



ICH ASSOCIATION
2015 ANNUAL REPORT

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

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ICH Association 2015 Annual Report

(October 23 – December 31, 2015)

Prepared by the Management Committee

With input from the ICH Secretariat

INTRODUCTION

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was established as a non-profit Association under Swiss law on October 23, 2015 (see Annex I for ICH Purpose & Aims). This, the ICH Association's first Annual Report covers the period of October 23 to December 31, 2015 and provides highlights from the Association during this period and describes the key activities undertaken by the Association's bodies: the Assembly; the Management Committee (MC) and the ICH Secretariat.

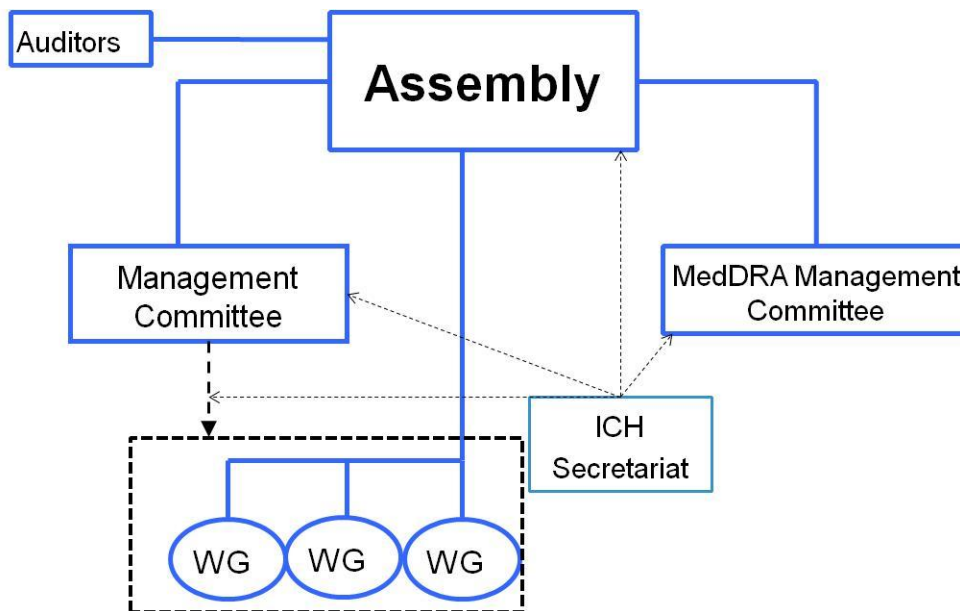


Figure 1: ICH Association Overview

It should be noted that the MedDRA Management Committee (MC), also a body of the Association, was not established in 2015 in view of the fact that MedDRA's ownership had not been transferred from trustee IFPMA to the new ICH Association. However, a summary of the activities of the MedDRA Management Board (MB), which was established under the former International Conference on Harmonisation of Technical Requirements for the Registration of Human Use (ICH), is provided for information.

1. Highlights from the ICH Association in 2015

1.1. ICH Association Establishment

The ICH Association was established at an Inaugural Assembly held virtually on October 23 at which the ICH Articles of Association were adopted by ICH Founding Members who included the following Founding Regulatory Members:

- ✿ the US Food and Drug Administration (FDA);
- ✿ the European Commission (EC);
- ✿ the Ministry of Health, Labour and Welfare of Japan (MHLW) also represented by the Pharmaceuticals and Medical Devices Agency (PMDA).

And the following Founding Industry Members:

- ✿ the Pharmaceutical Research and Manufacturers of America (PhRMA);
- ✿ the European Federation of Pharmaceutical Industries and Associations (EFPIA);
- ✿ the Japan Pharmaceutical Manufacturers Association (JPMA).

Both the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) were named as Standing Observers in the new ICH Association.

Both the ICH Articles of Association and the Minutes of the Inaugural Assembly were published on the ICH website.

1.2. ICH Association Membership & Observership

On October 23, 2016, the Inaugural Assembly endorsed the recommendation of the newly established MC to approve the applications for Standing Regulatory Member received from Health Canada and Swissmedic respectively, with the MC confirming to the Inaugural Assembly that both applicants met the criteria set forth in Article 10(1) of the ICH Articles of Association.

At the first ordinary Assembly meeting, which took place in Jacksonville, Florida, USA on December 9-10, the Assembly welcomed the Regional Harmonisation Initiatives SADC, GCC, PANDRH, APEC, as well as the Drug Regulatory Authority of Brazil (ANVISA) as the first ICH Observers of the Association. Each of these Observers availed of the privilege granted to former Global Cooperation Group members under Article 17(3) of the ICH Articles of Association to automatically become ICH Observers by confirming interest within three months of the establishment of the ICH Association.

1.3. ICH Association Harmonisation Activities

As of December 31, harmonisation activities on **Quality, Safety, Efficacy, and Multidisciplinary** topics were being undertaken by 22 active ICH technical Working Groups (WGs) consisting of Implementation Working Groups (IWGs), Expert Working Groups (EWGs) and Discussion Groups (see Annex II for an Overview of Active WGs as of December 31).

Work was progressed in the period by each of these WGs under the oversight of the MC, and with reporting to the Assembly at its meeting in Jacksonville, Florida, USA on

December 9-10 where 11 of these WGs met face-to-face (see Annex III for the list of WGs which met in Jacksonville).

2. Assembly

2.1. Assembly Members & Observers

The full list of Assembly Member Representatives and Observer delegates as of December 31 is provided in Annex IV.

2.2. Assembly Meetings

The Assembly met twice in the period:

- ✧ *Inaugural Assembly Meeting via teleconference – October 23;*
- ✧ *Ordinary Assembly Meeting in Jacksonville, Florida, USA – December 9 & 10.*

2.3. Assembly Chairmanship

At the Inaugural Assembly on October 23, Mrs. Lenita Lindström-Gommers (EC) and Dr. Toshiyoshi Tominaga (MHLW/PMDA) were elected as the Assembly Chair and Vice-Chair for a term of two years from the date of election in line with Article 23(6) of the ICH Articles of Association.

2.4. Assembly Key Decisions

The following key decisions were taken by the Assembly during the period:

October

- ✧ Adoption of ICH Articles of Association for publication on the ICH website;
- ✧ Approval of the applications of Health Canada and Swissmedic for Standing Regulatory Membership;
- ✧ Agreement that the ICH Secretariat work to identify potential auditors and seek proposals from different audit firms for presentation to the MC;

December

- ✧ Adoption of the Assembly Rules of Procedure for publication on the ICH website;
- ✧ Approval of the 2016 ICH budget;
- ✧ Adoption by the Regulatory Members of the Assembly of *Step 4* for the M8 EWG's Version 4.0 of the *Electronic Common Technical Document (eCTD)*;
- ✧ Adoption by the Regulators Members of the Assembly of *Step 4* for the E14 IWG's revised Question & Answer (Q&A) on *Concentration Response Relationships (CRR)* to the E14 ICH Guideline on *The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug*;
- ✧ Agreement that the E14 IWG revert back to E14/S7B Discussion Group status with experts in clinical (E14) and non-clinical drug development (S7B);
- ✧ Agreement with the change of title the E18 topic from *Genomic Sampling Methodologies for Future Use* to *Genomic Sampling and Management of Genomic Data*;
- ✧ Endorsement by Assembly Members of *Step 2a*, followed by endorsement by the Regulatory Members of the Assembly of *Step 2b* for the E18 EWG's draft ICH Guideline on *Genomic Sampling and Management of Genomic Data*;

- ✧ Endorsement of the M2 EWG on *ESTRI's Glossary of Terms and Abbreviation* document for publication on the ESTRI website;
- ✧ Endorsement for publication on the ICH website of the S1 EWG's modified *Regulatory Notice Document (RND)* in support of work regarding the revision of the S1 ICH Guideline on Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline, in addition to endorsement of the S1 EWG's Status Report;
- ✧ Endorsement of the Q3D EWG's final training modules 0-7 on the Q3 ICH Guideline for *Elemental Impurities*.

3. Management Committee

3.1. Management Committee Members & Observers

The full list of MC Member Representatives and Observer delegates as of December 31 is provided in Annex V.

3.2. Management Committee Meetings

The MC met several times in the period:

- ✧ Inaugural Meeting via teleconference – October 23;
- ✧ Teleconference – November 16;
- ✧ Jacksonville, Florida, USA – December 6-10;

3.3. Management Committee Chairmanship

At the Inaugural MC meeting on October 23, the MC agreed, that until the approval of the Rules of Procedure for the MC, it would implement as an interim measure a rotation system whereby the Chairmanship would rotate every 6 months depending on the location of the meeting, with the Vice Chairmanship similarly rotating every 6 months based on the location of the subsequent meeting. In line with this the Chairmanship in the period was as follows:

- ✧ October 23 - December 10: Dr. Mullen (FDA) – MC Chair; Mrs. Lindström-Gommers (EC) – Vice Chair;
- ✧ December 11 - 31: Mrs. Lindström-Gommers (EC) – Chair; Dr. Toshiyoshi Tominaga (MHLW/PMDA) – Vice Chair.

3.4. Management Committee Main Activities & Key Decisions

During the period the following represented the main activities of the MC:

- ✧ Taking measures to make the new ICH Association became operational;
- ✧ Taking decisions towards ensuring the financing of the ICH Association;
- ✧ Providing oversight and direction to ICH technical Working Groups;
- ✧ Providing oversight and direction to the ICH Secretariat;
- ✧ Contributing the work of the MC Sub-committees established on various topics (see below);
- ✧ Organising the first ordinary ICH Assembly meeting and accompanying ICH technical Working Group meetings in Jacksonville, Florida, USA on 5-10, December.

The following key decisions were taken by the MC during the period:

Operational Matters

- ✧ Agreed the persons entitled to represent the ICH Association vis-à-vis third parties with joint (by two) signatory rights:
 - Mrs. Lenita Lindström-Gommers (EC)
 - Dr. Toshiyoshi Tominaga (MHLW/PMDA)
 - Dr. Dawn Ronan (ICH Secretariat Director)
- ✧ Instructed two of the ICH signatories to jointly enter the ICH Association into a contract for Directors & Officers insurance with an international insurance company (Zurich);
- ✧ Instructed two of the ICH signatories to jointly open a bank account for the ICH Association (UBS);
- ✧ Supported that Health Canada investigate the possibility of hosting the spring 2017 meeting;
- ✧ Established several MC Sub-committees and confirmed the scope of work for each – MC Sub-committees as of December 31 included:
 - Communication Sub-committee
 - Financial Sub-committee
 - Membership Sub-committee
 - Rules of Procedure Sub-committee
 - Training Subcommittee

ICH Secretariat Matters

- ✧ Approved the appointment of Dr. Dawn Ronan as ICH Secretariat Director;
- ✧ Supported that Dr. Petra Doerr (Swissmedic) be appointed as the designated MC Representative to oversee the implementation of the rules laid out in the Employee Handbook for the new independent ICH Secretariat;
- ✧ Agreed that as per the ICH Employee Handbook, key contracts and contracts with a total financial commitment of more than CHF 100,000 would require authorisation sign-off by the MC;
- ✧ Supported that once fully independent, the ICH Secretariat contracts a fiduciary services company to ensure the ICH Association complies with necessary legal and fiscal requirements;
- ✧ Provided direction to the ICH Secretariat regarding communication on the reforms e.g., website, letters etc...

Financial Matters

- ✧ Agreed the proposed membership fees and financial contributions for 2016 when the MC Members will cover the funding of the ICH Association in line with the transition period referred to in Article 59 of the ICH Articles of Association;
- ✧ Supported that the 2016-2018 ICH Budget be shared on the ICH website in the interests of further increasing transparency on ICH;
- ✧ Supported that remaining one-time set-up costs related to legal/fiscal advice be covered by MedDRA funds since the remaining work relates to MedDRA;
- ✧ Supported that MedDRA funds could be used to address any ICH cash flow issues the ICH Secretariat has in 2016 until operations are transferred from IFPMA to the new ICH legal entity after which any MedDRA funds used would be repaid;
- ✧ Supported that the ICH Secretariat proceed with the submission of the FDA Grant Application in December 2015;

Other

- ✧ Provided input on the ICH work arrangement with the APEC Harmonization Center (AHC) for the development of E2 training modules by AHC based on ICH material and supported the establishment of a Review Committee to review the ICH content.

4. ICH Secretariat

4.1. ICH Secretariat Staff

The full list of ICH Secretariat Staff as of December 31 is provided in Annex VI.

4.2. ICH Secretariat Main Activities

During the period the following represented the main activities of the ICH Secretariat:

- ✧ Supported the organisation of the Inaugural Meetings of the Assembly and MC on October 23;
- ✧ Facilitated communication regarding ICH's organisational changes e.g., website, letters etc...;
- ✧ Provided input to the MC Sub-committees which were established on various topics (see above);
- ✧ Supported meetings of the Assembly, MC, WGs, as well as the MedDRA MB in Jacksonville, Florida, USA on December 5-11, including:
 - Provision of logistical support to meeting host, developing schedules, sending invitations etc...;
 - Development of draft agendas and compilation of background documents for the Assembly, MC and MedDRA MB meetings;
 - Development of draft reports of the Assembly and MC;
- ✧ Organised an informational webinar on December 15 for ICH Members and Observers on *Step 2* for the Integrated Addendum to the E6 ICH Guideline on *Good Clinical Practice*;
- ✧ Formatted and published the following documents on the ICH website in December:
 - *Step 2b* Draft E18 ICH Guideline on *Genomic Sampling and Management of Genomic Data*;
 - *Step 4* for the E14 revised Question & Answer (Q&A) on *Concentration Response Relationships (CRR)* to the E14 ICH Guideline on *The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug*;
 - Modified S1 EWG *Regulatory Notice Document (RND)*.
- ✧ Coordinated with the bank (UBS) for the administrative steps for the opening of the ICH bank account in November/December;
- ✧ Coordinated with the insurance company (Zurich) for the taking of the Directors & Officers insurance in November/December;
- ✧ Developed and submitted a Grant Application to FDA in December 2015;
- ✧ Issued invoices for 2016 membership fees in December;
- ✧ Conducted recruitment process for vacant Manager and Administration Officer ICH Secretariat positions in October – December;
- ✧ Coordinated ICH work regarding ICH's tax exemption application and the transfer of ICH assets from trustee IFPMA in October – December;

- ✧ Supported work related to the Call for Tender process for the contract for the MedDRA Maintenance and Support Services Organization in October – December.

5. MedDRA Management Board¹

5.1. MedDRA Management Board Members & Observers

The full list of MedDRA MB Member Representatives and Observer delegates as of December 31 is provided in Annex VII.

5.2. MedDRA Management Board Meetings

The MedDRA MB met:

- ✧ Jacksonville, Florida, USA – December 4-6;

5.3. Main Management Board Activities & Key Decisions

During the period the following represented the main activities of the MedDRA MB:

- ✧ Overseeing the activities of the MedDRA MSSO, including MedDRA development activities and support of MedDRA users – key MSSO activities in the period included:
 - Preparations for the release of a new 27th SOC (System Organ Class) with MedDRA 19.0 in March 2016 named *Product issues*;
 - Release of a new version of the MedDRA Desktop Browser (MDB).
- ✧ Providing oversight and direction to the (ICH) MedDRA Secretariat;

The following key decisions were taken by the MedDRA MB during the period:

- ✧ Approved the 2016 MSSO MedDRA Subscription Rates with no increase over the 2015 Rates;
- ✧ Approved the renewal for another year of the Memorandum of Understanding ICH has (through trustee IFPMA) with the Council for the International Organizations of Medical Sciences (CIOMS) to develop Standardised MedDRA Queries (SMQs).

¹ It should be noted that the MedDRA Management Committee (MC), also a body of the Association, was not established in 2015 in view of the fact that MedDRA's ownership had not been transferred from trustee IFPMA to the new ICH Association. However, a summary of the activities of the MedDRA Management Board (MB), which was established under the former International Conference on Harmonisation of Technical Requirements for the Registration of Human Use (ICH), is provided for information.

Annex I

ICH Association Purpose & Aims

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an international non-profit organisation which was established as an Association under Swiss law on October 23, 2015. The purpose of ICH is to promote public health through international harmonisation of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients, to the prevention of unnecessary duplication of clinical trials in humans, to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner, and to the minimisation of the use of animal testing without compromising safety and effectiveness.

The following summarises ICH's aims:

- ✧ to make recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration and the maintenance of such registrations;
- ✧ to maintain a forum for a constructive dialogue on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonisation of the technical requirements for pharmaceutical products;
- ✧ to contribute to the protection of public health in the interest of patients from an international perspective;
- ✧ to monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data;
- ✧ to avoid divergent future requirements through harmonisation of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
- ✧ to facilitate the adoption of new or improved technical research and development approaches which update or replace current practices;
- ✧ to encourage the implementation and integration of common standards through the dissemination of, the communication of information about and provision of training on, harmonised guidelines and their use.

Annex II

Overview all ICH WGs

December 31, 2015

Topic Code	Type of Working Group	Topic Name	Anticipated Milestones
S1	EWG	Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals	<i>Step 2a/b</i> is expected by November 2017 or 2019
S3A	IWG	Q&A on Note for Guidance on Toxicokinetics	<i>Step 2a/b</i> is expected by February 2016
S5(R3)	EWG	Revision on Detection of Toxicity to Reproduction for Medicinal Products	<i>Step 2a/b</i> is expected by November 2017
S9	IWG	Q&A on Nonclinical Evaluation for Anticancer Pharmaceuticals	<i>Step 2a/b</i> is expected by Q1 2016
S11	EWG	ICH Guideline on Nonclinical Safety Testing in Support of the Development of Paediatric Medicines	<i>Step 2a/b</i> is expected by June 2017
Q3C	EWG	Maintenance of the ICH Guideline for Residual Solvents	<i>Step 4</i> is expected by June 2016
Q3D	IWG	ICH Guideline for Elemental Impurities	Training Package for delivery by Q1 2016
Q11	IWG	Q&A on API Starting Materials	<i>Step 4</i> is expected by Q2/Q3 2016
Q12	EWG	ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	<i>Step 2a/b</i> is expected by June 2017
E6(R2)	EWG	Integrated Addendum to Good Clinical Practice	<i>Step 4</i> is expected by June 2016
E9(R1)	EWG	Addendum to Defining Appropriate Estimand for a Clinical	<i>Step 2a/b</i> is expected by Q4

		Trial/Sensitivity Analyses	2016
E11(R1)	EWG	Addendum to Paediatric Drug Development	<i>Step 2a/b</i> is expected by June 2016
E14	IWG/Discussion Group	Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug	N/A
E17	EWG	ICH Guideline on Multi-Regional Clinical Trials	<i>Step 2a/b</i> is expected by Q1 2016
E18	EWG	ICH Guideline on Genomic Sampling Methodologies	<i>Step 4</i> is expected by June 2017
E2B(R3)	IWG	Revision of Electronic Submission of ICSRs	N/A (Ongoing Activity)
M1	WG	MedDRA Points to Consider	N/A (Ongoing Activity)
M2	EWG	Electronic Standards for the Transfer of Regulatory Information	N/A (Ongoing Activity)
M4E(R2)	EWG	Revision on CTD-Efficacy (Benefit Risk Assessment)	<i>Step 4</i> is expected by June 2016
M4Q(R1)	IWG	Addressing CTD-Q-Related Questions/Change Requests Raised by the M8 EWG/IWG	<i>Step 4</i> is expected by December 2015
M7(R1)	EWG	Addendum to Assessment and Control of DNA Reactive Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	<i>Step 4</i> is expected by Q1/Q2 2016
M8	EWG/IWG	The Electronic Common Technical Document: eCTD	N/A (Ongoing Activity)

Annex III

ICH WGs which met in Jacksonville, Florida, USA

December 5-10, 2015

Topic Code	Type of Working Group	Topic Name	Meeting Days
M2	EWG	Electronic Standards for the Transfer of Regulatory Information	4 days
M8	EWG/IWG	The Electronic Common Technical Document: eCTD	4 days
Q12	EWG	ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	5 days
E9(R1)	EWG	Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses	4 days
E14	DG/IWG	Q&As on the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	4 days
E17	EWG	Multi-Regional Clinical Trials	4 days
E18	EWG	Genomic Sampling Methodologies for Future Use	4 days
S1	EWG	Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals	4 days
S5(R3)	EWG	Revision on Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility	4 days
S9	IWG	Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals	4 days
S11	EWG	ICH Guideline on Nonclinical Safety Testing in support of Development of Paediatric Medicines	4 days

Annex IV

Assembly Member Representatives & Observer delegates

December 31, 2015

Founding Regulatory Members

European Commission (EC)

Mrs. Lenita Lindström-Gommers (Chair)

Dr. Tomas Salmonson

Mr. Sébastien Goux

Ministry of Health, Labour and Welfare of Japan (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Toshiyoshi Tominaga (Vice Chair)

Dr. Nobumasa Nakashima

Mr. Naoyuki Yasuda

US Food and Drug Administration (FDA)

Dr. Theresa Mullin

Ms. Joan Blair

Founding Industry Members

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Mr. Richard Bergström

Dr. Sabine Luik

Japan Pharmaceutical Manufacturers Association (JPMA)

Dr. Hironobu Saito

Dr. Akira Kawahara

Pharmaceutical Research and Manufacturers of America (PhRMA)

Dr. Rajesh Ranganathan

Dr. Peter Honig

Standing Regulatory Members

Swissmedic

Dr. Petra Doerr

Ms. Cordula Landgraf

Health Canada

Ms. Catherine Parker

Standing Observers

WHO

Dr. Lembit Rägo
Mr. Mike Ward

IFPMA

Mr. Eduardo Pisani
Ms. Caroline Mendy

Observers

DRA of Australia

To be confirmed

DRA of Brazil

Ms. Patrícia Pereira Tagliari
Mr. Renato Alencar Porto

Asia-Pacific Economic Cooperation (APEC)

Dr. Young Ju Choi
Dr. Churn-Shiouh Gau

Gulf Cooperation Council (GCC)

Prof. Ibrahim A. Aljuffali

Pan-American Network for Drug Regulatory Harmonization (PANDRH)

Ms. Analía Porrás
Ms. Ana Paula Jucá Silva

Southern African Development Community (SADC)

Mrs. Fortunate Ntombi Fakudze
Mr. Joseph Mthetwa

Annex V

MC Member Representatives & Observer delegates

December 31, 2015

Founding Regulatory Members

European Commission (EC)

Mrs. Lenita Lindström-Gommers

Dr. Tomas Salmonson

Ministry of Health, Labour and Welfare of Japan (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA)

Dr. Nobumasa Nakashima

Mr. Naoyuki Yasuda

US Food and Drug Administration (FDA)

Dr. Theresa Mullin

Ms. Joan Blair

Founding Industry Members

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Mr. Richard Bergström

Dr. Sabine Luik

Japan Pharmaceutical Manufacturers Association (JPMA)

Dr. Hironobu Saito

Dr. Akira Kawahara

Pharmaceutical Research and Manufacturers of America (PhRMA)

Dr. Rajesh Ranganathan

Dr. Peter Honig

Standing Regulatory Members

Swissmedic

Dr. Petra Doerr

Ms. Cordula Landgraf

Health Canada

Ms. Catherine Parker

Dr. Celia Lourenco

Standing Observers

WHO

Dr. Lembit Rägo

Mr. Mike Ward

IFPMA

Mr. Eduardo Pisani

Ms. Caroline Mendy

Annex VI

ICH Secretariat Staff

December 31, 2015

Director

Dr. Dawn Ronan

Manager

Dr. Sarah Adam

Administration Assistant

Ms. Coralie Angulo

Annex VII

MedDRA MB Member Representatives and Observer delegates

December 31, 2015

Regulatory Members

European Commission (EC)

Dr. Sébastien Goux

Dr. Sabine Brosch

Ministry of Health, Labour and Welfare of Japan (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA)

Ms. Kiyomi Ueno

Ms. Yasuko Inokuma

Mr. Daisuke Sato

Mr. Daisuke Inoue

Ms. Yuka Tamura

Dr. Yuki Miyatake

US Food and Drug Administration (FDA)

Ms. MaryAnn Slack

Dr. Daniela Vanco

UK Medicines and Healthcare products Regulatory Agency (MHRA)

Mr. Mick Foy

Health Canada

Dr. Vicky Hogan

Industry Members

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Dr. Hilary Vass

Dr. Christina Winter

Mrs. Claudia Lehmann

Japan Pharmaceutical Manufacturers Association (JPMA)

Mr. Yo Tanaka

Mr. Hisaya Motojima

Pharmaceutical Research and Manufacturers of America (PhRMA)

Dr. Patrick Brady

Dr. Peter K. Honig

Observer

WHO

Dr. Lembit Rägo

Dr. Daisuke Tanaka

IFPMA

Dr. Odette Morin