



Update on ICH Reforms

Fukuoka June 2015

Goals

Future of ICH regarding 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

The focus of the proposed reform

- **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
- **An Important part of the reform:** Establishing a formal organization with new approach to membership and governance and shared funding among ICH members.

Structure of proposed new legal entity

Establishing a non-profit association under Swiss law

- ❖ Purpose/Objectives
- ❖ Resources
- ❖ Liability
- ❖ Members
- ❖ Assembly Meetings
- ❖ Management Committee
- ❖ Secretariat

Considerations

Legal provisions vs. operating procedures

Proposed ICH Governance and Membership

Two Main Bodies

- Assembly composed of all members
- Management Committee

Membership

- **Assembly**
 - **Members:** regulatory authorities and international pharmaceutical industry associations. There are different categories of members.
 - **Observers:** regulatory authorities and organisations. There are different categories of observers.
- **Management Committee**
 - **Permanent Representatives:** appointed by the current members of the Steering Committee.
 - **Elected Representatives:** appointed by the Assembly.

Proposed Role of the Assembly

- **Overarching body of the Association taking important decisions, such as on the adoption of ICH guidelines.**
- **In addition, the Assembly has competence for example on the following matters:**
 - amendments of the Articles of Association
 - admission or rejection of new Members and Observers
 - appointment of Elected Management Committee Representatives
 - approval of work plans and the annual budget
 - granting discharge to the other bodies of the Association

Proposed Role of the Management Committee

- **Overseeing operational aspects on behalf of all members of the Association with responsibility primarily for administrative and financial matters.**
- **Financial tasks including, initially, to ensure the continued funding of ICH operations (budget...)**
- **Preparation of the Assembly meetings including submission of proposals and recommendations to the Assembly.**

Proposed Membership in the Assembly -- Eligibility criteria for new Regulatory Members

- **Engagement in the ICH Process**
 - Past regular attendance in at least 3 ICH meetings during the previous 2 consecutive years
 - Past appointment of experts in at least 2 Working Groups
- **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*

Proposed Membership in the Assembly -- Eligibility criteria for new Industry Members

- **Type of organisation**
 - International pharmaceutical industry association representing members from several countries in at least 3 continents.
- **Impact of ICH Guidelines**
 - The Association and/or its members must be regulated or affected by ICH guidelines.
- **Engagement in the ICH Process**
 - Past regular attendance (as interested party or observer) in at least 3 ICH meetings (Global Cooperation sessions and/or Working Groups) during the previous 2 consecutive years.
 - Past appointment of experts in at least 2 WGs.

Main Expectations for Regulatory Members

- **Attend the Assembly meetings**
- **Appoint experts in Working Groups**
- **Participate in the decision-making of the Assembly (and vote, if no consensus can be reached)**

And would be expected to:

- **Commit to implement ICH Guidelines**

Main Expectations for Industry Members

- **Attend the Assembly meetings**
- **Appoint experts in Working Groups developing ICH Guidelines which will affect that Member**
- **Participate in the decision-making of the Assembly and vote (except for adoption, amendments and withdrawal of ICH guidelines)**

And would be expected to:

- **Actively support compliance with ICH Guidelines**
- **Appoint experts in at least 1 WG**

Proposed Approach to Observers

3 categories

- **Standing Observers (WHO, IFPMA)**
- **Observers**
- ***Ad-hoc* Observers**

- **Observers may be regulatory authorities or organisations**
 - Limited eligibility criteria for new Observers
- **Expectations for Observers:**
 - Right to attend ICH Assembly meetings but no right to vote and no automatic right to appoint experts in Working Groups.
- **Most of the Regional Harmonisation Initiatives (RHIs) will remain observers as they are unlikely to meet the eligibility criteria for regulatory members**

Proposed Functioning of the Assembly

Opening up of membership

As soon as the legal/formal entity has been established, any party eligible as member can apply for membership. Decisions on membership admission by the Assembly become effective on the date of the decision.

Decision-making is on consensus basis

Voting only in exceptional cases where consensus cannot be reached. Each member has one vote.

Proposal for Management Committee (MC)

Initial Membership

Initially to include Permanent Representatives (appointed by the current members of the Steering Committee) and WHO and IFPMA as Permanent Observers.

Expanding Membership

After two years, and in addition to the Permanent Representatives, to include Elected Representatives to be appointed by the Assembly from amongst its members.

Elected Representatives

Representing up to 4 Regulatory Members and up to 2 Industry Members. Term in office 4 years with possibility of re-election.

Proposed eligibility criteria for Elected Representatives of the MC

Among Regulatory Members, nominees have demonstrated commitment to ICH (prior to nomination for MC election) by:

- **Participating consecutively and regularly in ICH meetings during the previous 4 years.**
- **Appointing experts that have participated in at least 2 WGs.**
- **A good record of implementation of ICH Guidelines.**

Proposed Eligibility criteria for Elected Representatives of the MC

Among Industry Members nominees have demonstrated commitment to ICH (prior to nomination for MC election) by:

- Participating consecutively and regularly in ICH meetings during the previous 4 years.
- Appointing experts that have participated in WGs during the previous 4 years.
- Demonstrating that its industry association membership is affected or regulated by the majority of ICH Guidelines.

Continuing on the Path Forward

- **ICH participants will self-finance attendance in future ICH meetings with an expectation of continuity and stable participation**
- **The funding of ICH operations (secretariat, meetings etc.) will initially be ensured by the Permanent Members of the MC.**
- **Draft Articles of Association are undergoing legal review as required**
- **Targeted completion date for the reform is January 2016**