EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 March 2019
European Medicines Agency
Human Medicines Research and Development Support
Paediatric Medicines Office
EMA/127791/2019

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Director of the Department of HIV/AIDS, World Health Organization (hirnschallg@who.int)

Dr Chip Lyons
CEO of the Elizabeth Glaser Paediatric AIDS Foundation (clyons@pedaids.org)

Dear Dr Hirnschall and Dr Lyons

The European Medicines Agency (EMA) would like to thank you for the opportunity to participate in the Vatican meeting on 7 December 2018 about the current situation of the development of medicines against HIV in children. We appreciated the valuable discussions at the meeting.

The Paediatric Committee (PDCO) at the EMA is committed to continue the review of Paediatric Investigation Plans (PIPs) for medicines for treatment and/or prevention of HIV, as mandated by the EU Paediatric Regulation, taking into account the following considerations, while bearing in mind that PIPs are evaluated scientifically and on a case-by-case basis:

- Paediatric dosage form development must be integrated right from the planning phase of the whole paediatric drug development following completion of phase I trials in adults. It should then be initiated as soon as possible taking into account dose-finding and clinical studies.
- Adolescents should be included in adult trials, or trials in adolescents should be conducted in parallel with adults unless scientifically justified otherwise.
- Overall, drug development studies in children should be based on weight rather than on age and should align with the WHO weight bands. In very young children and particularly in neonates age should be also considered to account for their physiological organ immaturity.
- Where appropriate on the basis of a sound scientific rationale, studies of medicines should be conducted across the paediatric spectrum of weights and ages in parallel rather than in a sequential age-staggered approach, at least down to 4 weeks of age and potentially including neonates. Particular products with specific safety or drug disposition factors may still warrant a different approach.

Of note, these principles are already applied and used by the PDCO on a regular basis in discussions during the evaluation of PIPs for HIV medicines.

EMA also commits to improve the handling of PIP applications including the PIP modification process as agreed in the "EMA-EC action plan on paediatrics" published in October 2018 which also contains actions to strengthen cooperation between decision makers.

We sincerely appreciate this collaboration and hope it will contribute to improving the development of HIV medicines for children.

Kind regards

On behalf of the Paediatric Committee

Dr Dirk Mentzer
Chairman of the Paediatric Committee at the EMA

cc EMA: Dr Enrica Alteri, Dr Ralph Bax, Dr Agnes Saint-Raymond; WHO: Dr Martina Penazzato