunity to voice their opinions on the Paediatric Regulation in the European Commission's public consultation that ended on 28 November. It was therefore timely that the next day, the 'Annual European Medicines Agency Review of the Year and Outlook for 2013', a meeting organised with TOPRA, included an update on this very subject.

The Commission's Florian Schmidt (Unit D5, Medicinal products - authorisations, EMA, DG SANCO) told delegates he was pleased that 35-40 respondents representing 'a broad scope of customers' had sent responses to the consultation, the results of which will feed into a report mandated by the regulation. The report is due to be presented to the European Parliament and the Council next year and will focus on 'lessons learnt' in the first five years since the Paediatric Regulation's implementation.

Delegates were keen to know whether the report would also make recommendations for amending the legislation, but Mr Schmidt said that level of detail would be included in a second, more comprehensive report to be released in 2017. 'We need some time to really get sound data on the effects of the Paediatric Regulation due to the long development cycles involved,' he explained. The later report will address issues such as the economic impact of the rewards and incentives under the regulation.

Paediatric Committee Chair Daniel Brasseur suggested that pressing issues such as the continued off-label prescribing of paediatric medicines should be addressed within the current legal framework, rather than waiting several years for this to be addressed in the second report. Mr Florian made no promises but responded that the possibility 'was not excluded'.

In the meantime, the mid-term review, which will include a detailed inventory of all medicinal products authorised for paediatric use since the regulation's entry into force in 2007, is expected in spring or summer 2013. The benchmarks for the report are the key objectives of the regulation, namely ensuring: high-quality research; the majority of medicines used by children are authorised for such use; and the availability of high-quality information about medicines used in children.

It will address the main themes laid out in the public consultation, which builds on the EMA's five-year report to the Commission published in July this year. The themes include the regulation's impact, the PUMA (Paediatric Use Marketing Authorisation), clinical trials in children, receptiveness of healthcare professionals, off-label use and burden.

Emma Du Four, Abbott's Senior Director Regulatory Policy & Intelligence, provided an industry perspective based on highlights from EFPIA's response to the consultation. She said that although the Paediatric Regulation has become an integral part of drug development plans, there is a need for changes, some of which could be made within the current

framework. For example, a greater opportunity for paediatric dialogue prior to filing PIPs (Paediatric Investigation Plans) would support smoother assessment of the PIPs that follow. Furthermore, she said that for new compounds the limited data set at this early stage of development (ie, end of Phase I, when PIPs have to be submitted) must be recognised. She also expressed industry's concern about the lack of a process for inactivating a PIP, causing legal uncertainty. It is not clear what a company's obligations are if it stops developing a compound, she said. All the stakeholder responses to the consultation are expected to be published early next year.

NOTES FOR EDITORS

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