EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 630

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: **a) Identification of biological medicinal product - Implementation of Article 102(e) of Directive 2010/84/EC / INN for biosimilar medicinal products**

Agenda item 3a

Background

The European Commission has been approached by various stakeholders, with a focus on the INN to ensure adequate traceability and appropriate reporting of adverse events for biological medicinal products.
This topic is notably raised in the context of the on-going discussions on identification of biosimilar medicinal products by the International Non-proprietary Name (INN) at the WHO International Nonproprietary Names Programme. In April 2013, a discussion on the possibility of using a qualifier to distinguish the biosimilar medicinal product from the reference medicinal product took place with biological experts of the INN Expert Committee and representatives from worldwide regulatory agencies. Some regions (Australia, Japan and US) have already introduced qualifiers to the name of the active substance to identify certain biological/biosimilar medicinal products, while in the EU the active substance of a biosimilar medicinal product – as the general rule – would have the same INN as that of the reference medicinal product.

The European Medicines Agency (EMA) has participated in and contributed to the INN Programme. WHO are considering the possibility of offering an additional codification system to National Regulatory Authorities for biosimilar medicinal product, which could be modelled along the same lines as a codification system recently adopted by TGA in Australia.

The voluntary scheme where a qualifier or code is added to the name of the active substance for biosimilar medicinal products to identify them as biosimilar medicinal products seems be supported by other regions/countries in the INN Programme. If such a voluntary scheme is introduced and taken up by other regions, EU would need to evaluate the impact of that uptake on biosimilar medicinal products use in the Member States. Current EU thinking considers that biosimilar medicinal products should be

closely aligned with their reference products and identification by INN together with a qualifier or code for each biosimilar medicinal product would be contrary to such alignment.

Further discussion on an INN qualifier for Biosimilars will take place on 23 October 2013 in Geneva, Switzerland at the 57th Consultation on International Nonproprietary Names (INN) for Pharmaceutical Substances. Member States are invited to support the current EU thinking at the meeting on 23 October 2013 in Geneva.

During these last years, the pharmacovigilance system has been strongly reinforced in the European Union to ensure an appropriate and unambiguous reporting of adverse events in the EU. The legislation requires identifying clearly any biological medicinal product prescribed, dispensed, or sold which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product and the batch number (Article 102(e) of Directive 2001/83/EC, as amended).
According to Commission Regulation (EU) 520/2012 each individual case safety report has to contain the name of the medicinal product, as defined in Article 1(20) of Directive 2001/83/EC and for biological medicinal products, the batch number.
In addition, the new Commission implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State requests that the brand name appears on the prescription if the prescribed product is a biological medicinal product.

Consequently, the Commission services would be interested to know how the above mentioned provisions of the EU legislation are enforced and what is the experience of the Member States so far with the reporting of adverse events for biological medicinal products, including biosimilar medicinal products.

To this end, the Commission services would like to ask delegates to provide replies to the following questions:
1. When a biological medicinal product is subject to a suspected adverse reaction report, which information do you receive? The branded name and the INN ? Or just the INN ? Are batch numbers systematically reported?
2. Do you experience problems with systematically identifying the biological medicinal product subject to the suspected adverse reaction report?
3. Do you participate to the INN Programme at WHO? Would you support current EU thinking? If not what are the reasons?
4. What is your position on a distinct INN? If a distinct INN was to be introduced by WHO, would you see any impact on substitution of a biological medicinal product? If yes, how do you value this impact?

Action to be taken:

For discussion