



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 729

PHARMACEUTICAL COMMITTEE
27 March 2017

Subject: Report on use of additional monitoring list – experience of Member States

Agenda item 3ii

The concept of additional monitoring was introduced through the 2010 amendment of the pharmaceutical legislation with regard to the requirements on pharmacovigilance related activities¹. These requirements were further amended in 2012².

In accordance with Article 23 of Regulation (EC) No 726/2004 the European Medicines Agency shall make public a list of products subject to additional monitoring.

Article 23(1) of Regulation (EC) No 726/2004 lists the medicinal products which are mandatorily included in the list of products subject to additional monitoring. Whilst, Article 23(1a) provides the possibility for the European Commission or national competent authorities to request the inclusion of medicinal products that are authorised subject to certain conditions to be included in the list.

Article 23(4a) of Regulation (EC) No 726/2004 requires that by 5 June 2018 the Commission shall present to the European Parliament and the Council a report on the use of the additional monitoring list based on the information provided by the Agency and Member States.

To allow for the preparation of the requested report the information from the Member states and the EMA will need to be submitted to the Commission services by December 2017. The Member States are invited to consider how they wish to provide the information to the Commission. Specifically, whether information will be submitted as:

¹ Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1)

² Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38)

- reports from individual Member States, or
- one report compiling the information from all the Member States, or
- one report combining information from all the Member States and the European Medicines Agency.

Action to be taken:

For discussion