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PHARMACEUTICAL COMMITTEE
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Subject: **International developments**

Agenda item 5a)

Information from the Commission on the Reform of ICH and the Regulators Forum

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I. ICH Reform

Discussions to reform various aspects of ICH are on-going. The results of the last ICH meeting which took place in November 2012 and agreed actions to be carried out by the next ICH meeting in June 2013 are laid out below.

Governance: the modification of the rules of procedures reviewing the roles of regulators vis a vis industry in the development of ICH guidelines have been adopted. The modifications of the ICH procedures translating the principles which were agreed during the ICH Steering Committee meeting of June 2012 have been adopted. In accordance with these new rules, the development of ICH guidelines is now placed under the supervision of a Regulatory Chair, the agreement of all the industry parties is not needed to initiate or to progress on an ICH topic, and the process of developing an ICH guideline clearly distinguishes a first stage focussed on scientific and technical matters (resulting in a "technical document") and a second stage ("Draft ICH guideline") which is under the sole responsibility of the regulatory ICH Parties.

ICH and globalisation: expansion of ICH membership. All parties accepted to develop criteria for ICH membership with a view to accept gradually new ICH members. There is still, however, a need to find agreement on the actual criteria, timelines etc. DG SANCO advocates the following concepts:

- the six "founding" ICH parties will retain their veto rights;
- Health Canada and EFTA (current observers) will have a similar status as the "founding" members apart from veto right and chairmanship of the expert working groups;

- a new category of membership will be created with as minimum right to have a "seat at the table", the remaining rights and obligations of these members need to be further determined

- WHO (currently observer) and Regulators from countries not qualifying as "ICH member" but still demonstrating some commitment to ICH will have the status of "observer"

- The six founding members + Health Canada and EFTA will be part of a new supervisory body similar to an executive board that will take strategic decisions and decisions on the budget;

- The other ICH activities, notably the adoption of ICH guidelines will take place in a body similar to a general assembly attended by all ICH members and observers

The objective is to finalise this aspect of the reform during the next ICH meeting in June 2013.

Independency of ICH from IFPMA: creation of a legal entity for ICH. At the present time, ICH has no legal entity and is relying on the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to host the ICH secretariat and to sign contracts (acting as a trustee of ICH). The ICH secretariat has put forward a legal analysis indicating that an international "Association" under Swiss law could be a legal entity that would suit the needs of ICH. This form of legal entity is characterised by a very high flexibility (membership, formalities for establishment and operation, funding, etc.).

This aspect of the reform is under analysis within the Commission.

Alternative funding mechanism for ICH activities. At the present time, the costs of the ICH secretariat, the organisation of the bi-annual meetings as well as the participation of some non ICH parties to the Global Cooperation Group is funded by the industry parties. In the first semester of 2012, DG SANCO indicated that alternative mechanisms such as the use of the benefits generated by MedDRA should be considered for making ICH more independent from industry funding. A discussion took place on various scenarios including also possible direct funding by regulators .

Further analysis by the ICH secretariat and the ICH parties is on-going in order to identify the most appropriate mechanisms to address the different financial needs of ICH.

ICH transparency and communication. There is broad consensus amongst ICH parties that, while significant improvements have been achieved, there is still room for improvement of ICH transparency and communication.

The practical measures to meet this objective such as the publication of more documents in an appropriate format are under discussion.

II. Regulators Forum Reform

A preliminary discussion took place on a reform of the Regulators Forum, which is not part of ICH but which meets back to back with the ICH. There is a clear willingness to increase the level of interest of the Regulators Forum by initiating more in-depth

regulatory cooperation in this framework. This discussion has both the potential to meet identified gaps in international regulatory cooperation and bring major strategic partners from emerging countries around the table. The purpose is to build on an existing forum and expand the participation in order to have discussions between regulators at equal footing on identified topics of common interest (not only ICH-related ones). The links between the reformed Regulators Forum and the International Generics Drug Regulator Pilot (IGDRP) would need to be clarified.

The reform of the Regulators Forum will also be discussed during its next meeting in June 2013.

The Member States have been informed of these developments e.g. during the meeting of the Council Working Party on Pharmaceuticals and Medical Devices on 21 February 2013.

Action to be taken:

For information and discussion