EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 603

PHARMACEUTICAL COMMITTEE
28 March 2012

Subject: **Paediatric Regulation – Lessons learnt after five years of application**

Agenda item 2c)

The Paediatric Regulation (EC) No 1901/2006 is a relatively new instrument, adopted with the specific purpose of compiling more information on the use of medicinal products in children and to reduce the considerable amount of medicinal products that are administered to children off-label.

The Paediatric Regulation imposes on pharmaceutical companies, which research new medicinal products for adults or plan to extend the indications of existing patent protected adult products, the obligation to verify the potential paediatric use of those products. That additional research may, once the product is authorised, be rewarded with an extension of the IP protection of the product.

The balance between obligations and rewards is important for obtaining the full support of stakeholders for the goals of the Regulation. In this regard it is important to avoid imbalances, e.g. due to disproportionate requirements or administrative burden in the application of the Regulation without at the same time endangering the goals of the Regulation.

Now, after the first five years of its application it is appropriate to reflect on the lessons learnt. In this context, the Commission has to present in early 2013 a report to the European Parliament and the Council on experience acquired as a result of the application of the Paediatric Regulation. This exercise is not intended as a starting point for a general review of the paediatric regulation, but to verify what can be improved within the current framework provided by the Regulation.

From feedback received from industry the Commission knows that the Paediatric Regulation has lead to a change of mindset in companies being now aware of their 'paediatric' obligations and recognizing them early in the process of drug development. At the same time, the complexity of the systems has been often criticised as overburden

industry at a stage in the development process in which even the adult development may be subject to considerable changes.

As regards output, the Paediatric Regulation is still at early stages, given that the majority of paediatric investigations plans adopted by the Paediatric Committee are still ongoing. In this regard, the full impact of 'stick and carrot' approach of the Regulation on its beneficiaries, i.e. children, will only be visible in a couple of years.

The Commission would like to use the opportunity of the Pharmaceutical Committee to listen to the experience of Member States, so to take those comments on board in the further preparation of the Commission report.

Action to be taken:

For information