Approved by the Assembly on 18 November 2020

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ARTICLES OF ASSOCIATION

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I. GENERAL PROVISIONS

Article 1

Name and Domicile

1. An association has been established in accordance with these Articles of Association and Art. 60 et seq. of the Swiss Civil Code (hereinafter "Association").

2. The official name of the Association is "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use". The official abbreviation of the name of the Association is "ICH".

3. The domicile of the Association is Geneva, Switzerland. The Association performs its activities at a world-wide level. The working language of the Association is English.

Article 2

Purpose

1. The purpose of the Association 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.

2. The Association is an international non-profit organisation and does not pursue any commercial purposes. Notwithstanding the absence of a commercial purpose, the Association can engage in commercial activities solely in order to promote its overall purpose and facilitate the tasks and aims set out hereafter. The income and assets of the Association are exclusively and irrevocably assigned to its purpose as set out in these Articles.

Article 3

Tasks and Aims

The Association has the following tasks and aims:

a) 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;

b) 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;

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

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

e) 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;

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

g) to encourage the adequate implementation and integration of common standards through the dissemination of, the communication of information about and coordination of training on, harmonised guidelines and their use; and

h) 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.

Article 4

Cooperation with other organisations

The Association may enter into cooperation with other organisations. Cooperation requiring the Association to enter into an agreement or an exchange of letters with another organisation shall be proposed by the Management Committee and approved by the Assembly.

Article 5

Duration

The Association will exist for an indefinite period of time.

Article 6

Fiscal Year

The fiscal year of the Association shall begin on January 1 and end on December 31 of each calendar year (hereinafter "Fiscal Year").

II. MEMBERSHIP

Article 7

Categories of Membership

1. There are five categories of membership of the Association. These categories of membership are:

(a) Founding Regulatory Members;

(b) Founding Industry Members;

(c) Standing Regulatory Members;

(d) Regulatory Members;

(e) Industry Members.

2. The Founding Regulatory Members, Founding Industry Members, Standing Regulatory Members, Regulatory Members and Industry Members are hereinafter referred to individually, as "*Member*" or, collectively, as "*Members*".

Article 8

Founding Regulatory Members

1. The Founding Regulatory Members of the Association are:

(a) the European Commission (EC);

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

(c) the US Food and Drug Administration (FDA).

2. The Founding Regulatory Members have the right to vote in the Assembly in accordance with the applicable Rules of Procedures.

3. The Founding Regulatory Members shall:

(a) attend the meetings of the Assembly;

(b) appoint two (2) Permanent Management Committee Representatives;

(c) have the right to appoint up to two (2) MedDRA Management Committee Representatives;

(d) appoint experts in all Working Groups;

(e) serve and support the aims of the Association;

(f) act in good faith when exercising their rights.

4. The Founding Regulatory Members are expected to implement all ICH Guidelines in accordance with the applicable Rules of Procedures.

Article 9

Founding Industry Members

1. The Founding Industry Members of the Association are:

(a) the European Federation of Pharmaceutical Industries and Associations (EFPIA);

(b) the Japan Pharmaceutical Manufacturers Association (JPMA);

(c) the Pharmaceutical Research and Manufacturers of America (PhRMA).

2. The Founding Industry Members have the right to:

   (a) vote in the Assembly with the exception of decisions on the selection of topics for ICH Guidelines and the adoption, amendment or withdrawal of ICH Guidelines and in accordance with the applicable Rules of Procedures;

   (b) appoint experts in all Working Groups.

3. The Founding Industry Members shall:

   (a) attend the meetings of the Assembly;

   (b) actively support and encourage the compliance by the Founding Industry Member and/or its affiliated members with the ICH Guidelines;

   (c) appoint two (2) Permanent Management Committee Representatives;

   (d) have the right to appoint up to two (2) MedDRA Management Committee Representatives;

   (e) serve and support the aims of the Association;

   (f) act in good faith when exercising their rights.

Article 10

Standing Regulatory Members

1. A legislative or administrative authority of any jurisdiction is eligible to become a Standing Regulatory Member if it can demonstrate that it:

   (a) has the responsibility for the regulation of pharmaceutical products for human use; and

   (b) has been a member of the Steering Committee of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association.

2. The Standing Regulatory Members have the right to:

   (a) vote in the Assembly in accordance with the applicable Rules of Procedures;

   (b) appoint experts in all Working Groups.

3. The Standing Regulatory Members shall:

   (a) attend the meetings of the Assembly;

   (b) appoint two (2) Permanent Management Committee Representatives;

   (c) have the right to appoint up to two (2) MedDRA Management Committee Representatives;

   (d) serve and support the aims of the Association;

   (e) act in good faith when exercising their rights.

4. The Standing Regulatory Members are expected to implement all ICH Guidelines in accordance with the applicable Rules of Procedures.

Article 11

Regulatory Members

1. A legislative or administrative authority of any jurisdiction is eligible to become a Regulatory Member if it can demonstrate that it:

   (a) has legal personality;

   (b) has the responsibility for the regulation of pharmaceutical products for human use;

   (c) has during the previous two (2) consecutive years prior to the application for membership participated in at least three (3) Assembly meetings or meetings held by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association;

   (d) has appointed experts in at least two (2) Working Groups of the Association or International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association and that the appointed experts have participated in the meetings of at least two (2) Working Groups; and

   (e) is not represented in ICH by a Regional Harmonisation Initiative that is a Regulatory Member of ICH.

   Such authority is expected to have implemented the ICH Q1, ICH Q7 and ICH E6 Guidelines in accordance with the applicable Rules of Procedures.

   Notwithstanding this Article 11(1), paragraph 1, point (c) and (d) and paragraph 2, if a legislative or administrative authority of a jurisdiction has participated as an Observer in at least one (1) Assembly meeting and has implemented a high proportion of ICH Guidelines, that Observer is eligible to become a Regulatory Member under an expedited procedure in accordance with the applicable Rules of Procedures.

2. A Regional Harmonisation Initiative is eligible to become a Regulatory Member if it can demonstrate that it:

   (a) has legal personality;

   (b) comprises legislative or administrative authorities of any jurisdiction with responsibility for the regulation of pharmaceutical products for human use;

   (c) is represented by one legislative or administrative authority of a jurisdiction or the secretariat of such Regional Harmonisation Initiative;

   (d) has participated during the last two (2) consecutive years prior to the application for membership in at least three (3) Assembly meetings or meetings held by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association;

   (e) has appointed experts in at least two (2) Working Groups of the Association or International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association and that the appointed experts have participated in the meetings of at least two (2) Working Groups;

   (f) can make commitments and can speak on behalf of all its members; and

(g) is intended to be the sole Regulatory Member of its region in ICH and that none of the individual members of the Regional Harmonisation Initiative are intended to be concomitantly Members or remain Observers in the long term in ICH, in accordance with the applicable Rules of Procedures.

All the members of the Regional Harmonisation Initiative are expected to have implemented the ICH Q1, ICH Q7 and ICH E6 Guidelines in accordance with the applicable Rules of Procedures.

Notwithstanding this Article 11(2), paragraph 1, point (d) and (e) and paragraph 2, if a Regional Harmonisation Initiative has participated as an Observer in at least one (1) Assembly meeting and has implemented a high proportion of ICH Guidelines, that Observer is eligible to become a Regulatory Member under an expedited procedure in accordance with the applicable Rules of Procedures.

3. The Regulatory Members have the right to:

(a) attend the meetings of the Assembly;

(b) vote in the Assembly in accordance with the applicable Rules of Procedures;

(c) propose two (2) Elected Management Committee Representatives provided the criteria under Article 30 are met;

(d) appoint experts to Working Groups in accordance with the applicable Rules of Procedures.

4. The Regulatory Members shall:

(a) serve and support the aims of the Association;

(b) act in good faith when exercising their rights.

5. The Regulatory Members are expected to implement ICH Guidelines in the future in accordance with the applicable Rules of Procedures.

Article 12

Industry Members

1. An international organisation representing the industry of pharmaceutical products for human use is eligible to join the Association as an Industry Member provided this organisation can demonstrate that:

(a) it has legal personality;

(b) it represents members from several countries in at least three continents;

(c) it or its members are regulated or affected by all or some ICH Guidelines;

(d) it has been an Observer to the Association or an Interested Party as defined prior to the establishment of the Association and has participated during the last two (2) consecutive years prior to the application for membership in at least three (3) Assembly meetings or meetings held by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association;

(e) it has appointed experts in at least two (2) Working Groups of the Association or of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association and that the appointed experts have participated in the meetings of at least two (2) Working Groups.

2. The Industry Members have the right to:

(a) attend the meetings of the Assembly;

(b) vote in the Assembly with the exception of decisions on the selection of topics for ICH Guidelines and the adoption, amendment or withdrawal of ICH Guidelines and in accordance with the applicable Rules of Procedures;

(c) propose two (2) Elected Management Committee Representatives provided the criteria under Article 31 are met;

(d) in accordance with the applicable Rules of Procedures appoint experts to those Working Groups that are developing ICH Guidelines which will affect the Industry Members or its affiliated members or ICH Guidelines that the Industry Member or its affiliated members will be regulated by.

3. The Industry Members shall:

(a) actively support and encourage the compliance with the ICH Guidelines that the Industry Member or its affiliated members are regulated or affected by;

(b) appoint experts in at least one (1) Working Group that is developing an ICH Guideline by which the Industry Member or its affiliated members would be regulated or affected by;

(c) serve and support the aims of the Association;

(d) act in good faith when exercising their rights.

Article 13

Membership Admission

1. Any party eligible as a Member in accordance with Articles 10, 11 and 12 can apply for membership in writing to the ICH Secretariat.

2. The Management Committee shall review all membership applications and submit to the Assembly a recommendation for approval or rejection of each membership application.

3. The Assembly shall take a decision on the membership admission in accordance with the applicable Rules of Procedure. The Assembly shall decide on admission of membership in its discretion without indicating any reasons.

4. Decisions on membership admissions become effective on the date of the decision taken by the Assembly.

Article 14

Termination of Membership

1. The membership shall terminate by voluntary withdrawal and by exclusion. Any Member may withdraw from the Association at any time with effect on the end of any Fiscal Year as per the process specified in the Rules of Procedures. A Member withdrawing from the Association shall have no claim whatsoever to the assets of the Association or the reimbursement of any membership fee.

2. The Assembly may, after consultation of the Management Committee, exclude a Member from the Association if the Member has continuously failed to comply with its responsibilities as a Member or through its actions or behaviour seriously impairs the proper functioning or reputation of the Association. A Member having been excluded from the Association shall have no claim whatsoever to the assets of the Association or the reimbursement of any membership fee.

3. The exclusion of a Member shall become effective on the date of the decision taken by the Assembly. Re-application for membership is permissible.

III. OBSERVERSHIP

Article 15

Categories of Observership

1. There are three categories of observership of the Association. These categories of observership are:
   (a) Standing Observers;
   (b) Observers;
   (c) Ad-hoc Observers.

Article 16

Standing Observers

1. The Standing Observers of the Association are:
   (a) the World Health Organization (WHO);
   (b) the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

2. The Standing Observers have the right to:
   (a) attend the meetings of the Assembly and the Management Committee without any voting rights;
   (b) appoint experts to Working Groups;
   (c) exercise any additional rights granted to them in the applicable Rules of Procedures.

3. Standing Observers may nominate up to two (2) delegates to attend Assembly meetings.

Article 17

Observers

1. The following parties are eligible as Observers to the Association:
   (a) legislative or administrative authorities of any jurisdiction, supranational bodies or international organisations with responsibility for the regulation of pharmaceutical products for human use on the basis of their contribution or benefit to ICH, in accordance with the applicable Rules of Procedures;
   (b) Regional Harmonisation Initiatives representing legislative or administrative authorities of any jurisdiction with responsibility for the regulation of pharmaceutical products for human use on the basis of their contribution or benefit to ICH, in accordance with the applicable Rules of Procedures;
   (c) International pharmaceutical industry organisations that are not yet eligible to become Industry Members, but that fulfil the eligibility criteria referred to in Article 12(1) (a), (b) and (c) provided that the organisation or its members or constituents are not already represented by other Members or Observers in ICH, in accordance with the applicable Rules of Procedures;
   (d) International organisations that are represented at a global level, whose work and/or membership is regulated or affected by ICH Guideline(s) on the basis of their contribution or benefit to ICH provided that the organisation or its members or constituents are not already represented by other Members or Observers in ICH, in accordance with the applicable Rules of Procedures.

2. Observers have the right to attend the meetings of the Assembly without voting rights. They may nominate one (1) delegate and one (1) alternate delegate to replace the delegate when he/she is unavailable to attend Assembly meetings.

3. Observers have the right to appoint experts in Working Groups following a positive decision of the Management Committee in accordance with the Rules of Procedures.

Article 18

Ad-hoc Observers

1. The Assembly or the Management Committee may decide to invite a reasonable number of parties to attend an Assembly meeting as an Ad-hoc Observer. Decisions to invite a party to an Assembly meeting shall become effective on the date of the decision taken by the Assembly or the Management Committee.

2. Ad-hoc Observers have the right to attend those meetings of the Assembly to which they have been invited by the Assembly or the Management Committee without any voting rights. They may nominate one (1) delegate to attend Assembly meetings.

Article 19

Observership Admission

1. Any party eligible as an Observer can apply for admission in writing to the ICH Secretariat. The Management Committee shall review all such applications and submit to the Assembly a recommendation for approval or rejection of each application. The Assembly shall take a decision on observership admission in accordance with the applicable Rules of Procedure. Decisions on observership admissions shall become effective on the date of the decision taken by the Assembly.

2. The Parties eligible as Observers in accordance with Article 17 paragraph 1 which have been members of the Global Cooperation of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use immediately prior to the establishment of the Association are exempt from applying for observership admission and shall become Observers immediately after the establishment of the Association provided they submit a confirmation letter to the ICH Secretariat within three (3) months of the establishment of the Association. The observership shall become effective upon the receipt of the confirmation letter.

Article 20

Termination of Observership

1. The observership of Standing Observers and Observers shall terminate by voluntary withdrawal or by exclusion.

2. Any Standing Observer and Observer may withdraw from the Association at any time with effect on the end of any Fiscal Year by prior written six (6) months' notice to that effect to the ICH Secretariat.

3. The Assembly may, after consultation of the Management Committee, exclude a Standing Observer, or an Observer from the Association in case the Standing Observer, or Observer through their actions or behaviour seriously impairs the proper functioning or reputation of the Association.

4. The exclusion of a Standing Observer or an Observer shall become effective on the date of the decision taken by the Assembly. Re-application for observership is permissible.

IV. ORGANISATION

Article 21

Bodies of the Association

The bodies of the Association are:

(a) the Assembly;

(b) the Management Committee;

(c) the MedDRA Management Committee;

(d) the ICH Secretariat;

(e) the Auditors.

A. Assembly

Article 22

Composition

The Assembly consists of all Members of the Association.

Article 23

Competencies

1. The Assembly is the overarching body of the Association. The Assembly shall adopt decisions in particular on the following matters:

   (a) adoption and amendments of the Articles of Association;

   (b) adoption and amendment of Rules of Procedures of the Assembly;

   (c) approval or rejection of membership admission;

   (d) approval or rejection of observership admission;

   (e) exclusion of Members;

   (f) exclusion of Standing Observers and Observers;

   (g) appointment of Elected Management Committee Representatives;

   (h) dismissal of Permanent Management Committee Representatives and Elected Management Committee Representatives;

   (i) appointment and dismissal of the Auditors;

   (j) approval of the Management Committee annual report on the activities of the Association;

   (k) approval of the activities undertaken by the other bodies of the Association (discharge);

   (l) dissolution of the Association;

   (m) approval of membership fees or financial means to be raised and that are payable by all Members which will end the transition period referred to in Article 60;

   (n) approval of the annual work plan and a multi-annual strategic plan of the Association:

   (o) approval of the audited annual accounts of the Association;

   (p) approval of the Association's annual budget for the next Fiscal Year;

   (q) approval of the annual work plan of the MedDRA Management Committee, the annual budget for MedDRA, the annual report on the activities regarding MedDRA, and approval of policy relating to MedDRA;

   (r) approval of new topic(s) for ICH Guidelines or adoption, amendment or withdrawal of ICH

Guidelines;

(s) approval of cooperation between the Association and other organisations; and

(t) any other issues explicitly reserved for decision by the Assembly pursuant to these Articles of Association.

Article 24

Meetings of the Assembly

1. At least one ordinary meeting of the Assembly shall be held per calendar year. Additional ordinary meetings of the Assembly shall be called upon by decision of the Management Committee. In extraordinary circumstances where the decision to replace a face-to-face meeting with a virtual meeting is taken less than three (3) months before the date on which the face-to-face meeting was scheduled to commence, the date and duration of the virtual meeting shall be notified at least one (1) month in advance of the date on which the face-to-face meeting was scheduled to commence in line with the applicable Rules of Procedure.

2. The place, date and duration of a face-to-face meeting shall be determined by the Management Committee and notified to the Members, Standing Observers and Observers at least three (3) months in advance of the date on which the meeting is scheduled to commence. In extraordinary circumstances where the decision to replace a face-to-face meeting with a virtual meeting is taken less than 3 months before the date on which the face-to-face meeting was scheduled to commence, the date and duration of the virtual meeting shall be notified at least one (1) month in advance of the date on which the face-to-face meeting was scheduled to commence in line with the applicable Rules of Procedure. The formal invitation to the meeting and the draft agenda of the business to be transacted at the meeting shall be sent to the Members, Standing Observers and Observers by the ICH Secretariat at least one (1) month in advance. The final agenda and any relevant documentation shall be sent to the Members, Standing Observers and Observers at least two (2) weeks in advance. In case an amendment of these Articles of Association is proposed, the final agenda shall contain the proposed wording of such amendments.

3. Each Member may propose agenda items for a meeting of the Assembly. Such agenda items shall be submitted to the ICH Secretariat in writing no later than two (2) months before the date of the Assembly meeting.

4. The Management Committee, assisted by the ICH Secretariat, is responsible for preparing the agenda and the Assembly meeting.

5. The Management Committee may in urgent cases and in accordance with the Rules of Procedures convene an extraordinary meeting of the Assembly. The place, date and duration of an extraordinary meeting shall be determined by the Management Committee and notified to the Members, Standing Observers and Observers at least six (6) weeks in advance of the date on which the meeting is scheduled to commence.

6. The Chair of the Assembly shall be elected by the Assembly. Only Founding Regulatory Members, Standing Regulatory Members or Regulatory Members of the Management Committee are eligible

to serve as Chair. A Vice-Chair shall also be elected by the Assembly. Only Founding Regulatory Members, Standing Regulatory Members or Regulatory Members of the Assembly are eligible to serve as Vice-Chair of the Assembly. The Chair and Vice-Chair will each serve for two (2) years from the date of election. If the position of Chair or Vice-Chair for whatever reason becomes vacant, an election shall be held at the subsequent Assembly meeting for the remaining period of the term of office. In addition, an associate Vice-Chair may be appointed by the host Member country only for that meeting of the Assembly. The Chair and Vice-Chair may be re-elected.

Article 25

Representation

Each Member may nominate up to two (2) representatives to attend Assembly meetings not counting the Chair and Vice-Chair.

Article 26

Adoption of Decisions

1. The presence of each Founding Regulatory Member, one (1) Founding Industry Member and one (1) Standing Regulatory Member shall be required for the Assembly to constitute a quorum. Where the membership of the Association does not include any Standing Regulatory Members, the presence of a Standing Regulatory Member is not required for the quorum.

2. The Assembly shall adopt all its decisions by consensus. The Members shall in good faith attempt to reach consensus, assisted by the Chair and Vice-Chair of the Assembly. Only where a consensus cannot be reached for a decision, the Assembly shall proceed to voting where decisions shall be adopted by majority. Each Member shall have one vote to cast with the exceptions referred to in Articles 9(2)(a) and 12(2)(b). The vote can be cast by either representative nominated by the Member.

3. A three-quarter majority of the votes cast which must include the vote of each Founding Regulatory Member shall be required for decisions on:

   (a) amendments of the Articles of Association;

   (b) exclusion of Members, Standing Observers and Observers;

   (c) dissolution of the Association.

4. A simple majority of the votes cast, which must include the votes of each Founding Regulatory Member, shall be required for decisions on approval or rejection of membership and observership admission and for adoption and revision of the Rules of Procedures.

5. A simple majority of the votes cast of Founding Regulatory Members, Standing Regulatory Members and Regulatory Members, which majority must, however, include the votes of each Founding Regulatory Member, shall be required for decisions on the selection of topics for ICH Guidelines. The Founding Regulatory Members, Standing Regulatory Members and Regulatory

Members shall in good faith consider the opinions expressed by other Members on the selection of topics for ICH Guidelines.

6. A simple majority of the votes cast of Founding Regulatory Members, Standing Regulatory Members and Regulatory Members, which majority must, however, include the votes of each Founding Regulatory Member, shall be required for decisions on the adoption, amendment or withdrawal of ICH Guidelines.

7. Other decisions of the Assembly shall be adopted by simple majority of the votes cast.

8. The topics subject to decisions referred to under paragraphs 5, 6 and 7 may be taken by consensus through written procedure in accordance with the applicable Rules of Procedures.

9. Decisions are taken by open ballot with the exception of the appointment of Elected Management Committee Representatives as well as the Chair and Vice-Chair of the Assembly which shall be taken by secret ballot. On the basis of a proposal by at least (1) one Member and provided this proposal is supported by at least one (1) other Member, the Chair may decide to cast a secret ballot for other matters.

Article 27

Rules of Procedures

The Assembly shall adopt its Rules of Procedures which shall be consistent with these Articles of Association.

B. Management Committee

Article 28

Composition

1. The Management Committee shall consist of up to twenty-eight (28) representatives. The representatives are either Permanent Management Committee Representatives or Elected Management Committee Representatives. The Permanent Management Committee Representatives or Elected Management Committee Representatives can also be referred to individually as "*Management Committee Representative*" and collectively as "*Management Committee Representatives*".

2. The inaugural Management Committee following the establishment of the Association shall consist of up to sixteen (16) Permanent Management Committee Representatives. The term of office of the Permanent Management Committee Representatives shall be indefinite.

3. No later than 1 January 2018, the Management Committee shall consist of up to sixteen (16) Permanent Management Committee Representatives and twelve (12) Elected Management Committee Representatives. The Regulatory Members shall be entitled to up to eight (8) Elected

Management Committee Representatives in total representing up to four (4) Regulatory Members and the Industry Members entitled to up to four (4) Elected Management Committee Representatives in total representing up to two (2) Industry Members. The term of office of the Elected Management Committee Representatives shall be three (3) years. Elected Management Committee Representatives may be re-elected.

4. The WHO and IFPMA shall have the right to be Permanent Observers of the Management Committee. The WHO and IFPMA may nominate up to two (2) Permanent Observer delegates to participate in the meetings of Management Committee.

Article 29

Appointment of Permanent Management Committee Representatives

1. The Founding Regulatory Members and the Founding Industry Members shall in their sole discretion each appoint two (2) Permanent Management Committee Representatives at the inaugural Assembly meeting.

2. Within one (1) month of the date of the decision approving its membership admission, the Standing Regulatory Member shall in their sole discretion appoint two (2) Permanent Management Committee Representatives and notify the ICH Secretariat of the names of such Permanent Management Committee Representatives.

3. The Founding Regulatory Members, the Founding Industry Members and the Standing Regulatory Members shall notify without undue delay the ICH Secretariat of any change of their Permanent Management Committee Representatives.

Article 30

Proposal of Elected Management Committee Representatives by Regulatory Members

1. Each Regulatory Member has the right to propose two (2) Elected Management Committee Representatives to represent itself for appointment by the Assembly provided it has:
   (a) demonstrated commitment to the ICH activities through consecutive, regular participation in all ICH meetings during the previous four (4) years prior to proposing an Elected Management Committee Representative;
   (b) appointed experts that have participated in at least two (2) Working Groups prior to proposing an Elected Management Committee Representative; and
   (c) a good record of implementation of ICH guidelines in accordance with the Rules of Procedures.

2. Proposals of Elected Management Committee Representatives for appointment by the Assembly must be submitted to the ICH Secretariat in writing at least four (4) months prior to the next Assembly meeting.

Article 31

Proposal of Elected Management Committee Representatives by Industry Members

1. Each Industry Member has the right to propose two (2) Elected Management Committee Representatives to represent itself for appointment by the Assembly provided it has:

   (a) participated as an Industry Member in Assembly meetings during the previous four (4) years prior to proposing the Elected Management Committee Representatives or has been an Interested Party as defined prior to the establishment of the Association and has appointed experts that have participated in the Working Groups during the previous four (4) years prior to proposing the Elected Management Committee Representatives; and

   (b) demonstrated that the organisation and/or its members are regulated or affected by the majority of the ICH guidelines, in accordance with the Rules of Procedures.

2. Proposals of Elected Management Committee Representatives for appointment by the Assembly must be submitted to the ICH Secretariat in writing at least four (4) months prior to the next Assembly meeting.

Article 32

Appointment of Elected Management Committee Representatives

The Assembly shall review the proposals put forward under Articles 30 and 31 and, after consultation of the Management Committee, take a decision on the appointment of the Elected Management Committee Representatives.

Article 33

Withdrawal or Dismissal from the Management Committee

1. Any Management Committee Member may withdraw from the Management Committee at any time as per the process specified in the Rules of Procedures.

2. If a Management Committee Representative or Permanent Observer delegate through his or her actions or behaviour seriously impairs the proper functioning or reputation of the Management Committee or the Association, the relevant Management Committee Representative or Permanent Observer delegate may be dismissed from the Management Committee by the Assembly.

Article 34

Replacement of a Management Committee Representative

1. If the position of a Permanent Management Committee Representative for whatever reason becomes vacant, the Member having appointed the Permanent Management Committee Representative whose position has become vacant shall have the duty to appoint a new Representative without undue delay.

2. If the position of an Elected Management Committee Representative for whatever reason becomes vacant, the Member or Members having proposed the Elected Management Committee Representative whose position has become vacant shall have the duty without undue delay to appoint a replacement Elected Management Committee Representative to act until the remaining period of the three year-term of office.

Article 35

Rights and Responsibilities of Management Committee Representatives

1. The Management Committee Representatives have, in accordance with the applicable Rules of Procedures, the right to:

   (a) vote in the Management Committee in accordance with Article 38.

2. The Management Committee Representatives shall:

   (a) participate in the meetings and decision-making of the Assembly and the Management Committee;

   (b) exercise the rights and responsibilities granted to the respective Members of the Management Committee.

3. The Management Committee Representatives represent the interests of the Members by which they have been appointed or proposed and, while the Management Committee Members will be expected to pursue the interests of the Association, the individual Representatives do not have independent individual fiduciary duties to the Association.

Article 36

Competencies of the Management Committee

1. The role of the Management Committee is to oversee the operational aspects on behalf of all Members of the Association. The competence of the Management Committee is primarily in the area of administrative and financial matters.

2. The Management Committee shall, in particular, be responsible for:

   (a) determining the venue of the Assembly meetings;

   (b) preparing for and convening Assembly meetings in accordance with the applicable Rules of Procedures;

   (c) submitting to the Assembly proposals for the Association's annual work plan and multi-annual strategic plan;

   (d) appointing and dismissing the Director, who will serve as head of the ICH Secretariat, and determining the Director's objectives, responsibilities, and scope of authority;

   (e) designating any persons who are entitled to represent the Association vis-à-vis third parties;

(f) exercising oversight of the Working Group and Plenary Working Party processes and operations to ensure the efficiency and timeliness of ICH Guideline completion and the quality of the ICH Guideline;

(g) submitting recommendations or proposals to the Assembly, including recommendations on new topic(s) for ICH Guidelines, proposals for adoption, amendment or withdrawal of ICH Guidelines;

(h) submitting recommendations to the Assembly on membership and observership applications;

(i) supervising the sub-committees of the Management Committee including approving their programme priorities and the biannual reports;

(j) approving the membership fees and the financial contributions during a transition period referred to in Article 60 and proposing membership fees and financial means to be raised to the Assembly;

(k) using its reasonable efforts to take out and maintain commercial liability and Director & Officer insurances with an appropriate coverage;

(l) submitting to the Assembly the audited annual accounts of the Association for approval;

(m) submitting proposals and recommendations to the Assembly on financial matters including draft budgets.

3. The Management Committee may, to the extent consistent with these Articles of Association and in accordance with the applicable Rules of Procedures, establish sub-committees, working groups and plenary working parties. The responsibilities, competencies and the organisation of such committees, working groups and plenary working parties shall be set out in detail in Rules of Procedures which are to be adopted by the Management Committee.

4. The Management Committee shall be competent for any matters which are not explicitly reserved for the Assembly or delegated to another body of the Association in the Articles of Association.

Article 37

Meetings of the Management Committee

1. The Management Committee shall meet when required, either in person, by phone, or by video conference, but at least in conjunction with the Assembly meetings. The Director shall take part in the meetings of the Management Committee without voting rights.

2. The meetings of the Management Committee shall be chaired by one of the Management Committee Representatives appointed by the Permanent Regulatory Members. The inaugural meeting of the Management Committee shall be chaired by one of its Founding Regulatory Members appointed by the Founding Regulatory Members. The Member whose representative has been appointed as Chair shall have the right to appoint another representative to represent itself in the Management Committee until the termination of the chairmanship.

Article 38

Decision-making

1. Where the inaugural Management Committee does not have any Standing Regulatory Members, the presence of at least one (1) representative of each Founding Regulatory Member and of each Founding Industry Member shall constitute a quorum for the inaugural Management Committee. Where the composition of the inaugural Management Committee includes at least one (1) Standing Regulatory Member, the quorum shall be at least one (1) representative of each Founding Regulatory Member, each Founding Industry Member and at least one (1) Standing Regulatory Member.

2. Upon the Management Committee consisting of up to sixteen (16) Permanent Management Committee Representatives and twelve (12) Elected Management Committee Representatives, the quorum for the Management Committee to validly take decisions shall be at least one (1) Management Committee Representative appointed by each Founding Regulatory Member, each Founding Industry Member, one (1) Standing Regulatory Member and one (1) Elected Regulatory Member. If the composition of the Management Committee does not include Management Committee Members appointed by any Standing Regulatory Members or any Elected Regulatory Members, their presence is not required for the quorum.

3. Permanent Management Committee Representatives appointed by the same Member shall jointly have one vote to cast. Elected Management Committee Representatives proposed by the same Member and appointed by the Assembly shall jointly have one vote to cast. For decisions on the adoption, amendment or withdrawal of ICH Guidelines, only the Permanent Management Committee Representatives appointed by the Founding Regulatory Members and by the Standing Regulatory Members and the Elected Management Committee Representatives of Regulatory Members appointed by the Assembly shall have the right to cast a vote.

4. The Management Committee shall adopt all its decisions by consensus. The Management Committee Members shall in good faith attempt to reach consensus. Only where a consensus cannot be reached for a decision, the Management Committee shall adopt its decisions by qualified majority.

5. A two-thirds majority of the votes cast, which must include the joint votes cast by the Permanent Management Committee Representatives appointed by each Founding Regulatory Member, shall be required for decisions on administrative and operational matters not having a financial impact on the Association. Where a two-thirds majority cannot be reached, the Management Committee shall proceed to a vote in which only the Permanent Management Committee Representatives appointed by a Founding Regulatory Member have the right to cast a joint vote. The decision shall be adopted by unanimity of all the votes cast by the Permanent Management Committee Representative appointed by a Founding Regulatory Member.

6. A two-thirds majority of the votes cast, which must include the joint votes cast by the Permanent Management Committee Representatives appointed by each Founding Regulatory Member, shall be required for decisions having a financial impact on the Association. This paragraph shall be reviewed upon the introduction of annual membership fees or financial means to be raised as referred to in Article 58.

7. A two-thirds majority of the votes cast, which must include the joint votes cast by the Permanent Management Committee Representatives appointed by each Founding Regulatory Member, shall be required for decisions on the selection of topic(s) for ICH Guidelines and on the adoption, amendment or withdrawal of ICH Guidelines. Where a two-thirds majority cannot be reached, the Management Committee shall proceed to a vote in which only the Permanent Management Committee Representatives appointed by each Founding Regulatory Member are entitled to cast a joint vote. The decision shall be adopted by unanimity of all the votes cast by the Permanent Management Committee Representative appointed by each Founding Regulatory Member.

Article 39

Remuneration

The representatives of the Management Committee shall not be entitled to any compensation or remuneration from the Association for fulfilling their Management Committee function.

Article 40

Rules of Procedures

The Management Committee shall adopt its Rules of Procedures which shall be consistent with these Articles of Association.

C. MedDRA and the MedDRA Management Committee

Article 41

MedDRA Activities

The Association, through its Members, will actively participate in MedDRA by providing technical advice in the furtherance of MedDRA's activities. It is recognised, however, that some Members will not have any part in the management of MedDRA by the MedDRA Management Committee, including any aspects of ownership or disposition of assets regarding MedDRA.

Article 42

Role of the MedDRA Management Committee

1. The role of the MedDRA Management Committee is to manage, support and facilitate the maintenance, development and dissemination of MedDRA.

2. In its activities relating to the management of MedDRA, the MedDRA Management Committee shall act independently from the ICH Management Committee.

Article 43

Composition of the MedDRA Management Committee

1. The MedDRA Management Committee shall consist of representatives of the Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA). The representatives on the MedDRA Management Committee can be referred to individually as "*MedDRA Management Committee Representative*" and collectively as "*MedDRA Management Committee Representatives*".

2. The term of office of the MedDRA Management Committee Representatives shall be indefinite.

3. The World Health Organization (WHO) shall have observer status on the MedDRA Management Committee without any voting rights. The WHO may nominate up to two (2) delegates to participate in the meetings of MedDRA Management Committee and shall notify the MedDRA Secretariat of the names of such delegates. The MedDRA Management Committee may invite other parties to attend the MedDRA Management Committee meetings as non-voting observers.

Article 44

Appointments to the MedDRA Management Committee

1. The Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA) each have the right to appoint in their sole discretion up to two (2) MedDRA Management Committee Representatives.

2. The Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA) shall notify the MedDRA Secretariat of their choice to appoint any MedDRA Management Committee Representative. The names of the appointed MedDRA Management Committee Representatives will be notified to the MedDRA Secretariat one (1) month thereafter.

3. MedDRA Management Committee Representatives shall be individuals who are known to be of proven ability or expertise on MedDRA, and who have the commitment and time to serve in the capacity as MedDRA Management Committee Representatives.

4. The Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA) shall notify without undue delay the MedDRA Secretariat of any change of their MedDRA Management Committee Representatives.

Article 45

Withdrawal or Dismissal from the MedDRA Management Committee

1. Any MedDRA Management Committee Representative or observer delegate may withdraw from the MedDRA Management Committee at any time with effect on the end of any Fiscal Year by prior written six (6) months' notice to that effect to the MedDRA Management Committee.

2. If a MedDRA Management Committee Representative or observer delegate through his or her actions or behaviour seriously impairs the proper functioning or reputation of the MedDRA Management Committee, the relevant MedDRA Management Committee Representative or observer delegate may be dismissed from the MedDRA Management Committee by the MedDRA Management Committee.

Article 46

Replacement of a MedDRA Management Committee Representative

If the position of a MedDRA Management Committee Representative for whatever reason becomes vacant, the Founding Regulatory Member, Founding Industry Member, Standing Regulatory Member or the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA) having appointed the MedDRA Management Committee Representative whose position has become vacant shall have the duty to appoint a replacement MedDRA Management Committee Representative.

Article 47

Competencies of the MedDRA Management Committee

1. The MedDRA Management Committee is responsible for the oversight and management of MedDRA including ensuring MedDRA's integrity as a harmonised standard and MedDRA's viability and sustainability. In order to fulfil its responsibilities, the MedDRA Management Committee may outsource the dissemination, maintenance and support of MedDRA to third parties, e.g. to a maintenance and support services organisation (MSSO).

2. The MedDRA Management Committee shall, in accordance with its Rules of Procedures, in particular be responsible for:

   a) exercising oversight of the MedDRA activities, including MSSO operations;

   b) submitting to the Assembly proposals for the annual work plan of the MedDRA Management Committee and the annual budget for MedDRA;

   c) submitting to the Assembly an annual report on the activities regarding MedDRA;

   d) determining the objectives, responsibilities, and scope of authority of the MedDRA Secretariat;

   e) determining the persons with signatory powers who are entitled to represent the Association on matters relating to MedDRA vis-à-vis third parties; and

   f) determining the subscription fees for MedDRA, as part of the annual budget for MedDRA.

Article 48

Meetings of the MedDRA Management Committee

1. The MedDRA Management Committee shall meet when required either in person, by phone, or by video conference, but at least in conjunction with the Assembly meetings. The MedDRA Secretariat shall take part in the meetings of the MedDRA Management Committee without voting rights.

2. The meetings of the MedDRA Management Committee shall be chaired by one of the MedDRA Management Committee Representatives designated by the MedDRA Management Committee. The party whose MedDRA Management Committee Representative has been designated as Chair shall have the right to appoint another MedDRA Management Committee Representative to represent itself in the MedDRA Management Committee until the termination of the chairmanship.

Article 49

Decision-making of the MedDRA Management Committee

1. The presence of at least two-third of the MedDRA Management Committee Representatives shall be required for the MedDRA Management Committee to constitute a quorum.

2. The MedDRA Management Committee shall adopt all its decisions by consensus. The members of the MedDRA Management Committee shall act in good faith to reach consensus. Only when consensus cannot be reached for a decision, the MedDRA Management Committee shall proceed to voting where decisions shall be adopted by two-thirds majority of the votes cast, which must include the joint votes cast by the MedDRA Management Committee Representatives appointed by each Founding Regulatory Member. MedDRA Management Committee Representatives appointed by the same party shall jointly have one vote to cast.

Article 50

Financing of MedDRA

1. The activities relating to MedDRA shall be self-financed through the collection of annual subscription fees from organisations that are subscribers of MedDRA. Regulatory authorities and non-profit or non-commercial organisations shall be exempted from paying subscription fees.

2. The amount of the annual subscription fees that are raised for the next Fiscal Year shall be determined by the MedDRA Management Committee. The subscription fees shall be included in the annual budget for MedDRA which is submitted to the Assembly for approval or rejection.

3. The amounts of the annual subscription fees shall be set at a level that corresponds to the anticipated costs of all MedDRA activities, including MSSO activities. Where surplus exists from previous years' subscription fee collections, that surplus may be used to offset the MedDRA budget in line with the applicable Rules of Procedures.

Article 51

Remuneration of the MedDRA Management Committee

The representatives of the MedDRA Management Committee shall not be entitled to any compensation or remuneration from the Association for fulfilling their MedDRA Management Committee function.

Article 52

MedDRA Secretariat

1. The MedDRA Secretariat shall be responsible for the day-to-day management of MedDRA and, subject to the determination of signatory powers by the MedDRA Management Committee, represent the Association vis-à-vis third parties relating to MedDRA matters.

2. The MedDRA Secretariat shall assist the MedDRA Management Committee to prepare the annual budget for MedDRA for approval by the Assembly and otherwise carry out the directives of the MedDRA Management Committee.

3. The MedDRA Secretariat shall work closely with the ICH Secretariat for the coordination of their respective activities.

4. The MedDRA Secretariat shall be remunerated by the Association from the annual budget for MedDRA and in accordance with a decision of the MedDRA Management Committee.

Article 53

Rules of Procedures of the MedDRA Management Committee

The MedDRA Management Committee shall adopt its Rules of Procedures in accordance with these Articles of Association.

D. ICH Secretariat

Article 54

Composition and Oversight

The Director shall be in charge of the ICH Secretariat and shall report to the Chair of the Management Committee or to a designated Member of the Management Committee. The Director may recommend changes to the composition of the ICH Secretariat to the Management Committee. The Director and the ICH Secretariat shall be remunerated by the ICH Association.

Article 55

Competencies and Responsibilities

1. The ICH Secretariat shall be responsible for the day-to-day management of the Association and, subject to the determination of signatory powers by the Management Committee, represent the Association vis-à-vis third parties.

2. The ICH Secretariat shall assist the Management Committee to prepare budgets, coordinate the activities of the Association, support any established sub-committees, working groups or plenary working parties, and otherwise carry out the directives of the Management Committee. The ICH Secretariat shall work closely with the MedDRA Secretariat for the coordination of their respective activities.

3. The responsibilities, competencies and the organisation of the ICH Secretariat shall be set out in greater detail in an Employee Handbook approved by the Management Committee.

E. Auditors

Article 56

Appointment and Dismissal

The Assembly shall appoint an auditing firm as Auditors. The Auditors shall be appointed for a period of two (2) years. The Auditors may be re-appointed. The Assembly may dismiss the Auditors at any time without giving any reasons.

Article 57

Responsibilities

The Auditors shall audit the financial statements of the Association upon conclusion of each Fiscal Year. The Auditors shall ensure that the accounting of the Association complies with Swiss law and generally accepted Swiss accounting principles. Upon completion of the audit, the Auditors shall submit a written report summarising their findings to the Assembly.

V. FINANCIAL MATTERS

Article 58

Financial Means to Achieve the Purpose of the Association

1. The purpose of the Association shall be achieved by the financial means set out herein.

   All references to financial means shall be understood to mean that the Members can only provide such financial means in accordance with the laws under which such Member is organised and by

which it is governed. The Association has no authority to require these Members to contribute any financial means. It is recognised that these Articles of Association are not themselves a funding instrument and do not create a legal obligation to contribute any financial means. Notwithstanding the foregoing, the Members are expected to utilise appropriate mechanisms under their governing laws to provide the expected financial means to support the Association.

2. The necessary financial means shall be raised by:

   (a) annual membership fees; or

   (b) financial contributions through grants or other mechanisms by which regulatory members or others are able to provide contributions consistently with their applicable law. The Association has the authority to enter into grant agreements and to accept conditions applicable to such grants, and those conditions shall control with respect to those grants.

3. Additional financial means necessary to cover the costs of the ICH Association may also be raised by:

   (a) participation fees;

   (b) financial contributions;

   (c) income from meetings and events organised by the Association.

4. The Management Committee may decide on other, additional forms of funding in accordance with this Article.

5. The activities of the Association may also be supported by non-financial means.

Article 59

Annual Membership Fees and other Financial Means

1. The amount of the annual membership fees and other financial means that are raised for the next Fiscal Year shall be reviewed and approved by the Assembly for all the Members at least six (6) months prior to the end of each Fiscal Year.

2. The amounts of the annual membership fees and other financial means that are raised shall be fair, proportionate and transparent.

3. When reviewing and approving the amount of the annual membership fees and other financial means that are raised, the Assembly may distinguish between the different categories of membership.

Article 60

Costs of meetings hosted by a Member

The Management Committee may invite a Member to organise an ordinary or an extraordinary Assembly and/or a Management Committee meeting. If a Member agrees to do so, the costs incurred by

such a Member for the organisation of the Assembly and/or Management Committee meeting may be deducted from the membership fee or the financial contribution provided by that Member if doing so is consistent with the applicable laws of that Member.

VI. MISCELLANEOUS PROVISIONS

Article 61

Conflict with Governing Laws

The obligations of a Member under these Articles of Association are limited by the laws under which such Member is organised and by which it is governed. Nothing in these Articles of Association shall bind a Member to take actions that are not consistent with and authorised by the laws under which that Member is organised and by which it is governed. The laws under which a Member is organised and by which it is governed supersede and control any other statement in these Articles in case of conflict.

Article 62

Liability

1. The liabilities and obligations of the Association may only be enforced against the Association's assets and no Member, representatives/delegates or members or person designated to serve on an Association body or committee or working group or plenary working party shall have any personal liability for any liabilities of the Association. This includes all existing known and unknown liabilities and obligations transferred to the Association from or through predecessor organisations or trustees, or incurred in the future pursuant to such transfers.

2. The individuals serving on an Association body or committee or working group or plenary working party shall be liable to the Association and to its Members, as the case may be, only if they have acted in grossly negligent or intentional manner. Any other liability is excluded.

3. Nothing contained in these Articles shall be deemed a waiver, express or implied, of any immunity from suit, judicial process, confiscation, taxation or other immunity or privilege which the Members may enjoy.

Article 63

Dissolution of the Association

1. The Association may be dissolved on the basis of a decision of the Assembly.

2. In the event of liquidation, any liquidation proceeds shall be contributed to a Swiss organisation whose purpose is identical or similar to the Association's purpose, and which is exempt from Swiss corporate taxes at cantonal and federal level. In no event shall any membership fees, voluntary contributions by Members or third parties, or liquidation proceeds be returned to the Members, individuals or entities having paid such fees or made such contributions, nor to the successors of such individuals or entities.

Article 64

Dispute Resolution

All efforts shall be made by all parties involved, in accordance with the dispute resolution mechanism in the Rules of Procedures of the Assembly, to find a solution to any dispute, controversy, or claim between the Association and its Members, or among the Members, arising out of or related to the Association and these Articles, the Rules of Procedures or the other obligations undertaken in connection with membership in the Association, or the breach, termination, or invalidity thereof.

Article 65

Taking Effect of Articles of Association

These Articles were duly authorised and approved by the Founding Members of the Association at the occasion of the founding assembly held on October 23, 2015. These Articles were revised and approved by the Assembly at its meeting held on November 18, 2020 and shall immediately take effect.