EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
**Medicinal products – authorisations, EMA**

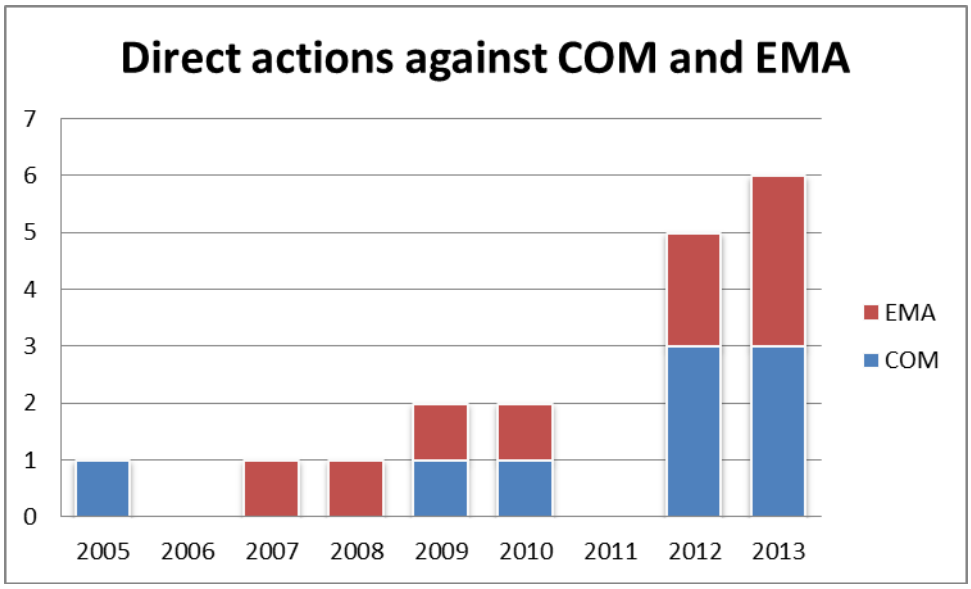
PHARM 641

**PHARMACEUTICAL COMMITTEE**
**26 March 2014**

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

**Agenda item 1a**

- **Direct actions before the General Court in Luxembourg – A trend?**




- **Case C-512/12, Judgment of 13 March 2014, Octapharma France**

The reference for a preliminary ruling inquires advice on the interaction between Directive 2001/83/EC on human medicinal products and Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. More specifically, it inquires which provisions apply to plasma from whole blood which is prepared by a method involving an industrial process.
The origins of the reference from the French Conseil d'Etat is a lawsuit initiated by Octapharma France against the Agence nationale de securité du medicament et des

produits de santé (ANSM) and the French Ministère des affaires sociales et de la santé. Octapharma contests the legality of an 'implementing decision' of ANSM determining a list of labile blood products in accordance with Article L. 1221-8 of the French Public Health Code.

That list includes fresh frozen plasma, leukocyte-reduced, virus inactivated by solvent-detergent within the category of labile blood products. Octapharma considers it as a medicinal product. Being categorised as 'labile blood product' under French law means that a specific scheme provided for in Article L. 1220-1 et seq. applies, distinct from that to which medicinal products are subject to under the provisions of the same Code.

Octapharma challenges the fact that neither the French legislation (Article L 1221-8) nor the list adopted pursuant to it make an exception to the notion of labile blood product in the case where plasma is prepared by a method involving an industrial process. Point 6 of Article 3 of Directive 2001/83/EC provides that while that Directive shall not apply to whole blood, plasma or blood cells of human origin, it may apply to plasma which is prepared by a method involving an industrial process.

- **Interesting pending cases**

Case **T-140/12**, a direct action against the European Medicines Agency, which focuses on the correct interpretation of Article 8 of the Orphan Regulation (EC) No 141/2000 defining the concept of market exclusivity for orphan medicinal products;

Cases **T-472/12** and **T-67/13** (*Novartis* v *Commission*), a direct action against the Commission concerning the application of the global marketing authorisation concept to products that received separate marketing authorisations under the 'old' Regulation (EEC) No 2309/93;

Case **T-547/12** (*Teva Pharma* v *EMA*), a direct action against the EMA on the application of the global marketing authorisation concept to fixed combination products;

Cases **T-29/13**, **T-44/13** (*AbbVie* v *EMA*) and **T-73/13** (*InterMune* v *EMA*), direct action against the European Medicines Agency, which deals with the disclosure of clinical trial data, which were submitted as part of a marketing authorisation application, under access to document provisions (Regulation (EC) No 1049/2001);

Case **T-189/13**, a direct action against the Commission decision to delete certain indications from national marketing authorisations of tolpersione-containing oral formulations ('Article 31 referral');

Case **T-583/13** (*Shire* v *Commission*), a direct action against a Commission letter providing interpretation as regards Article 37 of the Paediatric Regulation (reward for orphan products);

Case **T-48/14** (*Pfizer* v *Commission/EMA*), direct action concerning the alleged failure to include a compliance statement under the Paediatric Regulation into the marketing authorisation;

Case **C-269/13P,** appeal to the ruling of the General Court in case T-539/10 (*Acino* v *Commission*). The case deals with regulatory action in the framework of an 'Art. 20

referral' following a 'Good Manufacturing Practice' Inspection that discovered critical deficiencies in the production process of the active substance supplier in India;

Case **C-104/13** (*Olainfarm*) a preliminary reference that deals with the use of well-established medicinal use products as a reference product for generic applications;

Case **C-358/13** ('*Legal highs*') focuses on the correct interpretation of the term '*modifying*' ("*physiological functions*") contained in the definition of medicinal product set forth in Article 1(2)(b) of Directive 2001/83/EC, for the purpose of ascertaining whether certain synthetic drugs could be regarded as medicinal products within the meaning of the Directive;

Joined case **C-544 and C-545/13** a preliminary reference on the applicable advertising provisions for pharmacy and hospital preparations;

Case **C-661/13** ('*BOLAR'*), preliminary reference concerning the application of the BOLAR provision in Article 10(6) of Directive 2001/83 to third parties, basically API suppliers, in circumstances where the protected substance is sold by the third party to a pharmaceutical company for BOLAR purposes. BOLAR provisions are a feature of intellectual property law and enable manufacturers of generic pharmaceuticals to use the technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of the generic product, while the patent is in force.

**Action to be taken:**

For information