EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 604

PHARMACEUTICAL COMMITTEE
28 March 2012

Subject: **Interpretation of Pharmaceutical legislation – ECJ judgments**

Agenda item 3a)

- **T-52/09, judgment of 14 December 2011, "Nycomed"**
  Case C-125/10, judgment of 8 December 2011, "Merck"

Both cases relate to the Paediatric Regulation (EC) No 1901/2006.

In the *Nycomed* case a company challenged the refusal of the European Medicines Agency to grant a waiver from the obligation to submit a paediatric investigation plan. In accordance with Article 11 of the Regulation such waiver shall be granted if the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations.

In its application for the waiver the applicant argued that his product, an ultrasound imaging agent, was designed to diagnose coronary artery disease that existed only in the adult population. The Paediatric Committee disagreed with this narrow use description and considered instead that the imaging agent was designed to identify myocardial perfusion defects. Such defect could also be caused by diseases which occur in children so that the waiver was not justified.

In its ruling the General Court focussed on the question of identifying the disease or condition for the diagnosis of which the medicinal product 'is intended', as referred to in Article 11 of the Paediatric Regulation. Must this be assessed objectively, taking into account the properties of the medicinal product or subjectively, based on the diagnostic indication given by the product developer? The General Court basically supports the first view. While the diagnostic indication proposed by the product developer constitutes the starting point for the assessment of the Paediatric Committee, the Committee is entitled to establish whether the product may not only be associated with the disease or conditions covered by the proposed indication, but also with diseases or conditions,

which exist in the paediatric population. Such extrapolation must be based, however, on scientifically reasoned, objective evidence.

With this interpretation of the Court the door is shut for any circumvention of paediatric obligations by narrowly defining the indications of a medicinal product under development. In this regard the ruling provides clarity, while failing to do so concerning the precise limits the Paediatric Committee has in such extrapolation so to avoid obliging the applicant to develop the product in therapeutic indications for which it was never intended.

In the Case C-125/10 the Court confirmed the concept of a supplementary protection certificate with a zero or negative term. This allows marketing authorisation holders to benefit subsequently from the paediatric extension, as a reward for paediatric studies, even if initially the product in question was not entitled to an additional protection period. In consequence, the paediatric reward is becoming more attractive.

- **Interesting pending cases**

Case **C-185/10** focuses on the correct interpretation of Article 5 of Directive 2001/83/EC, which provides for exceptions to the general requirement that every medicinal product should possess a marketing authorisation before being placed on the market (Date of the ECJ ruling: 29 March 2012).

Case **C-221/10P** deals with an action for compensation for the damage allegedly suffered on account of the adoption of a Commission decision withdrawing the applicant's product. While the case focus on legal questions related to the non-contractual liability the Advocate-General proposed in his opinion also a change of interpretation as regards the conditions according to which the Commission would be entitled to withdraw a product from the market ('new scientific evidence' versus 'change in scientific assessment criteria').

In the pending case **C-308/11** the Court is called to give an interpretation of the meaning of the notion "pharmacological action", which is part of the definition of a medicinal product by function (Article 1 point 2(b) of Directive 2001/83/EC – Oral hearing: 26 April 2012).

Action to be taken:

For information