EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 650

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **International Pharmaceutical Regulators Forum (IPRF)**

Agenda item 5a

The first full meeting of the International Pharmaceutical Regulators Forum (IPRF) took place in Osaka in November 2013. The report of this meeting as well as the IPRF Terms of Reference and the public statement that was prepared to provide a general overview of IPRF are provided in Annex.

The first part of the meeting was devoted to matters related to the establishment of IPRF: review of Terms of reference, exchange of views on working procedures, logo and website. An interesting exchange took also place on the role and links between IPRF and other international initiatives like ICH or the activities currently developed by the International Generic Drug Pilot (IGDRP). This discussion will need to be pursued in the light of the agreement reached in December 2013 to establish the International Coalition of Medicine Regulatory Authorities (ICMRA) and its project on generics.

The second part of the meeting was devoted to recent regulatory developments in the different members, an update of the ongoing activities that were launched by the Regulators Forum (E6 Discussion Group Gene, Therapy Discussion Group Cell Therapy Discussion Group, Contact list (Safety information, GCP, GMP).

An exchange of views on future topics for IPRF was the third part of the meeting and the main decision taken during this discussion is the establishment of a working group on biosimilars. The Chair and the co-chair of IPRF will propose additional topics on the basis of suggestions by IPRF members. Finally, IPRF members were informed of the ongoing ICH reform and in particular of the new envisaged organisation and membership.

Representatives from the Commission and EMA are participating to IPRF meetings. The next IPRF meeting will take place in Minneapolis, USA, on 2-3 June 2014.

In order to facilitate greater information and involvement of Member States in the representation of the EU in the IPRF, the Commission suggests the creation of a specific IPRF group composed of representatives of Member States and EMA.

This group will:

- have access to all documents prepared in the context of the IPRF through a dedicated collaborative workspace supported by CIRCACB (for more information see https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp);

- be consulted on written contributions from the Commission to the IPRF;

- hold teleconferences in advance of each IPRF meetings as well as, where appropriate, ad hoc teleconferences to discuss important developments in IPRF.

Action to be taken:

For discussion