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

DG Health and Food Safety

Health and Food Safety

European Commission

Background

The concept of additional monitoring was introduced through the 2010 amendment of the pharmaceutical legislation with regard to the requirements on pharmacovigilance related activities. These requirements were further amended in 2012

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Legislative obligation

Article 23 of Regulation (EC) No 726/2004:

- Establishes the EMA shall make public a list of products subject to additional monitoring (Art. 23(1))
- Identifies the medicinal products which are mandatorily included in the list of products subject to additional monitoring (Art.23(1))
- Provides the possibility for the EC or NCAs to request the inclusion of medicinal products that are authorised subject to certain conditions to be included in the list (Art. 23(1a))
- Requires that by **5 June 2018** the EC 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 EMA and MSs (Art. 23(4a))

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Possible options for providing the information to the Commission:

1. Reports from individual Member States (based on a standard template created and agreed by the Member States)

2. One report compiling the information from all the Member States

3. One report combining information from all the Member States and the European Medicines Agency

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Thank you for your attention

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