ICH
harmonisation for better health

INAUGURAL ASSEMBLY OF THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

OCTOBER 23, 2015

FINAL MINUTES

Please find hereafter the final minutes of the Inaugural Assembly of the ICH Association which was held virtually on October 23, 2015 at 13h00 CET.

Yours sincerely,

Dr. Theresa Mullin
Inaugural Assembly Meeting Chair

Ms. Joan Blair
Minute Keeper

List of Attendees

Founding Regulatory Member Representatives

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 Member Representatives

European Federation of Pharmaceutical Industries and Associations (EFPIA)
Mr. Richard Bergström
Mr. Pär Tellner

Japan Pharmaceutical Manufacturers Association (JPMA)
Dr. Hironobu Saito
Dr. Akira Kawahara

Pharmaceutical Research and Manufacturers of America (PhRMA)
Dr. William Chin

Standing Regulatory Member Representatives
(Pronounced during Inaugural Assembly)

Swissmedic
Dr. Petra Doerr

Health Canada
Ms. Catherine Parker

Standing Observer Delegates
(Pronounced during Inaugural Assembly)

WHO
Dr. Lembit Rägo
Mr. Mike Ward

IFPMA
Mr. Eduardo Pisani

Other Attendees

Dr. Sébastien Goux
Dr. Milton Bonelli
Ms. Emer Cooke
Mr. Martin Harvey Allchurch
Mr. Fumihito Takanashi
Ms. Chieko Hirose
Dr. Michelle Limoli
Ms. Amanda Roache
Dr. Celia Lourenco
Mr. Nick Orphanos
Mr. Mitsuo Mihara
Dr. Peter Honig
Dr. Patrick Brady
Dr. Rajesh Ranganathan
Ms. Camille Jackson
Dr. Odette Morin
Dr. Dawn Ronan
Ms. Coralie Angulo
Dr. Nicolas Passadelis

1. Welcome

Dr. Mullin (FDA) welcomed the Founding Regulatory Members and Founding Industry Members, as well as the other attendees to the Inaugural Assembly of the Association of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

2. Election of Inaugural Assembly Meeting Chair and Minute Keeper

The Founding Regulatory Members and Founding Industry Members elected Dr. Mullin (FDA) as the Inaugural Assembly Meeting Chair and Ms. Blair (FDA) as Minute Keeper.

3. Presentation of the aims of the Association

Dr. Mullin (Inaugural Chair, FDA) presented the aims of the ICH Association as follows:

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;

a) 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;

b) to contribute to the protection of public health in the interest of patients from an international perspective;

c) to monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data;

d) 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;

e) to facilitate the adoption of new or improved technical research and development approaches which update or replace current practices;

f) 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; and

g) to develop policy for the ICH Medical Dictionary for Regulatory Activities Terminology (MedDRA) whilst ensuring the scientific and technical maintenance, development and dissemination of MedDRA as a standardised dictionary which facilitates the sharing of regulatory information internationally for medicinal products used by humans.

4. Determination of Founding Regulatory Members and Founding Industry Members present and their valid representation by Representatives

Dr. Mullin (Inaugural Chair, FDA) determined the presence of the three Founding Regulatory Members and three Founding Industry Members and confirmed that each Member was validly represented at the Inaugural Assembly by Representatives who had been confirmed via a written proxy from their respective Member.

The Founding Regulatory Members confirmed their Representatives as follows:

- 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

The Founding Industry Members confirmed their Representatives as follows:

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
  - Mr. Richard Bergström
  - Mr. Pär Tellner

- Japan Pharmaceutical Manufacturers Association (JPMA)
  - Dr. Hironobu Saito
  - Dr. Akira Kawahara

- Pharmaceutical Research and Manufacturers of America (PhRMA)
  - Dr. William Chin

5. Presentation of the Inaugural Assembly Meeting Agenda and possible amendments

Dr. Mullin (Inaugural Chair, FDA) presented the Inaugural Assembly Meeting Agenda which was adopted unanimously without amendment by the Founding Regulatory Members and Founding Industry Members.

6. Adoption of the Articles of ICH Association

Dr. Mullin (Inaugural Chair, FDA) presented the ICH Articles of Association (version dated October 5, 2015) to the Founding Regulatory Members and Founding Industry Members. No further amendments were requested and the Founding Members adopted this version of the Articles unanimously as final.

7. Appointment of the Permanent Management Committee Representatives

Dr. Mullin (Inaugural Chair, FDA) invited the Founding Regulatory Members and Founding Industry Members to each appoint their two Permanent Management Committee (MC) Representatives in line with Articles 8 (3b), 9 (3c) and 28 (1) of the ICH Articles of Association.

The Founding Regulatory Members confirmed the appointment of their MC Representatives as follows:

- 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

The Founding Industry Members confirmed the appointment of their Management Committee Representatives as follows:

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
  - Mr. Richard Bergström
  - Mr. Par Tellner

- Japan Pharmaceutical Manufacturers Association (JPMA)
  - Dr. Hironobu Saito
  - Dr. Akira Kawahara

- Pharmaceutical Research and Manufacturers of America (PhRMA)
  - Dr. Patrick Brady
  - Dr. Peter Honig

Noting the appointment of two Representatives by each of the six Founding Members, Dr. Mullin declared the MC established and pronounced the Permanent MC Representatives and the Members they represent.

Dr. Mullin (Inaugural Chair, FDA) adjourned the Inaugural Assembly at 13h17 CET to allow the Inaugural Management Committee to begin its meeting. The Inaugural Assembly resumed at 13h32 CET.

8. Approval of Standing Regulatory Member admission

The Founding Regulatory Members and Founding Industry Members noted that two applications for Standing Regulatory Membership had been received. One application was from Swissmedic (dated October 12, 2015), and the other application was from Health Canada (dated October 21, 2015).

Dr. Mullin (Inaugural Chair, FDA) in her capacity as the appointed MC Chair submitted to the Inaugural Assembly the MC's recommendation regarding approval or rejection of each application. Dr. Mullin informed the Inaugural Assembly that the MC recommended the approval of both applications and confirmed that both met the criteria set forth in Article 10 (1) of the ICH Articles of Association.

Dr. Mullin asked whether the Inaugural Assembly could support the recommendation of the MC. The Founding Members agreed unanimously to approve the applications of Swissmedic and Health Canada. Dr. Mullin pronounced both Swissmedic and Health Canada as Standing Regulatory Members of the ICH Association.

9. Determination of valid representation of Standing Regulatory Members

Dr. Mullin (Inaugural Chair, FDA) determined the presence of the Standing Regulatory Members and confirmed that each of the Standing Regulatory Members was validly represented at the Inaugural Assembly by Representatives who had been confirmed via a written proxy from their respective Standing Regulatory Member:

- Swissmedic
  - Dr. Petra Doerr
- Health Canada
  - Ms. Catherine Parker

10. Pronouncement of Standing Observers and determination of their valid representation

Dr. Mullin (Inaugural Chair, FDA) pronounced WHO and IFPMA as Standing Observers to the ICH Association in line with Article 16 of the ICH Articles of Association. Dr. Mullin determined the presence of the Standing Observers and confirmed that each of the Standing Observers was validly represented at the Inaugural Assembly by the representatives who had been confirmed via a written proxy from their respective Standing Observer:

- WHO
  - Dr. Lembit Rägo
  - Mr. Mike Ward
- IFPMA
  - Mr. Eduardo Pisani

11. Report on the development of Rules of Procedure for the Assembly

Dr. Mullin (Inaugural Chair, FDA) informed the Inaugural Assembly that the Rules of Procedure for the Assembly were currently under development and would be submitted for approval by the Assembly at its next meeting in Jacksonville, Florida, USA on December 9-10, 2015.

12. Report on procedure and criteria for selection of the Auditors and audit frequency

Dr. Mullin (Inaugural Chair, FDA) informed the Inaugural Assembly that in line with Article 55 of the ICH Articles of Association, the Assembly would need to appoint an auditing firm as Auditors for a period of two years. As per Article 56, the Auditors would be responsible to audit the financial statements of the Association upon conclusion of each Fiscal Year.

Dr. Mullin highlighted that the Auditors would need to be knowledgeable in Swiss law and Swiss accountancy principles as they would have responsibility to ensure that the accounting of the Association complies with the requirements of these.

The Members supported that the ICH Secretariat be tasked to identify potential auditors and seek proposals from different audit firms for presentation to the MC. The MC would then make a recommendation to the Assembly regarding appointment of an auditing firm.

13. Report on the status of the procedure for obtaining tax exemption for the ICH Association

Dr. Mullin (Inaugural Chair, FDA) highlighted that as per Article 2 (2) of the ICH Articles of Association, the ICH Association is a non-profit organisation. In view of this, Dr. Mullin confirmed that a request would be made to the relevant Swiss tax authorities for the Association to be granted a tax exemption.

Dr. Mullin informed the Inaugural Assembly that the ICH Secretariat was working with the assistance of a fiscal advisor to progress this request. The Inaugural Assembly noted that the timeframe for a ruling from the tax authorities could be in the range of several months.

14. Report on the status of the procedure for transferring the assets from IFPMA to the ICH Association

Dr. Mullin (Inaugural Chair, FDA) informed the Inaugural Assembly that there was work on legal and fiscal aspects which needed to be completed before the assets can be transferred from IFPMA (as the trustee of the Steering Committee of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) to the new ICH Association. The Inaugural Assembly noted that the asset transfer was expected to be completed in early 2016.

15. Election of the Chair and Vice-Chair of the Assembly

Dr. Mullin (Inaugural Chair, FDA) noted the names of the persons nominated by the Founding Regulatory, Founding Industry and Standing Regulatory Members to be elected as Chair and Vice-Chair of the Assembly. Dr. Mullin confirmed that these persons were eligible pursuant to Article 23 (6) of the ICH Articles of Association which states that only Founding Regulatory Members, Standing Regulatory Members or Regulatory Members of the MC are eligible to serve as Chair. And only Founding Regulatory Members, Standing Regulatory Members or Regulatory Members of the Assembly are eligible to serve as Vice-Chair of the Assembly.

Dr Mullin presented Mrs. Lindström-Gommers (EC) as the nominee for the position of Assembly Chair and Dr Toshiyoshi Tominaga (MHLW/PMDA) as the nominee for the position of Vice-Chair. No additional nominees were put forward at the inaugural Assembly meeting.

In line with Article 25 (8) of the ICH Articles of Association, Dr. Mullin invited the Members to each anonymously confirm their choice of Chair and Vice-Chair using the links provided to the online polling tool. The poll for the Chair was conducted first and Mrs. Lenita Lindström-Gommers (EC) was elected unanimously. The poll for the Vice-Chair was subsequently conducted and Dr. Toshiyoshi Tominaga (MHLW/PMDA) was elected unanimously.

Dr. Mullin pronounced Mrs. Lenita Lindström-Gommers (EC) and Dr. Toshiyoshi Tominaga (MHLW/PMDA) as the elected Chair and Vice-Chair and confirmed that their term would be for two years from the date of election in line with Article 23 (6) of the ICH Articles of Association.

Dr. Mullin noted that since the US is the host Member country for the next Assembly, she on behalf of FDA, would be pleased to serve as Associate Vice-Chair for that meeting in line with Article 23(6) of the ICH Articles of Association.

All members unanimously agreed to elect Dr. Mullin as the Associate Vice-Chair for the Assembly meeting in Jacksonville.

16. Approval of the Press Release

Dr. Mullin (Inaugural Chair, FDA) presented the Draft Press Release which had been developed to announce the establishment of the ICH Association. Dr. Mullin invited any amendments.

All Members confirmed their approval of the Press Release for publication on the ICH public website (www.ich.org) and circulation to ICH contacts.

The Assembly confirmed that the press release should be issued on Monday, October 26, 2015 at 9h00 CET.

Ms. Cooke (EC) inquired if the names of the Management Committee should be included in the press release. Dr. Mullin proposed that a roster be provided on the ICH website. All parties unanimously agreed that the roster of the Members of the Inaugural Assembly and the Permanent Management Committee Representatives should be available and accessible on the ICH website. The ICH Secretariat Director confirmed that this list would be updated on the ICH website.

17. Miscellaneous

18. Approval of the Inaugural Assembly Meeting Minutes

Dr. Mullin (Inaugural Chair, FDA) informed the Inaugural Assembly that the Meeting Minutes would be circulated within the next few hours for approval or any amendments from the Assembly Members. All of the Members confirmed that any revisions to the minutes would be provided by 12h00 CET on Monday, October 26, 2015. Dr. Mullin noted that the minutes once approved by all Members would be signed by Dr. Mullin as the Inaugural Assembly Chair and Ms. Blair as the Minute Keeper.

All parties unanimously agreed that the final approved minutes from the ICH Inaugural Assembly should be published and made publicly available with the ICH Articles of Association.

The Inaugural Assembly Meeting concluded at 13h59 CET.