IFPMA

Terms of Reference

First version: 26 June, 2017

IFPMA Engagement in ICH

Background

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.
Since its inception in 1990, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has provided the Secretariat to the ICH organization and participated as a non-voting member of the ICH Steering Committee which oversaw all harmonization activities. IFPMA was also acting as a trustee of ICH.
On October 23, 2015 ICH was established as an international non-profit Association under Swiss law for which IFPMA has been named as a Standing Observer under Article 16 of the ICH Articles of Association and under Article 27(4) as having a right to be a Permanent Observer of the Management Committee.

After more than 25 years of involvement, IFPMA agreed to continue its long-term participation it has had as an Observer to ICH under the following Terms of Reference.

Objectives

In June 2016, at the ICH Assembly Meeting held in Lisbon, Portugal, IFPMA presented to the Assembly its proposed new role in ICH, which consists of providing a global advocacy platform to National Trade Associations (NTAs) that are interested in engaging with ICH as their national authorities become new ICH Regulatory Members; convening a broad and consensus industry voice into ICH; and supporting ICH Guidelines' implementation through outreach and/or training efforts across different regions.

IFPMA contribution is intended to be framed around the following guiding principles:

- Consensus-building and research-based industry parties' alignment beyond the original three ICH regions; and
- Resource efficiency to facilitate global industry coordination.

With the rapid evolution of the regulatory pharmaceutical environment to become more global, and the interest of many new countries to be part of ICH, there is a growing need to ensure the consistent interpretation and implementation of ICH Guidelines amongst industry and regulators globally. IFPMA as a Standing Observer of ICH will play a key role in promoting global convergence towards ICH Regulatory Standards and their harmonized interpretation.

To date, the ICH Assembly and its Management Committee oversee the activities of more than 20 Experts Working Groups (EWGs) for which over 600 experts from ICH regulatory and industry parties, (i.e. EFPIA, JPMA and PhRMA) actively participate. IFPMA will collaborate closely with EFPIA, JPMA and PhRMA in ICH activities to identify any potential gaps and fill those with specific technical expertise/resource from its Member companies and national trade associations (NTA)[1] as their National Regulatory Authority became a new Member of ICH.

[1] Only NTAs which have corresponding regulator members

So far, Industry experts from non-represented ICH regions have not had the possibility to participate at the EWG level. IFPMA as a Standing Observer has a seat to be filled on each of the current EWGs these will be offered to IFPMA NTAs interested in participating in EWGs with its regulatory counterpart, and will ultimately facilitate the implementation of ICH Guidelines at the national level.

Methodology

Assembly and /Management Committee Participation: The IFPMA Director General (DG) and RPTS Vice-Chair, with support of IFPMA Secretariat, will participate in ICH bi-annual meetings (Assembly and Management Committee level) and teleconferences. The RPTS Vice-Chair will provide an update on major decisions to the RPTS Committee following each ICH meeting.

Industry Executive Council* (IEC) Participation: The IFPMA DG and RPTS Vice-Chair, with support of IFPMA Secretariat, will also participate in IEC meetings and teleconferences (* The IEC is composed of ICH Representatives from EFPIA, JPMA and PhRMA).

ICH Training Subcommittee: The IFPMA Secretariat will follow/contribute in the development and the implementation of the ICH Training Strategy in line with RPTS objectives to work towards regulatory system strengthening.

Information Sharing: The IFPMA Secretariat plays a key role in sharing important public information with its Regulatory Committees regarding the organisation of bi-annual ICH Meetings (Meeting Announcement, final Public Agenda and Report, Press Release). In addition, the IFPMA Secretariat will inform its Regulatory Committees and National Trade Associations (NTAs) if requested of any draft ICH Guidelines, or other ICH documents, for public consultation and the proposed process to provide comments.

Expert Working Groups: A call for expert nomination in ICH Expert Working Groups, which are new or at an initial stage of development (*Step 1*), will be made to NTA(s) interested to participate in the development/revision of a Guideline. Current ICH Guidelines under *Step 2* are listed in the annex, under Table 1.

The IFPMA Secretariat will focus on NTAs for which regulatory counterparts are already a Member of ICH as indicated in the Annex, under Table 2.

Proposed Process:

The RPTS Vice-Chair will present IFPMA Terms of Reference to the ICH Management Committee and Assembly at their meeting on 27 May - 1 June 2017, in Montreal, Canada.

The IFPMA Secretariat will draft a letter to inform NTAs of the proposed process and invite them to join an informational webinar organized by the IFPMA Secretariat and the RPTS Vice-Chair in July 2017.

Following the webinar, the IFPMA Secretariat will launch a ‘call for nominations’ for NTA experts in July 2017. The IFPMA Secretariat will create and maintain a Membership list of nominated NTA experts and will inform the ICH Secretariat regularly of any membership updates.

As per the ICH Rules of Procedures under 4.3.6, and as indicated under section 4.1., Standing Observers have the right to appoint a maximum of one (1) Standing Observer expert and one (1)

alternate expert to replace the Standing Observer expert when he/she is not available. Further to Article 16(2)(b), the appointment of experts by the Standing Observers is entirely voluntary and it is the choice of each of them to decide whether to appoint experts and to which EWG. The experts that are appointed to a given EWG should have the necessary and adequate expertise in the area concerned as they are expected to actively contribute to the work of the EWG until the work is completed.

As indicated in the ICH Standard Operating Procedures under 1.5.4., ICH does not cover the cost of travel or accommodation for EWG participants. Participation is at the expense of the expert concerned.

Two scenarios are foreseen:

(1) In the event, that only 1 expert from an NTA expressed interested to participate in an EWG:
- it is proposed that the technical expert will sit in the ICH EWG and represent its own Association.

(2) Alternatively, in the case several NTAs expressed interest to participate in a same EWG, the IFPMA Secretariat will:
- Establish an IFPMA WG on the specific ICH topic;
- Nominate a lead amongst experts who will sit at the ICH EWG and be responsible to consolidate views of all NTAs, in preparation of any TC/meeting and designate an alternate to replace the lead expert when he/she is not available; and
- Participate in face-to-face meetings and convey the position of the different NTAs, provide regular feedback on outcomes of discussions and progress made by the ICH EWG to IFPMA WG and the IFPMA Secretariat.

The lead NTA expert sitting in the ICH EWG should follow the ICH Standard Operating Procedures including its Annex 2 on *Ground Rules for Good Practices of ICH Working Groups.*

Reporting:

The IFPMA Secretariat will be responsible for monitoring expert's participation in ICH EWGs. It is proposed that following each ICH meeting (bi-annually) a short-written report on EWGs activities for which NTAs participates (including any progress/issues) is provided by the lead expert and will be shared with the RPTS and NTAs for information.

Timelines

Process	Timeline
Endorsement of ToRs	May 2017
Presentation at ICH Assembly and MC	June 2017
Inform NTAs*	June 2017
Webinar with NTAs	July 2017
Call for Nomination	August 2017
NTA expert participation in EWGs	September 2017
Report to RPTS meeting	November 2017

*NTAs: As of June 2017, Brazil, China and Korea.

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Review of Terms of Reference

It is proposed that the Terms of Reference are reviewed on an annual basis or as needed. The Annex will be updated bi-annually after each ICH meeting.

Annex (As of June 2018)

Table 1: Current ICH Topics under *Step 2*

ICH Code	Topic	Status
M10	Bioanalytical Method Validation	*Step 1*
M11	Clinical electronic Structured Harmonised Protocol (CeSHarP)	*Concept Paper*
E11A	Paediatric Extrapolation	*Step 1*
E8(R1)	Revision of General Considerations for Clinical Trials	*Step 1*
E17	Multi-regional Clinical Trials – training material	*Step 1*
E19	Optimisation of Safety Data Collection	*Step 1*
Q2/Q14	Analytical Procedure Development and Revision of Q2 (R1) (Quality topic) / Analytical Validation	*Concept Paper*
Q13	Continuous Manufacturing	*Concept Paper*

Table 2: Regulatory Authorities Members of ICH and their Industry Counterparts

Regulatory Authority Member of ICH	Country	Industry Association Member of IFPMA
ANVISA, National Sanitary Surveillance Agency	Brazil	INTERPHARMA
CFDA, China Food and Drug Administration	China	PhIRDA, China Pharmaceutical Innovation and Research Development Association RDPAC, R&D-based Pharmaceutical Association Committee
HSA, Health Sciences Authority	Singapore	SAPI, Singapore Association of Pharmaceutical Industries
MFSD, Ministry of Food and Drug Safety	Korea	KPMA, Korea Pharmaceutical Manufacturers Association KRPIA, Korea Research-based Pharmaceutical Industry Association
TFDA, Chinese Taipei	Chinese Taipei	IRPMA, International Research-Based Pharmaceutical Manufacturers Association

More information is available on the ICH website: http://www.ich.org/home.html

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