EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 656

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **Identification of biological medicinal products - Implementation of Article 102(e) of Directive 2001/84/EC**

Agenda item 2a

Background
The Commission has been approached by the European Biopharmaceutical Enterprises (Ebe) concerning a potential problem with the attribution of adverse reaction reports to the correct biological medicinal product.

During the last meeting of the Pharmaceutical Committee held on 23 October 2013, we asked questions concerning the appropriate identification and traceability of biologicals when adverse events occur and the correct implementation of the provisions vested in Article 102(e) of Directive 2001/83/EC, as amended. This provision stipulates that Member States should take all appropriate measures to identify clearly any biological medicinal product prescribed, dispensed or sold in their territory which is the subject of a suspected adverse reaction report. In general, members of the Pharmaceutical Committee informed the Commission that both branded name and INN are reported, that batch number is often reported (frequency seems to vary between Member States) and that it is not problematic to identify the biological medicinal products which are the subject of adverse reaction reports.

Despite the reassuring answers, Ebe has now sent to the Commission a survey claiming that many Member States have not complied with their obligations under Article 102(e) and have failed to introduce legal provisions or other measures to ensure the identification of biologicals.

Before considering any need for further action, the results of this survey have been shared by email with the concerned Member States prior to the meeting.

The Member States have been invited to complement the information or clarify which legislative, non-legislative and administrative steps have been taken necessary to comply with the obligations regarding the identification of biological medicinal products.

Action to be taken:
For discussion.