EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 700

PHARMACEUTICAL COMMITTEE
21 October 2015

Subject: **International developments – Update on bilateral negotiations: TTIP – Preparation of technical paper on generics**

Agenda item 5b

In the context of the negotiations of the Transatlantic Trade Investment Partnership (TTIP), the Commission is preparing the submission of a technical paper identifying objectives for regulatory cooperation and harmonisation of technical requirements for the authorisation of generics.

The purpose of this background document is to collect the views of the pharmaceutical committee on the following potential objectives.

Objective 1. Working with other strategic partners on the development of international regulatory collaboration on generics

The International Generic Drug Pilot (IGDRP)[1] was launched in April 2012 in Washington by an international group of regulators and WHO. Given the success of the initial phase of the Pilot, members of the IGDRP have decided to deepen the exploratory phase through engaging in a Program that will end in December 2016[2]. As part of IGDRP activities, the EU with the regulatory agencies of Health Canada, Swissmedic, Taiwan FDA and Therapeutic Goods Administration of Australia, is involved in an information sharing pilot. The objectives of this pilot are to facilitate and to strengthen the scientific assessment of generic medicines through the exchange of information related to the assessment of applications submitted to the different jurisdictions. This information sharing is building on the mechanisms that are in place in the EU in the framework of the decentralised and the centralised procedures for the authorisation of medicinal products. IGDRP is also pursuing other projects aiming to facilitate the exchange of information for the scientific assessment of generic products notably through the development of converging requirements for the presentation of the Active

[1] http://www.who.int/medicines/publications/druginformation/DI_28-1_Regulatory-Harmonization.pdf
[2] http://www.igdrp.com/

Substance Master File (ASMF)/Drug Master File (DMF) or BCS (Biopharmaceutics Classification System) Biowaiver assessment reports and documentation.

The EU and the US should be fully engaged on these activities and seize the opportunities to increase regulatory collaboration for generic medicines and convergence of authorisation procedures. This collaboration would contribute to improve patient access to generic products meeting high standards of safety, efficacy and quality in the EU, in the US as well as in international partners.

Objective 2. Harmonisation of BCS (Biopharmaceutics Classification System)-based biowaivers

As described in the EMA guidance[3], the BCS-based biowaiver approach allows to reduce the number of *in vivo* bioequivalence studies by addressing, under certain conditions, the question of bioequivalence between specific test and reference products on the basis of satisfactory *in vitro* data. The approach may be used to establish bioequivalence in applications for generic medicinal products, extensions of innovator products, variations that require bioequivalence testing, and between early clinical trial products and to-be-marketed products.

The EU and US could work towards the harmonisation of their guidelines on BCS-based biowaivers. This work could be performed in the framework of the International Conference for Harmonisation of technical requirements for the registration of medicinal products (ICH).

Objective 3. Towards harmonisation of clinical data requirements for products subject to hybrid applications often referred to as "complex generics"

In the same way as biosimilars, "complex generics" require the performance of pre-clinical tests and clinical trials for their authorisation. Applications for this type of products are subject in the EU to Article 10.3 of Directive 2001/83 (« hybrid applications ») and in the US to "abbreviated applications". In line with the common EU-US approach on biosimilars, the EU and the US could consider whether it is appropriate to review their respective guidelines for hybrid/abbreviated applications. The objective would be to decrease the duplication of clinical trials and facilitate the global development of this type of products. In the case of the EU, this revision would allow an applicant to compare its product, in certain studies and under certain conditions, with a non-EU comparator that is authorised by a regulatory authority with scientific and regulatory standards similar to the EU (e.g. US). The applicant would have to demonstrate that the comparator authorised outside the EU is representative of the reference product authorised in the EU.

Action to be taken:
For discussion

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500070039.pdf