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Product Development Scientific Support

Highlights of the 2nd EMA-Industry Stakeholders Platform meeting on Paediatric medicines

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1.1. Introduction to the 2nd EMA-Industry Stakeholders Platform meeting on Paediatric medicines

EMA welcomed all participants to the meeting and clarified that the scope of all stakeholders meeting platforms are to promote dialogue with industry stakeholders and to enrich the EMA's understanding of issues that are pertinent from the industry perspective.

Stakeholders meetings follow the principles listed in the 'Framework for interaction between the European Medicines Agency and industry stakeholders EMA/591272/2014'.

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1.2. Electronic transmission of PDCO opinions and EMA decisions

EMA informed about plans for electronic transmission of EMA decisions and PDCO opinions to applicants.

EMA is planning to replace the distribution of paper copies of the PDCO opinions and EMA decisions to by electronic distribution as of July 2016.

EMA clarified that also modalities of application of submission will be revised to facilitate distribution to PDCO members from applicants.

- Action: participants were invited to send feed-back on the proposal of electronic distribution of EMA decision and PDCO opinion by 30 May 2016.

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1.3. Early interaction on paediatric development and PRIME

EMA provided a reminder on the early paediatric interaction meeting. Such meetings take place in the early phase of drug development, focus on overall development strategies to discuss potential paediatric needs and scope of development for paediatrics but are not intended for evaluation of data to support PIP applications. On the other hand PRIME is an initiative to foster the development of medicines with high public health potential. Cases where the two initiatives can be interlinked were explained.

- Actions: EMA to explore development of an overview of the scope of the different types of interaction meetings to facilitate dissemination of information.
  Industry to send comments on their experience with the Early Paediatric Interaction Meeting.

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1.4. Revised templates (scientific part of application, summary report)

EMA has revised the template for the EMA/PDCO Summary report and for the scientific part of the application for agreement of a PIP/waiver with the objective to increase the focus of the submission and of the assessment.

Plans for introduction of the revised template include a pilot phase where EMA will offer the revised template for use.

Industry enquired about the possibility of providing feed-back - regardless of direct participation trough submission of documents with the new template and participants were reassured that comments will be welcome from everyone.

- Action: EMA will offer revised Summary template to applicants identified based on letter of intent for submitting PIP applications from June to October 2016 inclusive. EMA to transmit template to all participants for comments.

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1.5. EFPIA feedback on EMA standard PIPs

EFPIA presented their feed-back on the uptake of the standard paediatric investigation plans (PIPs).

If more standard PIPs are to be planned industry would like to discuss in detail with EMA/PDCO the basis for priority setting for standard PIPs.

EMA will be open to work with stakeholders for further refinements and reminded the aim of standard PIPs was to present applicant with what the PDCO is likely to request based on precedents.

- Action: EMA to address in writing some questions raised at the meeting. EMA to explore a suitable platform and format to discuss standard PIP with industry involvement in case of future ones to be developed.

1.6. Recruitment of paediatric subjects in clinical trials and the proposal to create a pan-European Paediatric Clinical Trials network (EUPCTN)

EFPIA presented their views on challenges in conducting paediatric clinical trials impacting on their conduct and completion. An iterative discussion to address foreseen challenges should occur prior to agreement of a PIP as well as when running a paediatric study. A number of possible strategies to progress in discussing the matter were proposed, including multi-stakeholders meetings.

EMA welcomes a coordinated approach to ensure prompt start and completion of all paediatric trials and will contribute by analysing current experience so far to identify key strategies that can help overcome obstacles in recruitment.

EMA stressed that the issue is multifaceted and requires multi-stakeholder collaboration. As such it needs to be addressed from different perspectives. Forums such as EnprEMA or the EFGCP-DIA-EMA Annual Paediatric Meeting can provide an adequate platform for developing and supporting dialogue around such meetings would be of mutual benefit.

In the context of ongoing initiatives, the IMI2 Proposal to build a sustainable pan-European Paediatric Clinical Trials Network (EUPCTN) was also presented.

1.7. Interactions Scientific Advice Working Party (SAWP) and PDCO

The PDCO collaborates closely with the Scientific Advice Working Party to address questions on pharmaceutical, non-clinical and clinical development.

As mentioned in the EMA published procedural advice, Industry participants were reminded that parallel submission of an application for a paediatric scientific advice and an application for paediatric investigation plan at the same time is not recommended. Participants discussed the outcome of the experience gained so far in case where scientific advice was requested for paediatric development and it was concluded that prospective planning is key and early interaction should be sought in unclear cases.

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Other updates

1.8. Expert meeting on paediatric development of fixed-dose combinations for the treatment of the human immunodeficiency virus (HIV)

EMA outlined the main conclusions of the meeting, reminded participants that the outcome of the meeting has been published on the EMA website and highlighted that plans for a prioritisation strategy in development of FDCs should be proposed proactively by the applicants.

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1.9. Update on recent activities by Enpr-EMA

EMA presented an update informing participants of the activities and publications of the various EnprEMA working groups. A call was launched for participation of industry representatives at the 8th annual Enpr-EMA Workshop 2 June 2016.

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1.10. A.O.B.

Stakeholders expressed positive feedback on the range of topics covered during the meeting, nevertheless, EMA will be strengthening interactions in the preparatory phase of the future ones to increase opportunity for exchange of views. The frequency of the stakeholder platform meeting will be annual, however, more frequent meetings could be organised depending on the number of topics being raised for discussion.