EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA
Head of Unit

PHARM 605

DRAFT COMMISSION PAPER – DOES NOT REPRESENT THE VIEWS OF THE COMMISSION

PHARMACEUTICAL COMMITTEE
28 March 2012

Subject : **Agenda item 3.b Interpretation of the legislation on biosimilars**

Simplifying the rules for authorising biosimilars would facilitate the development of such products and contribute consequently to affordable medicines. To date, the European Commission has authorised only 14 biosimilars while many biosimilars are under developments. The authorisation of generics is based on the comparison of a medicinal product with a reference product authorised in the EU as laid down in Directive 2001/83/EC. However, the information required in the marketing authorisation dossier of a generic does not permit the demonstration of the similar nature of two biological medicinal products. Therefore, additional data, in particular, the toxicological and clinical data are required for authorising biosimilars. The type and amount of additional data shall be determined on a case by case basis in accordance with relevant scientific guidelines currently published by the European Medicines Agency. So far, we have always interpreted our legislation in a way that all data provided in the marketing authorisation dossier should be established with a reference product authorised in the EU and that the batches are sourced from the EU. However, such interpretation obliges the applicants to repeat clinical studies with batches sourced from various continents.

The forthcoming revision of the EMA guideline on similar biological products (CHMP/437/04) is currently subject to various expectations from stakeholders. Indeed, the European Commission has been approached by stakeholders to promote a global biosimilar development which would avoid repeating expensive clinical trials against reference biological product sourced from different territories. Recently, the US FDA published a draft guideline for authorising biosimilars. Under certain circumstances, an applicant may seek to use data derived from animal or clinical studies comparing a proposed product with a non-US licensed product. In such case, an applicant will have to

demonstrate by state of the art analytical tests that the two reference products are so highly similar that they can substitute to each other in the clinical trial.

Therefore, the European Commission would like to seek the views of the Pharmaceutical Committee whether in certain specific cases it would be possible to introduce such flexibility to facilitate the authorisation of biosimilars without compromising the protection of public health in the European Union. We believe that most of the data provided in the dossier shall be produced with the reference products sourced from the EU to be in compliance with our legislation. However, when the applicant can demonstrate the comparability of the batches sourced from the EU and from an other continent by appropriate studies (biological, physicochemical characterisation, pharmacokinetic and or pharmacodynamic), the applicant could be authorised to launch the clinical trial with batches sourced from this continent. From a legal point of view, such interpretation could be compatible with our regulatory framework which mentions that the type of data to demonstrate similarity shall be determined on a case by case basis in accordance with relevant scientific guidelines.

Action to be taken:

The European Commission would like to discuss with the Pharmaceutical Committee about a possible change in the interpretation of the rules for biosimilar medicinal products.