A Reformed ICH: Better Equipped for Global Harmonisation and Regulation of Technical Requirements for Medicines

76th Pharmaceutical Committee

28 April 2016

Lenita Lindström-Gommers/European Commission
Chair of the ICH Assembly

Health and Food Safety

Contents

- *Background on ICH*
- *Goals of ICH reform*
- *New ICH structure and governance*

ICH Background

INTERNATIONAL COUNCIL FOR HARMONISATION
of
Technical Requirements
for Pharmaceuticals for Human Use

http://www.ich.org

Hosted by ICH Secretariat
Geneva, Switzerland

Health and Food Safety

ICH Background

- *Unique harmonisation project involving the Regulators and research-based Industries of US, EU and Japan with WHO, IFPMA, Health Canada and EFTA (represented by Swissmedic) as ICH Observers*
  → started in 1990

- *Well-defined objectives:*
  - **To improve efficiency of new drug development and registration process**
  - **To promote public health, prevent duplication of clinical trials in humans and minimise the use of animal testing without compromising safety and effectiveness**

- *Accomplished through the development and implementation of harmonised Guidelines and standards*

ICH Keys to Success

- Involvement of both regulators and industry
- Science-based, consensus driven
- Well managed
- Limited number of players with comparable regulatory and technical capability
- Commitment of regulators to implement products of harmonisation
- A common global platform and tools

ICH Products (in March 2016)

Over 60 Guidelines on technical requirements 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)

ICH Work Products: Harmonised Guidelines (Examples in each area)

Safety	
▪ Carcinogenicity studies	▪ Biotechnology products
▪ Genotoxicity studies	▪ Pharmacology studies
▪ Toxicokinetics and Pharmacokinetics	▪ Immunotoxicology studies
▪ Toxicity testing	▪ Nonclinical evaluation for anticancer pharmaceuticals
▪ Reproductive toxicology	▪ Photosafety evaluation
Efficacy	
▪ Clinical safety	▪ Clinical trials
▪ Clinical study reports	▪ Clinical evaluation by therapeutic category
▪ Dose-response studies	▪ Clinical evaluation
▪ Ethnic factors	▪ Pharmacogenomics
▪ Good clinical practice	
Quality	
▪ Stability	▪ Good manufacturing practice
▪ Analytical validation	▪ Pharmaceutical development
▪ Impurities	▪ Quality risk management
▪ Pharmacopoeias	▪ Pharmaceutical quality system
▪ Quality of biotechnology products	▪ Development and manufacture of drug substances
▪ Specifications	
Multidisciplinary	
▪ MedDRA terminology	▪ Data elements and standards for drug dictionaries
▪ Electronic standards	▪ Gene therapy
▪ Nonclinical safety studies	▪ Genotoxic impurities
▪ CTD and eCTD	

ICH Reform

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

http://www.ich.org/ichnews/press-releases/view/article/ich-announces-organisational-changes-as-it-marks-25-years-of-successful-harmonisation.html

- 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 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.

Focus of Reforms

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

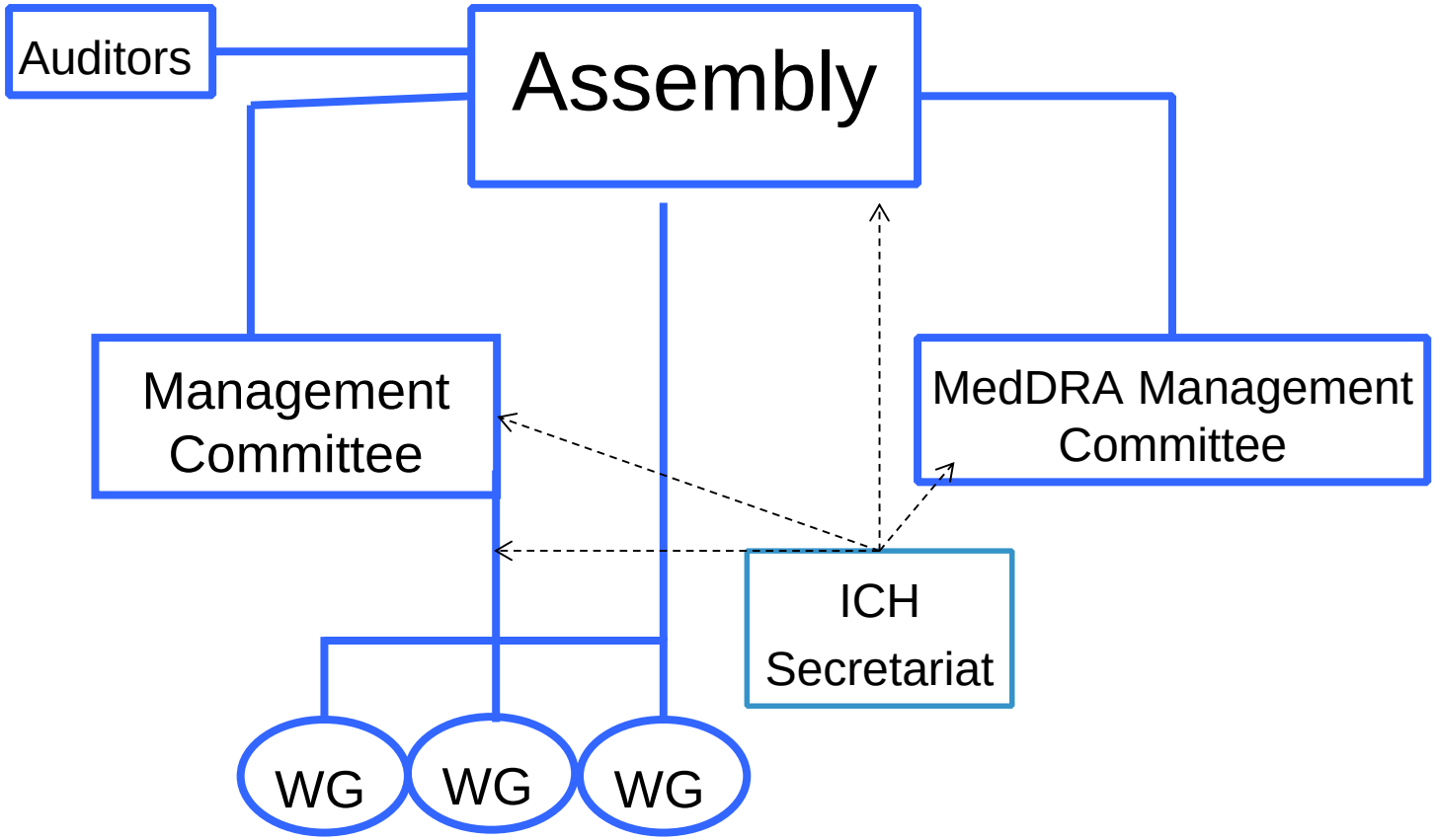
Transparency: Improve transparency and openness of ICH and its processes –provide more on website about ongoing activities and work products

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

Governance of the ICH Association



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.

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.

- **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

Decision-making relating to ICH Guidelines

- 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.

Steps in the ICH Process for Guidelines

Membership in the Assembly and the Management Committee

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

Management Committee

Includes initially (representatives of) Permanent Members and subsequently also Elected Members. In addition, there are Permanent Observers (WHO and IFPMA).

Membership in Management Committee – eligibility criteria for Elected Members

- ***Eligibility for Elected Regulatory Members***
  - Past regular attendance in ICH meetings during the previous 4 years;
  - Past appointment of experts in at least 2 Working Groups;
  - Good record of implementation of ICH Guidelines.

- ***Eligibility for Elected Industry Members***
  - Past regular attendance in ICH meetings during the previous 4 years (or having been an Interested party);
  - Past appointment of experts in WGs during previous 4 years;
  - Regulated by the majority of ICH Guidelines.

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
- 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

Membership in the Assembly— 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

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*

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

ICH Observers

- *Limited eligibility criteria for new Observers*
- *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*

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.) will initially be ensured by the Permanent Members of the Management Committee.
  - This ensures continuation of ICH operations and contributes to a smooth transition allowing time to prepare for introducing membership fees.
  - 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.

Next Steps

- The Articles of Association are finalised and published on the ICH website:

  http://www.ich.org/ichnews/press-releases/view/article/ich-announces-organisational-changes-as-it-marks-25-years-of-successful-harmonisation.html

- Rules of Procedures of the Assembly have been adopted in December 2015 and Rules of Procedures of the Management Committee are expected to be adopted soon.
- Membership/Observership applications have already been submitted which will be assessed by the Management Committee for issuing its recommendation to the Assembly.
- Future membership fee proposals are being developed by the Management Committee.

Thank you for your attention

Visit the website:
www.ich.org