EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Survey to estimate patients and HCP awareness of the additional monitoring concept

Presented by Justina Januskiene, PCWP/HCPWP joint meeting, 27th June 2017

Background

- Article 23 of Regulation (EU) 726/2004 as amended: "*the Agency, in collaboration with the Member States, set up, maintain and make public a list of products subject to additional monitoring* ".
- *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 (Article 23(4a) of Regulation (EC) No 726/2004 as amended).*

Background

Planned content of the report to the EC will consist of information collected from 3 data sources:

1. Member States experience with Additional Monitoring (AM) circulated on the 11th May, responses awaited by 12th June.
2. The results of a survey to estimate patients and HCP awareness of the black triangle and the AM concept;
3. EMA descriptive analysis of the reporting of ADR following the introduction of the black triangle.

The approach has been agreed via TC with the EC, and the EC further consulted with the Pharmaceutical Committee.

Survey addressed to patients and HCPs:

- To evaluate patients and HCPs awareness of the concept of additional monitoring and reporting of ADRs;
- Launch of the survey is foreseen in August/beginning of September 2017, responses by end of September 2017;
- The Agency will summarise the responses and provide them to the EC.

Survey addressed to patients and HCPs:

- Online survey (via ‘EU survey’ tool), about *12* questions;
- One questionnaire with some questions differing by HCP/patient.
- The questionnaire will be pre-tested at EMA;
- Comments from PRAC, EMA medical writers, PCWP and HCPWP;
- As target audience are patients and HCPs across the EU, the survey will be made available in all EU languages;
- Technical possibility to place a link to survey on other websites or to send a link to the survey via email.
- Online survey will be available on the Agency’s web-site.

Thank you for your attention

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**