



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 654

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: International Non-proprietary Names (INN) for biosimilar medicinal products

Agenda item 5c

Background

At the WHO International Nonproprietary Names (INN) Programme a discussion is ongoing on a codification for biosimilar medicinal products for their identification and to distinguish biosimilar medicinal products from the reference medicinal products.

At the 71st meeting of the Pharmaceutical Committee held in October 2013 the European Commission sought support of the Member States to the current EU thinking that considers that biosimilar medicinal products should be closely aligned with their reference medicinal products and identification by INN together with a qualifier or code for each biosimilar medicinal product would be contrary to such alignment. A vast majority of the Member States expressed support for the current EU thinking.

At the 57th Consultation on INN for Pharmaceutical Substances in October 2013, the INN Expert Group unanimously agreed that the Secretariat should take forward the idea of a voluntary qualifier – now called "Biological Qualifier" (BQ) – and to explore the application and administration of a system in more detail. Four key issues to be considered are: the nature of the BQ, what information it should convey, who makes an application for a BQ, and who should have access to the BQ information. Furthermore, there should be information on who is going to use the code and how.

For further details on the discussion at the 57th Consultation on INN for Pharmaceutical Substances in October 2013, please see the Executive Summary: http://www.who.int/medicines/services/inn/57th_Executive_Summary.pdf.

The 58th Consultation on INN for Pharmaceutical Substances takes place 8-10 April 2014 and is to be preceded by an ad hoc meeting on the BQ on 7 April 2014. At the Open Session with INN stakeholders on 8 April 2014 the BQ is anticipated to be discussed as

well. However, the European Commission is not a member of the INN Expert Group and has currently no further information to share.

Action to be taken:

For information.