EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 757

PHARMACEUTICAL COMMITTEE
23 October 2018

Subject: **Commission's Report on Product Information Leaflets and related activities**

Agenda item 3ii

The Commission will present to the Members of the Committee the latest information on the activities related to the Commission's report on the current shortcomings in the summary of products characteristics and package leaflet that was adopted in March 2017[1]. The report identified a number of recommendations on how to improve them in order to better meet the need of patients and healthcare professionals.

EMA Action Plan[2] in November 2017 was prepared on the basis of the Commission report for the implementation of the recommendations of the report with outlined priorities and indicative timelines. The highest priority is given to the activity on electronic product information leaflet formats.

A survey was launched as a follow up for the stakeholders on the initiatives for electronic EU product information[3] in order to explore how electronic/digital means can be used to improve accessibility to medicines' information by patients and healthcare professionals. Based on the mapping exercise results key principles of electronic product information leaflets will be developed together in the multi-stakeholder workshop meeting on 28-29 November 2018.

Action to be taken:
For information

[1] Commission report on product information leaflets
https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf
[2] EMA Action Plan in relations to the Commission report on product information leaflets
https://ec.europa.eu/health/sites/health/files/files/committee/pharm740_3ii_report-on-pil-and-ema-action-plan_0.pdf
[3] EMA survey on the initiatives on electronic/digital formats for the product information leaflets was launched by end of February 2018