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# Highlights of the EMA industry platform meeting on Paediatric medicines held on 11 May 2015

The purpose of the "Platform on paediatric medicines" meeting is to provide an opportunity for both a general update and more focused discussion on specific processes or issues to support continuous improvement, and generally to foster a constructive dialogue with industry stakeholders. The first meeting aimed to provide an update on the current operations, achievements to date, and planned improvements. Particular focus was placed on the class waiver list review, the possibility for early interaction with regulators, public summaries and paediatric investigation plan (PIP) compliance check during validation.

**General update on Paediatric medicines**

slide presentation

This session introduced the scope of the new paediatric platform meetings, and set the expectations for the meetings. A general update on Paediatric medicines was presented, focusing on new and ongoing activities of relevance to Industry stakeholders.

On the topic of extrapolation across age groups, the EMA will organise a workshop with experts on 30 September 2015. Following that workshop, a meeting with industry representatives on extrapolation is planned for Q1 2016.

- **Action:** Industry associations will be contacted in Sept 2015 to nominate participants for the industry meeting.

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**Class waiver list review**

slide presentation

This presentation focused on the class waiver list review. It provided general background, the approach for class waiver review by the PDCO and the anticipated outcome of class waiver list review. EMA circulated the draft class waiver list review opinion, to the Industry stakeholder organisations in advance of the meeting.

Industry asked whether a mapping could be provided comparing the existing and new approach and for clarity on the basis for defining the condition. EMA confirmed that the definition is literature based.

- **Actions:** EMA to circulate a tabulated comparison of previously granted and anticipated revised waivers to Industry as additional background to the discussion.
  Industry stakeholder organisations' were asked to forward consolidated comments to EMA by 29 June 2015.

**PIP Early interaction meetings**

slide presentation

The early interaction meetings have been introduced by the Agency and the Paediatric Committee to foster medicine development for children. In this session the Agency provided a background to early interaction meetings, presenting the importance and defining the scope, and format of early interaction. Emphasis was placed on considerations and benefits for the developers to discuss the Paediatric development strategy. These meetings will commence with a 6-12 month pilot phase.

A question was raised about the possibility to discuss new indications for already authorised medicines. It was noted that these would generally be rather handled though a PIP pre-submission meeting. Regarding the interaction with EMA scientific advice, the PDCO have strong links into SAWP and one of the outcomes of an early interaction meeting may be a recommendation for scientific advice. The difference between PIP early interaction, early interaction, adaptive pathways and pre-submission meetings was also clarified.

- **Action:** EMA to consider the development of a Q&A to clarify the difference between PIP early interaction, early interaction, adaptive pathways and pre-submission more widely.

**Public summary of the evaluation of a proposed PIP or product-specific waiver**

slide presentation

Questions were raised from industry stakeholder organisations in relation to the Public summary of the evaluation of a proposed PIP or product-specific waiver. Questions were related to the planning process for feedback collection on whether the document fulfils the audience's needs, the possibility of updating the existing public summaries and preparing summaries for existing PIPs.

It was noted that the PIP summaries were launched in July 2014, and are prepared prospectively (i.e will not be prepared for PIPs existing prior to that date). Applicants are provided with the opportunity to point out factual errors (if any) and comment. Once published, they will be updated with an additional statement where subject to modification. The possibility of conducting a survey of the target audience will be discussed with the Patients and Consumers Working Party.

**PIP Compliance check during submission validation**

slide presentation

In this final session industry stakeholder organisations raised questions on the EMA process for Compliance Check and its application for Type II Variations. Specifically, industry requested clarification on the process for the compliance check against the PIP and on the possibility to complete a partial compliance check each time a completed paediatric measure/study is submitted post marketing, and then a final partial compliance check at the time the final PIP measure is submitted. The EMA referred to the SOP published on compliance check that will be updated. However, it was noted that as industry have a number of general questions, EMA will look into updating the Q&A to offer more clarity.

- **Action**: EMA to consider update of Q&A to include additional practical advice to industry on the procedure for compliance checking.

**Overall conclusions**

The meeting was closed, with all stakeholders expressing positive feedback on this inaugural meeting of the platform for Paediatric medicines. Currently an annual paediatric platform meeting has been proposed, however, EMA agreed to consider holding more frequent meetings depending on the number of topics being raised for discussion.

**Future meetings**

- The next industry platform meeting on Paediatric medicines is expected to take 1Q2016 (tbc).
- Topics which may be considered for next meeting may cover:
  - Extrapolation and challenges on compliance;
  - New paediatric processes/Paediatric survey;
  - Conduct and completion of paediatric clinical trials;
  - "Matrix" and other innovative trials;
  - Experience and benefit of PIP to guide EC decision.