ICH
harmonisation for better health

Overview of ICH and its reform

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Presentation Objectives

- **To provide an overview of ICH and its reform**
- **Explain the governance of the reformed ICH**
  - Structure
  - Membership
  - Guideline Steps

ICH

INTERNATIONAL COUNCIL FOR HARMONIS/ZATION of Technical Requirements for Pharmaceuticals for Human Use

医薬品規制調和国際会議

http://www.ich.org

Hosted by ICH Secretariat
Geneva, Switzerland

ICH Background

- **Unique harmonisation project involving the Regulators and research-based Industries of US, EU and Japan with WHO, Health Canada and EFTA (represented by Swissmedic) as ICH Observers**
  → started in 1990
  - In 2014, promotion of Health Canada and Swissmedic to ICH SC members
- **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 Reform

- ***After many months of negotiation the new ICH Association was officially established during the Inaugural Assembly Meeting 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 new association will now be 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 web-site.***
- ***Under the new structure the ICH will operate as a non-profit legal entity under Swiss Law with the aim to focus global pharmaceutical regulatory harmonization work in one venue.***

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 business 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 current informal setting will be difficult in the changed environment e.g. with more members

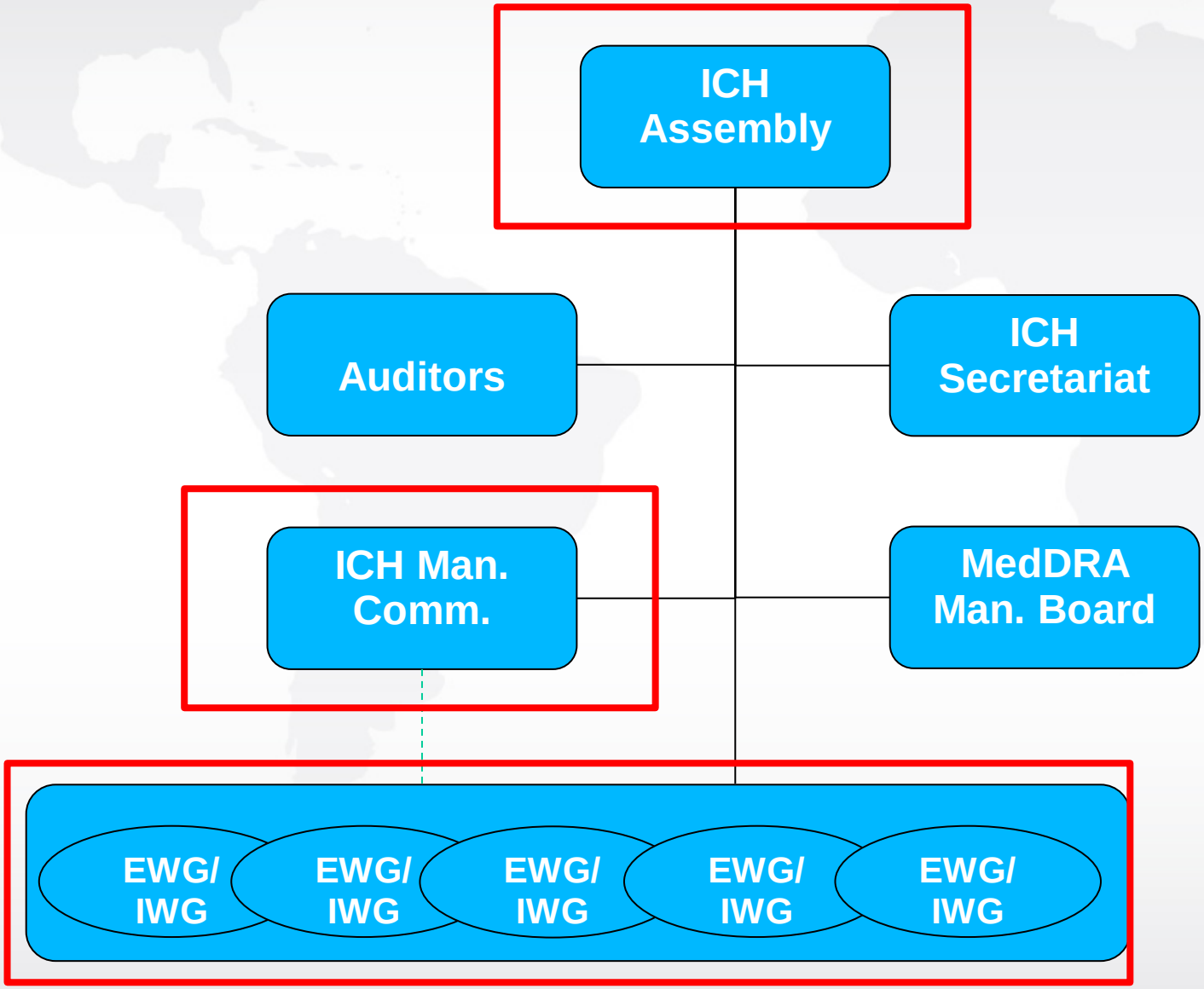
Funding: Identify an alternative funding model that would make ICH less dependent in the future of the current form of industry funding

Earliest reform achieved concerned agreement on procedures for the adoption of guidelines

The enhanced role of regulators has been introduced through the following measures (reflected also in the Articles of Association and which will be reflected in the new rules of procedures to be adopted):

- 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-distinguished parts:** (a) development of a technical document (involving industry and regulatory experts) in ***Step 2a***, and (b) development and adoption of the guideline (under the responsibility of the regulators) in ***Step 2b***

Governance of the ICH Association



Remit of the Assembly vs. the Management Committee

Assembly

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

Management Committee

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

Membership

Assembly

Members -- to include 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 – to include authorities and organizations that are not (or not yet) eligible for or interested in becoming ICH Members

Management Committee

Includes initially Permanent Members and subsequently also Elected Members

Steps in the ICH Process

Before *Step 1* - Adoption of New Topics

- **When ICH party consensus cannot be achieved, the ICH Regulatory Members can jointly decide to adopt the concept paper considering that regulators have the ultimate responsibility to ensure the protection of public health and have the authority for issuing regulatory guidelines.**

Steps in the ICH Process

Expert sign-offs are organised by the ICH Secretariat

ICH Guidelines (including the different steps) are adopted by the Assembly (previously the SC); sign-off only at the level of the WGs

- ***Step 1:***
  - *WG works to prepare a consensus draft of the technical document, based on the objectives set out in the Concept Paper.*
  - *When consensus is reached among all party experts on the technical document, the Topic Leaders in the WG will sign the Step 1 Experts Sign-off sheet.*
- ***Step 2a:***
  - *The Assembly is invited to adopt the technical document under Step 2a of the ICH process.*
- ***Step 2b*:**
  - *On the basis of the Technical Document, the ICH Regulatory Members take the actions they deem necessary to develop the draft Guideline.*
  - *The ICH Regulatory Members are invited at the Assembly to adopt as Step 2b the draft Guideline which is released for public consultation.*

The technical document is made public on the ICH website alongside the draft Guideline.

Expert sign-offs are organised by the ICH Secretariat

Steps in the ICH Process

Cont.

- ***Step 3:***
  - *Regional consultation is conducted by all ICH Regulatory Members and international consultation is conducted by the ICH Secretariat.*
  - *Comments received by each of the ICH Regulatory Members shall be consolidated before provision to the WG.*
  - *Comments received by the Secretariat are consolidated by the WG.*
  - *All comments are considered by the WG and the draft Guideline is revised as appropriate.*
  - *Step 3 is signed-off by the regulatory Topic Leaders once concensus is reached in the WG.*
- ***Step 4:***
  - *The Assembly approves the final document and decision is recorded in the minutes.*
- *Upon reaching Step 2b or Step 4, the Rapporteur shall develop a presentation to be published along the Guideline on the ICH website, as support documentation.*

Steps in the ICH Process

Cont.

- The Management Committee provides **recommendations** on new topics and 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 (simple majority of the Regulatory Members including each Founding Regulatory Member)

Steps in the ICH Process

Expert sign-offs are organised by the ICH Secretariat

- ***Step 5:***
  - *Having reached Step 4, the Guideline enters Step 5 of the ICH process → implementation by the ICH Regulatory Members.*
  - *This step is carried out according to the same national/regional procedures that apply to other regional regulatory guidelines and requirements in that jurisdiction/country/region.*

Responsibilities of Rapporteur & Regulatory Chair

- **Rapporteur:**
  - Organise work of the WG
  - Report to the Assembly* on progress of the WG
- **Regulatory Chair :**
  - Regulatory oversight throughout the process *Steps 1-4*
  - Report to the MC where there are issues to be resolved
- **Regulatory Chair and Rapporteur are complementary**
  - Close collaboration
  - Mutual assistance

Next Steps

- **The Articles of Association are now finalized 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

- **New Rules of Procedures are being developed for both the Assembly and for Management Committee as well as Standard Operating Procedures for the Working Groups (this SOP will replace the current procedures). No major changes are foreseen in respect of the operations of the Working Groups.**

- **Further work will continue in 2016 to implement all the aspects of the ICH reform, including the funding (e.g. introducing membership fees payable by all Members).**

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Thank you for your attention

Visit our websites:
www.ich.org
www.meddra.org

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use