European Medicines Agency
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PRESS RELEASE

Meeting highlights from the Paediatric Committee, 29-31 August 2007

The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) held its third meeting on 29-31 August at the EMEA. The PDCO made progress with the assessment of the first requests for paediatric investigation plans (PIPs) and waivers and continued to refine the procedural aspects for the operation of paediatric activities.

First draft list of waivers
The PDCO adopted a draft list of waivers covering a number of conditions that do not affect children and for which a paediatric investigation plan will not be required. This is to ensure that research in the paediatric population is only conducted to meet their therapeutic needs. The list is to be released shortly on the EMEA website for public consultation prior to final adoption by the PDCO. As set out in the Paediatric Regulation, the Agency shall maintain a complete list of waivers, which will be updated regularly (at least every year), and made available to the public.

Survey of existing use of medicines in children
The PDCO also agreed on a proposal on the format and content of the information to be collected by the Member States on all existing uses of medicinal products in the paediatric population by January 2009. This will be the basis for an inventory of paediatric needs.

Draft implementing strategy for a network of paediatric networks in the EU
Following the conclusion of the public consultation phase, the PDCO finalised the draft implementing strategy for a network of paediatric networks in the European Union (EU). This new network aims to bring together the best available scientific expertise in the performance of studies in the paediatric population in the EU. The draft implementing strategy will be sent to the Commission, and presented to the EMEA Management Board in October. Its final adoption is anticipated for January 2008.

First applications
The PDCO had a first discussion on requests for PIPs or waivers that have reached day 30 of the evaluation procedure. So far, the PDCO has received applications corresponding to 86 requests for PIPs or waivers, including one PIP for a paediatric use marketing authorisation (PUMA), a new type of marketing authorisation that covers off-patent medicines developed specifically for paediatric use and with an appropriate formulation.

Other operational issues
The PDCO continued its discussion of other operational issues and fulfilled responsibilities derived from the Paediatric Regulation, in particular:

- Procedures for application for PIPs, waivers and modifications;
- The draft PDCO recommendation for the European Commission on the symbol for medicinal products having a paediatric indication;
- The proposal for update of the summary of product characteristics to include paediatric information;
- Practicalities for further collaboration on paediatric issues with the US Food and Drug Administration (FDA) based on the 'Principles of Interaction between EMEA and FDA Office of Paediatric Therapeutics'.

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The next meeting of the PDCO, to be held on 26-28 September, is expected to involve appointment of the Committee's chair and vice-chair, and adoption of the first requests for modification of proposed PIPs, and/or PDCO opinions for PIPs or waivers.

-- ENDS --

Notes:

1. The EMEA's 'Medicines for children' site can be consulted here.
2. The list of waivers for paediatric investigation plans (PIPs) will be published shortly on the EMEA website.
3. The 'Principles of Interactions: Between EMEA and FDA Pediatric Therapeutics' can be found here.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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