EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 756

PHARMACEUTICAL COMMITTEE
8 March 2018

Subject: **Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use**

Agenda item 3iv

According to Art. 86 of Regulation (EC) 726/2004, at least every ten years the Commission shall publish a general report on the experience acquired as a result of the operation of the centralised procedure, mutual recognition procedure and decentralised procedure for medicinal products for human. In addition, according to Art. 38(2) of Directive 2001/83/EC, at least every ten years the Commission shall publish a report on the experience acquired on the basis of the mutual recognition procedure and the decentralised procedure for medicinal products for human use and shall propose any amendments which may be necessary to improve those procedures. The Commission shall submit this report to the European Parliament and to the Council.

The last such report was published by the Commission in January 2010 and it is available on the Commission website.[1]

In order to gather necessary evidence for the next Commission report, the Commission requested an external contractor to conduct a study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use.

The contractor started the work on the study in June 2018 and should deliver the final report within 12 months. The study should cover five "work packages":

1. The European Medicines Regulatory Network
2. Procedures preceding submission of marketing authorisation applications
3. Initial marketing authorisation procedures

[1] http://ec.europa.eu/health//sites/health/files/files/pharmacos/news/emea_final_report_vfrev2.pdf

4. Post-marketing authorisation procedures

5. Support activities.

The scope of the study comprises centralised, decentralised and mutual recognition procedures (except for subjects falling exclusively within the competence of the Member States. Purely national authorisation procedures are excluded from the scope. The study focuses on the period from 2009 to 2017 and only on the medicinal products for human use.

The data and evidence will be collected through documentary review, interviews, surveys and consultations with the key actors (including the EU institutions and national competent authorities) and national case studies.

This external study should enable the Commission to address all the elements required in the legislation and to adopt the final Commission report to the European Parliament and the Council in early 2020.

Action to be taken:
For information