Tuesday, 30 September 2014 to Wednesday, 1 October 2014

The EU paediatric regulation is now in force since 2007. Drug development is no longer possible without considering children. Furthermore, companies developing medicines need to consider the paediatric requirements early in the development. This legislation has transformed paediatric drug development from a topic discussed by a few interested paediatricians, clinical pharmacologists and regulators to an issue that is broadly known within pharmaceutical industry and regulatory authorities, and to a lesser degree in the clinical world. More than 1000 PIP decisions are now published on the EMA website, and virtually everybody within pharmaceutical industry has heard of paediatric investigation plans and waivers. The EU Commission has published a 5-year report, and a 10-year report will be submitted by the Commission to the European Parliament and Council in 2017.
The aim of this conference is to discuss on a high level how the EU paediatric regulation is working and how it contributes to children's health. This will include a discussion on the preparedness for the 10-year report; strategic thoughts within the EMA on how to streamline paediatric development and a session dedicated to paediatric oncology.
As always, experts from all involved parties will be present, and on day 1 participants will discuss more specialized and hot topic issues in four breakout sessions. This will allow participants to discuss face-to-face with all stakeholders, which otherwise usually occurs by email or phone. Questions on any topic relating to the Agency's activities can be submitted before the conference to paediatrics[at]efgcp[dot]eu [1], and will be answered by the Paediatric Medicines office at the EMA.

Last update: 25 July 2014

Links
[1] https://www.eahp.eu/contact/paediatrics/efgcp/eu