ICH Reform

Update after one year of operation of the ICH Association (legal entity)

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Harmonisation: ICH Products (2016)

Since the establishment of ICH in 1990, **over 60 Guidelines** have been developed on:

Quality - 23 Guidelines

Safety - 14 Guidelines

Efficacy - 20 Guidelines

Multidisciplinary - 5 Guidelines

Electronic Standards for the Transfer of Regulatory Information (ESTRI, E2B)

CTD/eCTD

MedDRA (standardised medical terminology)

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Focus of Reforms

Governance: Focus the role of regulators in ICH and further distinguish decision-making role of regulators vs. regulated industry

Transparency: Improve transparency and openness of ICH and its processes –provide more on website about ongoing activities and work products

International outreach: Increase the involvement of other regulators as well as those global industry sectors that are affected by ICH guidelines

Legal entity: Set up ICH as a legal entity as continuing activities in the previous informal setting would be difficult with a broader participation

Funding: Identify an alternative funding model that would make ICH less dependent in the future of the previous form of industry funding

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ICH Reform

- The new ICH Association was officially established on October 23, 2015.

- The ICH Association is now known as the "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)." The Articles of Association as well as Rules of Procedures are published on the ICH website.

- The ICH Association is a non-profit legal entity under Swiss Law with the aim to focus global pharmaceutical regulatory harmonisation work in one venue that allows pharmaceutical regulatory authorities and notably concerned industry organisations to be more actively involved in this harmonisation work.

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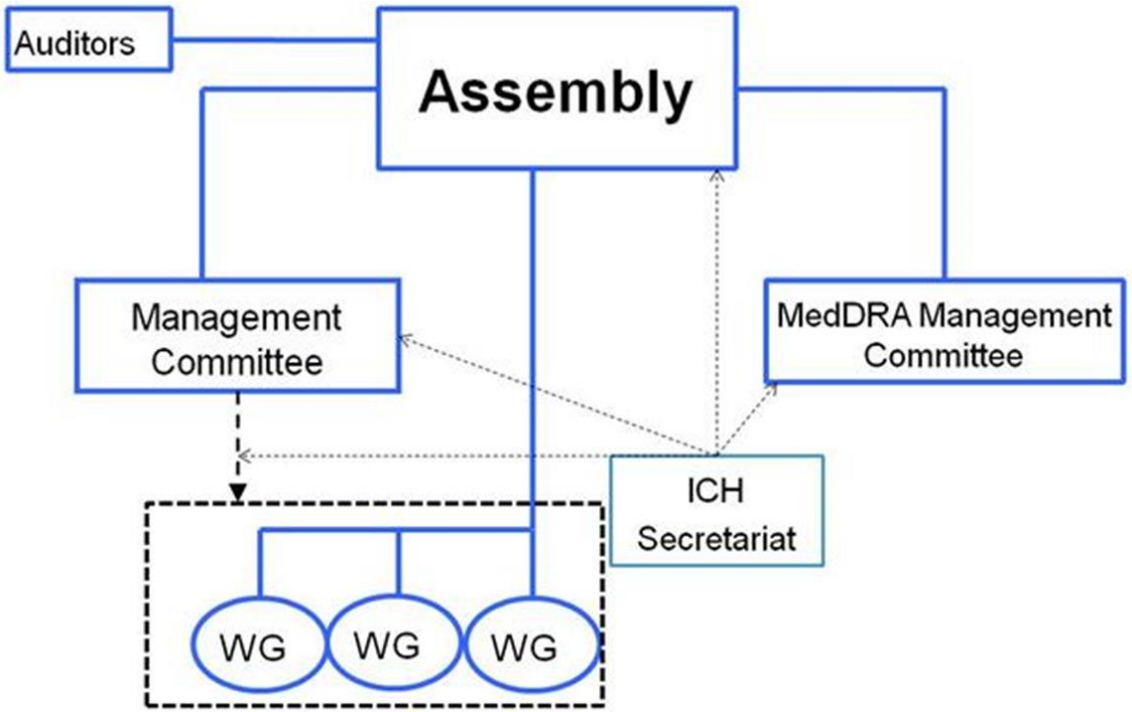
Governance of the ICH Association



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Remit of the Assembly vs. the Management Committee

Assembly is:

- The overarching body of the ICH Association composed of all Members that takes decisions, regarding the Articles of Association, admission of new Members, adoption of ICH Guidelines, etc.

Management Committee is:

- The body that oversees operational aspects on behalf of all members of the Association and has responsibility primarily for administrative and financial matters.
- During a transition period, responsible for the continued funding of ICH operations, and for the oversight of the organization and preparation of the ICH Assembly meetings including oversight of the Working Groups.

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Functioning of the Assembly

- **Decision-making is on consensus basis**
  - Voting only in exceptional cases where consensus cannot be reached. Each member has one vote (with some exceptions, e.g. no voting right for industry members regarding the adoption of final guidelines).

- **Opening up of Membership in the ICH Association**
  - Any party eligible as member/observer can apply for Membership/Observership
  - Decisions on Membership/Observership admission by the Assembly become effective on the date of the decision

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Decision-making relating to ICH Guidelines – role of Assembly and MC

- The Management Committee provides recommendations on new topics for harmonisation as well as on the adoption, withdrawal or amendments of ICH Guidelines.

- ***The Assembly takes decisions***
  - By consensus
  - In the absence of consensus: vote in accordance with the Articles of Association where only Regulatory Members have the right to vote

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Steps in the ICH Process for Guidelines

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Composition of the Assembly

- Members - includes drug regulatory authorities and international pharmaceutical industry associations, who apply to become an ICH Member and meet the eligibility criteria, subject to admission by the Assembly.

- Observers - includes authorities and organizations that are not (or not yet) eligible for or interested in becoming ICH Members

- The Assembly Chair/Vice-Chair are elected from the Regulatory Members for a period of 2 years (current Chair: EC, Vice-Chair: MHLW/PMDA).

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Composition of the Management Committee

- Includes initially (representatives of) Permanent Members and subsequently also Elected Members.
- In addition, there are Permanent Observers (WHO and IFPMA).
- The MC Chair is elected by the Permanent Regulatory Members for a period of 1 year.

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Membership

The Members of the ICH Association are listed below (each Member to appoint up to 2 representatives in the Assembly):

- *Permanent Members*
  - Founding Regulatory Members (EC, MHLW/PMDA, FDA)
  - Founding Industry Members (EFPIA, JPMA, PhRMA)
- *Standing Regulatory Members* (Health Canada, Swissmedic)
- *Regulatory Members*
- *Industry Members* (WSMI, IGBA)

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Observership

The Observers are listed below:

- *Standing Observers* (WHO, IFPMA)
- *Observers:*
  - *RHIs:* APEC, ASEAN, EAC, GCC, PANDRH, SADC
  - *Regulatory authorities* from Australia, Chinese Taipei, India, Korea, Mexico, Russia, Singapore
  - *International organisations:* BIO, CIOMS, EDQM, IPEC, USP
- *Ad-hoc observers*: upon invitation

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ICH Management Committee

Membership categories (each Member to appoint 2 representatives):

- *Permanent Members*
  - Founding Regulatory Members (EC, MHLW/PMDA, FDA)
  - Founding Industry Members (EFPIA, JPMA, PhRMA)
  - Standing Regulatory Members (Health Canada, Swissmedic)
- *Elected Members*
  - At the latest on 1.1.2018, and in addition to the Permanent Members, include up to 6 additional Members (up to 4 Regulators and up to 2 Industry) to be elected by the Assembly from among its Members.

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Membership of the Association— Eligibility Criteria for Regulators

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 certain number of WGs

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

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Membership of the Association— Eligibility Criteria for Industry

Type of Organisation

- Be a global pharmaceutical industry association representing a global constituency

Engagement in the ICH Process

- Past regular attendance (as former ICH Interested Party or observer) in at least 3 ICH meetings (Working Groups) during the previous 2 consecutive years
- Past appointment of experts in certain number of WGs

Impact of ICH Guidelines

- The Association and/or its members must be regulated or affected by ICH Guidelines

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Rights and Duties of Regulatory Members

Rights of Regulatory Members

- Attend the ICH Assembly meetings
- Appoint experts in Working Groups
- Vote in the Assembly (if no consensus)

Main duty of Regulatory Members

- Expectation to implement ICH Guidelines

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Rights and Duties of Industry Members

Rights of Industry Members

- Attend the ICH Assembly meetings
- Appoint experts in Working Groups developing ICH Guidelines which will affect that Member
- Vote in the Assembly with some exceptions, e.g. adoption of ICH Guidelines

Main duty of Industry Members

- Actively support the compliance with ICH Guidelines

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ICH Observers

- Limited eligibility criteria for Observers (as regards organisations, they need to be international)
- Rights of Observers
    - Observers have the right to attend ICH Assembly meetings but no right to vote and no automatic right to appoint experts in Working Groups
    - The former observers in the Steering Committee (WHO and IFPMA) are Standing Observers in the Assembly, maintaining their right to appoint experts in WGs
- No duties are imposed on Observers

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Funding

- ICH Members and Observers commit to self-financed attendance in ICH meetings with an expectation of continuity and stable participation.
- The funding of ICH operations (Secretariat, meetings etc.) is currently ensured by the Permanent Members of the Management Committee.
- The ICH Association shall be funded by membership fees which are payable by all members.
    - The membership fees need to be approved by the Assembly, on the basis of a proposal from the Management Committee.

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Next Steps

- Membership fee proposals are being developed by the Management Committee and are expected to be adopted by the Assembly at the next ICH meeting in Osaka, Japan, in November 2016.
- Once the amount of the memberhip fee has been fixed, there is an expectation of more members joining ICH especially from regulatory authorities from amongst the current observers.
- Strategic topic discussion at the November meeting to identify new topics for harmonisation.

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Thank you for your attention

Visit the website:
www.ich.org

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