EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 686

PHARMACEUTICAL COMMITTEE
17 March 2015

Subject: **International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)**

Agenda item 4a

Goals

Goals for Future of ICH -- to be achieved through the proposed changes to ICH membership and governance

- **Goal 1: Focus global pharmaceutical regulatory harmonization work in one venue**
- **Goal 2: Create a venue that allows all key pharmaceutical regulatory authorities and industry stakeholders the opportunity to be more actively involved in pharmaceutical harmonization work**
- **Goal 3: Maintain efficient and well-managed operations and harmonisation work processes**

Overall, the reform has focused on 4 areas:

- ✓ **Governance and transparency**: focus the role of regulators in ICH and improve transparency and openness of ICH and its processes
- ✓ **International outreach**: increase the involvement of other regulators as well as those global industry sectors that are affected by ICH guidelines
- ✓ **Funding**: identify an alternative funding model that would make ICH less dependent in the future of the current form of industry funding
- ✓ **Legal entity**: set up ICH as a legal entity as continuing activities in the current informal setting will be difficult in the changed environment e.g. with more members

Agreement on new procedures for the adoption of guidelines

As regards the development of guidelines, i.e. the core business of ICH, the enhanced role of regulators has been introduced through the following measures:

- ✓ Decisions to **open a new topic or re-opening an existing guideline** are taken by regulators only in case of absence of consensus with industry.
- ✓ **Regulatory chairs**, in addition to the rapporteur, are appointed in working groups to ensure the integrity of the whole process.
- ✓ The guideline development process is divided into **2 well-distinct parts:**
  (a) development of a technical document (involving industry and regulatory experts), and
  (b) development and adoption of the guideline (under the responsibility of the regulators).

Adoption process

- **ICH Members Rights and Obligations in the WGs:**
  - At *Step 2a* - Parties that have experts in the WG signoff to confirm that the technical document adequately reflects their technical contribution.
  - At *Step 2b* - Regulatory Parties that have experts in the WG sign off. Other regulatory Parties may sign off to endorse the *Step 2b* draft guideline.
  - At *Step 3* - Draft Guideline is subject to "normal wide-ranging regulatory consultation" by regulators in accordance with their internal rules on the development of guidelines.
  - At *Step 4* - Sign-off by the Regulatory Parties agreeing to endorse the guideline.
  - At *Step 5* - Regulatory Parties may implement the new guideline per their national/regional rules.

Transparency

Major improvements regarding transparency of ICH have been achieved by making more information available to the public regarding on-going ICH activities. Notably the following is published on the ICH website:

- ✓ Agendas and minutes of the Steering Committee meetings
- ✓ Work plans of the active expert working groups
- ✓ ICH procedures and a summary of their key elements

Governance under new legal entity

1. Structure

- **ICH Assembly** -- The ICH Management Committee (in previous draft Executive Board) and ICH Members will convene as the ICH Assembly.
- **ICH Management Committee** -- The ICH Management Committee will be in charge of operational matters.

2. Membership

- **ICH Assembly**
  - **ICH Members** -- to include drug regulatory authorities ('DRAs') and regional harmonisation initiatives ('RHIs' as well as international pharmaceutical industry associations, who apply to become an ICH Member and meet the eligibility criteria, subject to approval by the Assembly.
  - **ICH Observers** – **to include primarily future ICH members that are** not (yet) eligible for or interested in becoming ICH Parties.
- **ICH Management Committee** -- to include initially Permanent Members and subsequently also Elected Members.

Competence of the Assembly vs the Management Committee

Assembly:

- Is the overarching body of the Association and takes important decisions, e.g. amendments to the Statutes as well as decisions to adopt ICH guidelines.

Management Committee:

- Its role is to oversee operational aspects on behalf of all members of the Association and the responsibility primarily for administrative and financial matters.
- Its financial tasks include, initially, to ensure the continued funding of ICH operations (budget…) as well as the organisation and preparation of the ICH Assembly meetings.

Membership in the Assembly -- Eligibility criteria for Regulators

- **Engagement in the ICH Process**
  - **Past regular attendance in at least 3 ICH meetings during the previous 2 consecutive years.**
  - **In addition for RHIs: to be able to speak and make commitments on behalf of all its members.**
- **Application of ICH Guidelines**
  - **Having implemented at least the following ICH guidelines upon application for membership:**
    - *Q1: Stability Testing guidelines*
    - *Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*
    - *E6: Good Clinical Practice guideline*
  - **For RHIs: implementation of these three guidelines by all the members of the RHI.**

Membership in the Assembly -- Eligibility criteria for Industry associations

- **Type of organisation**
  - Be a global pharmaceutical industry association representing a global constituency (i.e. may include a global umbrella organisation representing companies that are only active at national level).
- **Engagement in the ICH Process**
  - Evidence of past regular attendance (as interested party or observer) in at least 3 ICH meetings (GC and/or Working Groups) during the previous 2 consecutive years.
- **Impact of ICH Guidelines**
  - The Association and/or its members must be regulated or affected by ICH guidelines.

Summary of the rights/obligations of Observers

Rights of Observers in the Assembly:

- Observers have the right to attend ICH Assembly meetings but no right to participate in the decision-making or to vote and no automatic right to appoint experts in Working Groups
- The current observers in the Steering Committee will be Standing Observers in the Assembly, maintaining their right to appoint experts in WGs.

No obligations are imposed on Observers in the Assembly.

Observers in the Management Committee:

- There will be no observers in the Management Committee, apart from Permanent Observers which are the current observers in the Steering Committee.

Functioning of the Assembly

- **Timing**: as soon as the legal entity has been established, membership in the Assembly will be open to those parties that meet the eligibility criteria.
- **Decision-making is on consensus basis**. Voting only in exceptional cases where consensus cannot be reached. Each member has one vote.
- **Rights/obligations for Members**
  - **Right** to attend ICH Assembly meetings, right to vote and to appoint experts in Working Groups.
  - **Obligation for regulatory members** to commit to implement ICH guidelines (without specific time frame), while submitting a 5-year implementation plan for E2A, E2B, E2D, M1 and M4 guidelines.

Functioning of the Management Committee

Membership: Initially to include as Permanent Members the current members of the Steering Committee and as Permanent Observers the current observers in the SC.

Timing: After two years, and in addition to the Permanent Members, to include Elected Members to be elected by the Assembly from amongst its members.

Eligibility criteria: Similar but somewhat higher than those for Assembly members. Details to be laid down in the Rules of Procedures.

Action to be taken:
For information