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

Rules of Procedure of the Assembly

Version 17.0
Approval by the Assembly on 13 May 2025

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

Route de Pré-Bois 20, 1215 Geneva, Switzerland

Telephone: +41 (22) 710 7480 - admin@ich.org, http://www.ich.org

Assembly RoPs

Document History

Version number	Action	Date
V17.0	The ICH Assembly approved amendments to the Assembly RoP including clarification on the meeting participation (in person/virtual); revision to the WGs quorum; amendments to replace the Secretariat's Director with a Secretary General; amendments further to a new Article 54 on Conflict of Interest; and additional revisions related to transformation of MedDRA Management Committee into MedDRA Steering Committee.	**May 2025**
V16.0	The ICH Assembly approved amendments to the Assembly RoP regarding the transformation of the MedDRA Management Committee into the MedDRA Steering Committee.	**March 2025**
V15.0	The ICH Assembly approved amendments to the Assembly RoP including clarification on the meeting participation criterion towards Membership application; revision to the Annex 1: Definitions of terms in the context of the implementation of ICH Guidelines; and amendments further to a new Article 53 on confidentiality of information in the ICH Articles of Association (AoA).	**November 2024**
v14.0	The ICH Assembly approved amendments to the Assembly RoP regarding the procedure for notification by Members of any additional participants to ICH meetings.	**October 2023**
v13.0	The ICH Assembly approved amendments to the Assembly RoP to provide for a new Coordinator Position for ICH Standing Observers.	**June 2023**
v12.0	The ICH Assembly approved an amendment to the Assembly RoP regarding a revision to Observer representation in the Assembly.	**November 2022**
v11.0	The ICH Assembly approved amendments to the Assembly RoP, including a revision shortening the time period for review of draft and revised reports and minutes as well as clarification on the Expert Appointment and Participation process.	**May 2022**
v10.0	The ICH Assembly approved amendments to the Assembly RoP, including a clarification on the rules on confidentiality and a clarification on the rules on the additional participants at meetings.	**June 2021**
v9.0	The ICH Assembly approved amendments to the Assembly RoP, including on the process for revising Assembly minutes; criteria for Membership related to expert participation in WGs; process for enabling proxies between ICH Observers; Assembly virtual meetings in extraordinary circumstances; expedited Process for Membership applications and the need identified for certain minor clarifications.	**November 2020**

v8.0	The ICH Assembly approved amendments to the Assembly RoP, including on the process for nominating experts to the 3 additional industry seats; the Reflection Paper process; general principles for Discussion Groups; the attendance of experts to their WG meetings; synchronization of the terms of office of the MC Elected Representatives; replacement of MC Elected Representatives; clarification on the synchronization of the terms of office of the Assembly Chair and Vice-Chair; and the need identified for certain clarifications and streamlining of procedures.	**November 2019**
v7.0	The ICH Assembly approved amendments to the Assembly RoP, including on: the management of the size of ICH Working Groups; the definitions of the degrees of implementation of ICH Guidelines; and ICH Cooperation with other organisations.	**June 2019**
v6.0	The ICH Assembly approved amendments to the Assembly RoP, including: clarification on the process to replace the Assembly Chair or Vice Chair in the event of his/her resignation; clarification on the appointment process of Rapporteurs; clarification on confidentiality considerations; and a reduction of the time before publication of a press release following ICH meetings.	**November 2018**
v5.0	The ICH Assembly approved several amendments to the Assembly RoPs, many of which reflected changes also made to the ICH Articles of Association in June 2018. Changes included: avoiding overlapping membership of Regional Harmonisation Initiatives and their individual members with a view to avoiding double representation; and managing the size of Working Groups by revising the process for appointing experts.	**June 2018**
v4.0	The ICH Assembly approved several amendments to the Assembly RoPs, many of which reflected changes also made to the ICH Articles of Association in May 2017. Changes included: revisions to the criteria for an international organisation to become a Member; changes related to managing the size of delegations to ICH meetings; clarifications regarding the Assembly Chair & Vice Chair role; adjustment of procedures related to minutes and press releases; as well as other changes for clarity and consistency.	**May 2017**
v3.0	The ICH Assembly approved several amendments to the Assembly RoPs to reflect changes made to the ICH Articles of Association in November 2016, as well as for clarification and consistency. Changes made included: clarification on Assembly decision-making; clarification of procedures related to Working Groups and expert nominations; removal of need for a proxy from Observers; and introduction of new procedures regarding photography and donations.	**November 2016**
v2.0	The ICH Assembly approved amendments to the Assembly RoP, including: addition of a procedure for the appointment of Elected Management Committee Representatives;	**June 2016**

	clarification on appointment of Rapporteurs; and clarification on confidentiality considerations.	
v1.0	The ICH Assembly approved the first version of the Assembly RoP.	**December 2015**

TABLE OF CONTENT

Rules of Procedure Overview 1

1. Member Admission, Termination and Representation 2

1.1. Membership Application for Regulatory Members 2

1.1.1. Eligibility Criteria for a Legislative or Administrative Authority 2

1.1.2. Avoiding overlapping membership of the individual members of a Regional Harmonisation Initiative and the Regional Harmonisation Initiative itself 3

1.1.3. Eligibility Criteria for Regional Harmonisation Initiative (RHI) 4

1.1.4. Avoiding overlapping membership of a Regional Harmonisation Initiative and its individual members 5

1.1.5. Implementation of ICH Guidelines 6

1.2. Membership Application for Industry Members 8

1.2.1. Eligibility Criteria for Industry 8

1.3. Membership Application Process 8

1.3.1. Application Form 8

1.3.2. Application Review Process 9

1.3.3. Decision by the Assembly 9

1.4. Termination of Membership 9

1.5. Member Representation 10

1.6. Member Name 11

1.7. Member Appointment of Coordinators 11

2. Observer Admission, Termination and Representation 11

2.1. Standing Observers 11

2.1.1. Standing Observer Appointment of Coordinators 11

2.2. Observers 11

2.2.1. Eligibility criteria for Observers 11

2.2.2. Observership Application Process for Observers 14

2.2.3. Decision by the Assembly 15

2.2.4. Representation 15

2.2.5. Observer Name 16

2.3. Ad-hoc Observers 16

2.4. Termination of Observership 16

3. The Assembly 17

3.1. Election of Assembly Chair and Vice-Chair 17

3.2. Role of Assembly Chair and Vice-Chair 17

3.3. Calling of Assembly Meetings 18

3.3.1. Regular Assembly Meetings 18

3.3.1.1. Virtual Assembly Meetings 19

3.3.2. Extraordinary Assembly Meetings 19

3.4. Preparation for and Conduct of Assembly Meetings 19

3.4.1. Selection of new topics for harmonisation 20

3.4.2. Development and Review of Reflection Papers 20

3.5. Participation in Assembly Meeting 21

3.5.1. Member Participation in Assembly Meeting 21

3.5.2. Standing Observer and Observer Participation in Assembly Meeting 22

3.5.3. ICH Secretariat Participation in Assembly Meeting 22

3.5.4. Notification of Non Participation in Assembly Meeting 22

3.5.5. Assignment of Vote in Event of Non Participation in Assembly Meeting 22

3.5.6. Funding of Participation in Assembly Meeting 23

3.6. Assembly Decision-Making Process 23

3.6.1. Decisions on Selection of ICH topics 24

3.6.2. Decisions on Adoption, Amendment or Withdrawal of ICH Guidelines 24

3.6.3. Granting of Discharge by the Assembly 25

3.6.4. Appointment of Elected Management Committee Representatives 25

3.7. MedDRA Policy 26

3.8. Communication of Assembly Discussions 26

3.8.1. Minutes of Assembly Meetings 26

3.8.2. Press Release Following Assembly meetings 27

3.8.3. Photography 28

4. Working Groups 28

4.1. General 28

4.1.1. Procedure for the appointment of experts in Working Groups 28

4.1.2. Number of experts in the Working Groups 28

4.1.2.1. Informal Working Groups, Expert Working Groups, Implementation Working Groups 28

4.1.2.2. Discussion Groups 29

4.1.3. Limiting the number of experts in Working Groups 30

4.1.4 Plenary Working Party 30

4.2. Appointment of Rapporteurs 30

4.3. Expert Appointment and Participation 31

4.4. Working Group Quorum 32

5. Financing of ICH 32

5.1. Member Responsibility to Finance ICH Association 32

5.2. Determination of Annual Fees / Contributions 33

5.3. Non-Payment of Annual Fees / Contributions 33

5.4. Support by Other Means 34

5.4.1. Additional Financial Means 34

5.4.2. Non-Financial Means 34

5.4.3. Other Means 34

6. Cooperation 34

6.1. Cooperation with Other Organisations 34

7. Supporting ICH 35

7.1. Supporting Aims 35

7.2. Promoting ICH Guidelines 35

7.3. Maintaining Confidentiality 36

8. Legal Considerations 36

8.1. Member Conflicts with Governing Laws 36

8.2. Conflict of interest 37

8.3. Liability 39

8.4. Dissolution of Association 39

8.5. Dispute Resolution 39

ANNEX 1: Definitions of terms in the context of the implementation of ICH Guidelines 41

ANNEX 2: ICH Policy Regarding Additional Financial Contributions 44

Rules of Procedure Overview

Further to Article 27 of the Articles of Association, these Rules of Procedure (RoP) of the Assembly are intended to provide guidance and clarification in respect of the various Articles of the Association. These RoP also provide interpretation of the meaning of some of the provisions in these Articles. The RoP cannot override the Articles of the Association as the latter have precedent in the case of contradiction between the two.

In the event of discrepancy or inconsistency between the RoP and the Articles of Association, the latter will prevail. In such a case, the RoP should be amended to ensure that they are consistent with the Articles of Association. These RoP of the Assembly, in addition to the Articles of Association, should be published on the website of the ICH Association. The RoP are amended in accordance with Articles 26(2) and 26(4) of the Articles of Association.

As regards the work of the Working Groups, a Standard Operating Procedure of the Working Groups (SOP) has been developed. Should there be a discrepancy or inconsistency between the SOP and the RoP, the latter has precedent.

1. Member Admission, Termination and Representation

1.1. Membership Application for Regulatory Members

1.1.1. Eligibility Criteria for a Legislative or Administrative Authority

This section provides guidance and clarification on the eligibility criteria referred to in Article 11(1).

Criteria 1: The reference to legislative or administrative authority, in Article 11(1), under Swiss law, should be understood as an authority of a country or a region and refers to the manner in which the authority functions; both types of authority are referred to since both could be possible depending on how the body is organised in its own jurisdiction. The term "jurisdiction" refers to a geographic area with a dedicated set of regulations without any political connotation, e.g., a country, a constituent state, or even a community. The legislative or administrative authority applying for Membership should not be already represented by another Member or Observer in as far as the same legislative framework on pharmaceuticals for human use applies to both the applicant and the Member or Observer.

Having legal personality in the sense of Article 11(1)(a) means that the authority has capacity to assume rights and obligations in order to establish a legal relationship with the ICH Association. The criteria of having legal personality would be met if the law applicable to the Regulatory Member accorded it legal personality.

Criteria 2: As per Article 11(1)(b), the responsibility should normally be related to the authorisation/registration of pharmaceutical products for human use. In most cases, this responsibility lies with the relevant Ministry or Department and/or with a national (regional) medicines agency. In any event, it is under the discretion of each Regulatory Member, in line with Section 1.5, to decide which entity represents that Member in the ICH Association as well as to decide who to nominate as its (individual) representatives in the various bodies of the Association, including the experts in the Working Groups.

Criteria 3: In line with Article 11(1)(c), past participation will be verified by the ICH Secretariat from the meeting records. Only in-person participation will be considered towards Membership in case of face-to-face meetings, with exception of circumstances beyond the control of parties to be communicated in advance of the meeting. As regards participation in ICH meetings prior to the establishment of the ICH Association, this means the Global Cooperation sessions.

Criteria 4: In line with Article 11(1)(d), the appointment of experts and their participation in Working Groups as per the Assembly RoP 4.3, will be verified by the ICH Secretariat from the available records.

Criteria 5: In line with Article 11(1)(e), the ICH Secretariat will verify whether the authority is a member of any Regional Harmonisation Initiative and if so, whether that/those Regional Harmonisation Initiative(s) is/are a Member(s) of ICH. If this is the case, the provisions outlined in section 1.1.2 should be applied in respect of membership applications submitted after 7 June 2018;

Criteria 6: Further to Article 11(1), second sub-paragraph, adequate implementation of ICH Q1, Q7 and E6 Guidelines – see the section on implementation of Guidelines under RoP 1.1.5 below**.**

Expedited procedure: Further to Article 11(1) third paragraph, after a legislative or administrative authority has become an Observer in ICH and has attended at least one (1) Assembly meeting as an Observer and has implemented at least 75% of ICH Guidelines, including all Tier 1 and 2 Guidelines, that were adopted by ICH at *Step 4* one (1) year or more before the submission of the membership application, that Observer is eligible for membership at the subsequent ICH Assembly meeting or at any ensuing Assembly meetings, notwithstanding Article 11(1) first paragraph, point (c) and (d) and paragraph 2 and provided the other provisions of Article 11(1) first paragraph are met. The participation by the Observer in the Assembly meeting will be verified by the ICH Secretariat from the meeting records.

1.1.2. Avoiding overlapping membership of the individual members of a Regional Harmonisation Initiative and the Regional Harmonisation Initiative itself

Below are various scenarios applicable in situations where the legislative or administrative authority referred to in Article 11(1) (hereinafter 'the authority') that applies for membership in ICH is a member of one or several Regional Harmonisation Initiatives.

1. If the Regional Harmonisation Initiative(s) is/are not Member(s) or Observer(s) of ICH, the application should be assessed.
2. If the Regional Harmonisation Initiative(s) that is/are already an Observer(s) of ICH, the application should be assessed.
3. If the Regional Harmonisation Initiative(s) that is/are already a Member(s) of ICH, the application should not be considered admissible in accordance with Article 11(1)(e) of the Articles of Association given that the Regional Harmonisation Initiative, as an ICH Member, is in a position to assume rights and obligations on behalf of its members (Article 11(2)(a)) and to commit on their behalf to adequately implement ICH guidelines (Article 11(2)(f)).

The application may, however, be assessed if the intention is to change the membership representation of the region (represented by the Regional Harmonisation Initiative) in ICH or if the authority that is applying for membership in ICH intends to leave the RHI. There should be prior coordination between the Regional Harmonisation Initiative and its individual members in order to decide whether the Regional Harmonisation Initiative or its individual members should be the Member(s) in ICH. If the intention is that the individual members of the Regional Harmonisation Initiative should replace the Regional Harmonisation Initiative as Members in ICH, the ICH secretariat should be informed. In this case, the authority should include in its application written documentation to support the change in membership representation of the region in ICH or documentation to support the termination of the membership of the authority in the RHI e.g., press release or meeting minutes.

1.1.3. Eligibility Criteria for Regional Harmonisation Initiative (RHI)

This section provides guidance and clarification on the eligibility criteria referred to in Article 11(2). It should be noted that in order for an RHI to be eligible for membership, it should have similar characteristics as supranational bodies referred to in Article 17(1)(a) and have competences in the field of pharmaceuticals that have been conferred to the RHI by its members. This is notably because one of the membership criteria for RHIs outlined below is having the competence to make commitments and speak on behalf of its members. This implies that there should be a common regulatory framework for pharmaceuticals, including for the authorization/licensing of medicinal products for human use and for the maintenance of these authorizations/licenses, in the jurisdiction of the RHI. Such a regulatory framework is supported and complemented by technical and scientific guidelines, such as ICH guidelines.

Criteria 1: Further to Article 11(2)(a), having legal personality means that the RHI or the representative of the RHI has the capacity to assume rights and obligations on behalf of the RHI (i.e., all its members) in order to establish a legal relationship with the ICH Association. The criteria of having legal personality would be met if the law applicable to the RHI accorded it legal personality.

Criteria 2: As per Article 11(2)(b), the responsibility should normally be related to the authorisation/registration of pharmaceutical products for human use. For an RHI, this means that scientific/technical Guidelines, not necessarily only ICH Guidelines, relating to the authorisation/registration of pharmaceuticals apply to all members of the RHI.

Criteria 3: As per Article 11(2)(c) only one entity (e.g., a member of the RHI or a Secretariat) can represent the RHI in the ICH Association. It is under the discretion of each RHI, in line with Section 1.5, to decide which entity represents that RHI in the ICH Association as well as to decide who to nominate as its (individual) representatives in the various bodies of the Association, including the experts in the Working Groups.

The RHI should not, however, as a general rule be represented by a Regulatory Member, i.e., a legislative or administrative authority (DRA) that is itself already a Member of the ICH Association.

Criteria 4: In line with Article 11(2)(d), the past participation will be verified by the ICH Secretariat from the meeting records. Only in-person participation will be considered towards Membership in case of face-to-face meetings, with exception of circumstances beyond the control of parties to be communicated in advance of the meeting. As regards participation in ICH meetings prior to the establishment of the ICH Association, this means the Global Cooperation sessions.

Criteria 5: In line with Article 11(2)(e), the appointment of experts and their participation in Working Groups as per the Assembly RoP 4.3, will be verified by the ICH Secretariat from the available records.

Criteria 6: As per Article 11(2)(f), the representative of the RHI should be able to commit on behalf of all its members, e.g., that the adopted ICH Guidelines will be adequately implemented by all the members of the RHI in the same way;

Criteria 7: As per Article 11(2)(g), the ICH Secretariat will verify whether any of the individual members of the Regional Harmonisation Initiative are Members of ICH and for all applications submitted after 7 June 2018, the provisions in section 1.1.5 should apply;

Criteria 8: Further to Article 11(2) second sub-paragraph, adequate implementation of ICH Q1, Q7 and E6 Guidelines – see the section on implementation of Guidelines under RoP 1.1.3.

Expedited procedure: Further to Article 11(2) third paragraph, after a Regional Harmonisation Initiative has become an Observer in ICH and has attended at least one (1) Assembly meeting as an Observer and has implemented at least 75% of ICH Guidelines, including all Tier 1 and 2 Guidelines, that were adopted by ICH at *Step 4* one (1) year or more before the submission of the membership application, that Observer is eligible for membership at the subsequent ICH Assembly meeting or at any ensuing Assembly meetings, notwithstanding Article 12(1) first paragraph, point (d) and (e) and paragraph 2 and provided the other provisions of Article 12(1) first paragraph are met. The participation by the Observer in the Assembly meeting will be verified by the ICH Secretariat from the meeting records.

1.1.4. Avoiding overlapping membership of a Regional Harmonisation Initiative and its individual members

As mentioned under section 1.1.2, there should not be any overlapping membership of a Regional Harmonisation Initiative on the one hand and of its individual members on the other as stipulated in Article 11(2)(g) of the Articles of Association taking into account that the Regional Harmonisation Initiative, as an ICH Member, is in a position to assume rights and obligations on behalf of its members and to commit on their behalf to adequately implement ICH guidelines. For this reason, membership in ICH of a Regional Harmonisation Initiative will also make it desirable to avoid long-term observership of its individual members as mentioned under section 2.2.1.

For applications by RHIs submitted after 7 June 2018, the provisions outlined below apply.

1. If none of the individual members of the Regional Harmonisation Initiative are Member(s) or Observer(s) of ICH, the application should be assessed. However, before submitting the application, there should be prior coordination between the Regional Harmonisation Initiative and its individual members in order to decide whether the Regional Harmonisation Initiative or its individual members should be the Member(s) of ICH. Therefore, in its application for membership, written documentation should be provided by the Regional Harmonisation Initiative showing the support of its individual members for the membership application. This documentation may be in the form of meeting minutes where the agreement has been given or co-signatures by all the individual members on the application form submitted by the Regional Harmonisation Initiative.
2. If any of the individual members of the Regional Harmonisation Initiative are Observers in ICH, the application should not be considered admissible in accordance with Article 11(2)(g) unless the individual members of the Regional Harmonisation Initiative commit in writing to withdraw its/their observership within two (2) months of the admission of the Regional Harmonisation Initiative as a Member of ICH.

3. If one or several members of the Regional Harmonisation Initiatives are already Members of ICH, the application should not be considered admissible in accordance with Article 11(2)(g) unless the individual members of the Regional Harmonisation Initiative commit in writing to withdraw their membership in ICH within two (2) months of the admission of the Regional Harmonisation Initiative as a Member of ICH.

1.1.5. Implementation of ICH Guidelines

Further to Article 11(5), the aim and intention is that all ICH Regulators should adequately implement and adhere to all ICH Guidelines. ICH Regulators are encouraged to implement ICH Guidelines through direct references. In this context, it should be recalled that the ICH Guidelines are not legally binding and that the ultimate adequate implementation in the different jurisdictions is a responsibility of the competent regulator in each jurisdiction. Therefore, the notion that ICH Regulators are "expected to adequately implement" the ICH Guidelines needs to be considered in this light. After the adoption of an ICH Guideline by the Assembly, the decision on any subsequent actions is a responsibility of the competent regulator in each jurisdiction.

It is, nevertheless, expected that the adopted ICH Guidelines will be adequately implemented and adhered to by the ICH Regulators. For the Regulatory Members, which have not been Members of ICH prior to the establishment of the ICH Association, it is recognised that adequately implementing and adhering to all the ICH Guidelines (which in 2015 amounted to approximately 60 in total) will take some time.

It is also recognised that not all ICH Guidelines are of equal importance. In addition to the three (3) ICH Guidelines (Q1, Q7 and E6; also referred to internally as "Tier 1 Guidelines") whose adequate implementation is included amongst the Membership criteria further to Article 11(1) second sub-paragraph and Article 11(2) second sub-paragraph, once a Regulatory Member has become a Member of the ICH Association, that Regulatory Member is expected to adequately implement and adhere to all the other ICH Guidelines. It is, however, recognised that this will probably be done gradually.

When prioritising amongst the ICH Guidelines to be implemented, the ICH Guidelines referred to below should, if possible, be implemented as a priority (also referred to internally as "Tier 2 Guidelines"). Therefore, specific plans with identified milestones and timeframes for implementation of these ICH Guidelines within the next five (5) years should be submitted by the Regulatory Member after the approval of its Membership:

- **E2A:** Clinical Safety Data Management: Definitions and Standards for Expedited Reporting;
- **E2B:** Data Elements for Transmission of Individual Case Safety Reports;
- **E2D:** Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting;
- **M4:** Common Technical Document for the Registration of Pharmaceuticals;
- **M1:** MedDRA.

The other, remaining ICH Guidelines (also referred to internally as "Tier 3 Guidelines") should be implemented in the near term and as soon as possible. A plan with indicative timeframes for the ICH Guidelines that are already foreseen to be implemented should be provided.

There should be a process for the Assembly to monitor the progress of international harmonisation and coordinate efforts in this regard. There should be a specific item on the Agenda of the Assembly meeting on the current state of play of the implementation of the ICH Guidelines where all ICH Regulators provide an update on implementation of the ICH Guidelines. This also provides an opportunity for these Members to share their experience, explain challenges and how to overcome them and develop good practice relating to the implementation of ICH Guidelines.

In exceptional cases, a Regulatory Member may consider that it is not appropriate to implement the ICH Guideline adequately or may choose to implement it not adequately. In such a case, the Member should notify the ICH Secretariat thereof and provide explanations and justification as to why the Member is not in a position to adequately implement this particular guideline. ICH Guidelines should be adequately implemented by all Regulatory Members in accordance with the applicable national/local/regional rules for such (technical/scientific) guidelines. Similarly, as in the case of the Founding Regulatory Members and the Standing Regulatory Members, the implementation of the ICH Guidelines should be made public e.g., on the website of the Regulatory Member or through the publication in the official journal or register of the Regulatory Member.

In order to achieve true international harmonisation, it is important that the ICH Guidelines are adequately implemented in a consistent manner by all ICH Regulators. There may be differences in terms of how the guidelines are actually implemented, i.e., the procedure or whether it is implemented through regulatory or administrative measures, but it is expected that ICH Guidelines are implemented in the same manner as national or other international scientific and technical guidelines (such as WHO Guidelines). Nevertheless, the Regulatory Members should refrain from not adequately implementing ICH Guidelines, for example by arbitrarily adding further requirements based on national or regional considerations if these are not based on objective grounds as this may lead to disharmony, or by omitting requirements as this may lead to the same situation, particularly if those requirements are important aspects of the ICH Guideline.

Adding requirements or omitting requirements should be avoided as this would render the ICH Guideline devoid of purpose or it would significantly reduce the purpose or meaning of the ICH Guideline. In any case, any deviation from any of the requirements laid down in ICH Guidelines should always be justified on objective grounds. The assessment, however, can only be made on a case-by-case basis. Further information on the degrees of implementation is provided in Annex 1.

The process for discussing and monitoring the state of the implementation of the "Tier 2 and 3 ICH Guidelines" of a Regulatory Member at the Assembly is described below:

1. For ICH Guidelines that are already implemented (in addition to the "Tier 1 Guidelines"): the Regulatory Member should submit the reference to the relevant document that implements the ICH Guideline in question. In addition, a copy of the relevant document may be provided. If this document does not exist in English, an English translation or at least an English summary of the document should be provided, if possible;
2. For ICH Guidelines, part of the "Tier 2 Guidelines", which are not yet implemented: the Regulatory Member should submit a specific plan with identified milestones and timeframes for their implementation in the next five (5) years (already required in the Application form);

3. If the Regulatory Member considers that a given ICH Guideline has not been adequately implemented, it should provide information on the deviations compared to ICH Guidelines;
4. The ICH Secretariat should keep a register of the current state of play of implementation regarding all ICH Guidelines of all authorities that are Regulatory Members of the ICH. It is the responsibility of the Regulatory Members to provide the information to the ICH Secretariat with a view to ensure that the register is kept up-to-date.

1.2. Membership Application for Industry Members

1.2.1. Eligibility Criteria for Industry

This section provides guidance and clarification on the eligibility criteria referred to in Article 12(1).

Criteria 1: Further to Article 12(1)(a), having legal personality means that the organisation has the capacity to assume rights and obligations on its behalf of its affiliate members in order to establish a legal relationship with the ICH Association. The criteria of having legal personality are met if the law applicable to the organisation has accorded it legal personality.

Criteria 2: Further to Article 12(1)(b), as an illustration of the international character of the organisation, the organisation should have a global constituency. In view of this, it is expected that the industry organisation, in addition to having affiliate members in at least three continents, that it has well-established international offices at least in the regions of the three Founding Regulatory Members. The organisation or its members or constituents should not already be represented by other Members or Observers in ICH and should provide justification of the incremental value of their Membership to unrepresented constituents or to ICH.

Criteria 3: In line with Article 12(1)(c), when applying for Membership, the Industry Member should provide information about those ICH Guidelines by which it, or its affiliate members, is affected by.

Criteria 4**:** In line with Article 12(1)(d), past participation should be verified by the ICH Secretariat. Only in-person participation will be considered towards Membership in case of face-to-face meetings, with exception of circumstances beyond the control of parties to be communicated in advance of the meeting. For Interested Parties, the participation in ICH meetings prior to the establishment of the ICH Association means in the Working Groups.

Criteria 5: In line with Article 12(1)(e), the appointment of experts and their participation in Working Groups as per the Assembly RoP 4.3, will be verified by the ICH Secretariat from the available records.

1.3. Membership Application Process

1.3.1. Application Form

Further to Article 13(1), the applicant should use the application form which is available for downloading on the website of the ICH Association. All parts of the application form should be fully filled in, and the necessary documentation should be provided. For questions or requests for clarifications, the applicant may contact the ICH Secretariat.

1.3.2. Application Review Process

Further to Article 13(2), the Management Committee, through the ICH Secretariat, or the ICH Secretariat may come back to the applicant in order to request missing or additional information and/or clarification. The Management Committee should process the applications as soon as possible, but the duration of the assessment will naturally depend on the completeness, accuracy and complexity (e.g., evaluation of partial implementation of ICH Guidelines) of the information provided by the applicant as well as on the workload of the Management Committee.

The applicants for Membership, irrespective of whether they have Observer status or not in the ICH Association, whose application has been provisionally assessed and considered by the Management Committee as fulfilling the Membership criteria should, in principle, be invited as Ad-hoc Observers within the meaning of Article 18 to the forthcoming Assembly meeting where their application will be dealt with.

The ICH Secretariat will reject any expressions of interest/applications where an organisation / applicant clearly does not meet the eligibility criteria (e.g., individual person / individual company / no past ICH participation) and will provide the applicant with information about the reasons for the rejection. The organisation / applicant may choose to resubmit its expression of interest/application and provide any necessary clarification on its eligibility. The ICH Secretariat will inform the Management Committee of any such rejected expressions of interest / applications.

1.3.3. Decision by the Assembly

As per Article 13(3), the Assembly should take a decision on the Membership admission in any of its subsequent meetings. The Assembly may request that additional information is provided by the applicant in order to take a decision. It would be optimal for applications to be submitted sufficiently in advance of Assembly meetings, e.g., preferably at least two months before the forthcoming Assembly meeting.

The applicant may be present during the Assembly meeting when the Membership admission is being discussed. The Chair may, however, decide on his/her own initiative or on the basis of a proposal from a Member to hold all or part of the discussion without the presence of the applicant. As indicated in section 3.6, the Chair may decide on the basis of a proposal by a Member, provided this proposal is supported by at least one (1) other Member, that the decision be taken on the basis of a secret ballot under Article 26(9).

1.4. Termination of Membership

Further to Article 14(1), a Member wishing to withdraw from the Association should send a letter to the ICH Secretariat expressing its intention to withdraw and provide explanation for its decision. As the withdrawal takes effect at the end of the Fiscal Year during which the withdrawal was notified to the ICH Secretariat, the Member may, if it wishes, continue its activities in ICH, including participating in meetings, until the end of the Fiscal Year. The Membership fee for that Fiscal Year (when the Member withdraws) will not be reimbursed given that the withdrawal takes effect at the end of the Fiscal Year.

Further to Article 14(2), exclusion of a Member should only take place in exceptional circumstances and provided the conditions in this Article are met. Examples of continuous failure to comply with the responsibilities of a Member are the recurrent non-payment of the required annual Membership fee or financial contribution referred to in Article 50 (for more than one Fiscal Year) or the repeated, consecutive non-attendance of Assembly meetings. The latter should be interpreted as meaning that if a Member has been absent during the previous two consecutive Assembly meetings, the Member may be excluded if it does not attend the subsequent third Assembly meeting.

Actions or behaviours which seriously impair the proper functioning or reputation of the ICH Association can take the form of engaging in political, nationalist, propagandist, private profit-oriented or other behaviour which is extraneous and detrimental to the technical scientific scope and mission of ICH. It includes intimidating behaviour and other uncivil or disrespectful treatment of the ICH Secretariat or other ICH Members, Observers, and their staff and expert representatives. It can also include seeking to exert pressure and undue influence on the ICH Secretariat, ICH Members or Observers through financial, political, diplomatic, or other channels outside of ICH. It can also take the form of disclosing confidential or sensitive information to outside parties in violation of the requirement to respect professional secrecy / confidentiality undertaking referred to in RoP 7.3 or making insulting or harmful statements publicly regarding the ICH Association, including its bodies, or regarding any of its Members or Observers.

Before taking a decision pursuant to Article 14(2), the Assembly should hear the affected Member. The affected Member may be present during the Assembly meeting when the Membership exclusion is being discussed. The Chair may, however, decide on his/her own initiative or on the basis of a proposal from a Member to hold all or part of the discussion without the presence of the affected Member. As indicated in section 3.6, the Chair may decide on the basis of a proposal by a Member, provided that proposal is supported by at least one (1) other Member, that the decision be taken on the basis of a secret ballot under Article 26(9).

1.5. Member Representation

It is under the discretion of each Member to decide which entity represents that Member in the ICH Association as well as to decide who to nominate as its (individual) representatives in the various bodies of the Association, including the experts in the Working Groups, as long as there is an arrangement so that the nominee can appropriately represent the views of the Member in ICH. Representatives should be made aware, by the Members who nominated them, of their responsibilities in regards to ICH as described in the ICH procedures, including section 7.3 of the Assembly ROP. These representatives of the Members and the Standing Observers should have access to the "members-only" part of the ICH website.

Following the establishment of the ICH Association on October 23, 2015, the European Commission (EC) referred to under Article 8(1)(a) has in its delegation representatives from the European Medicines Agency (EMA). The Ministry of Health, Labour and Welfare of Japan (MHLW) is represented by the Pharmaceuticals and Medical Devices Agency (PMDA) as referred to under Article 8 (1)(b) and there are thus both PMDA and MHLW representatives in its delegation. The US Food and Drug Administration (FDA) referred to under Article 8(1)(c) is represented by the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

The Founding Industry Members referred to under Article 9(1) (a-c) may nominate representatives from the (umbrella) Association or from their affiliate members (individual companies).

1.6. Member Name

All Members of ICH will be referred to using the name of the entity as listed in the official membership list maintained by the ICH Secretariat and posted on the ICH website. This includes the names as they will appear on slides featuring the ICH logo, ICH documents, publications, name tags, name tents, table cards, and all other instances in ICH.

1.7. Member Appointment of Coordinators

Members should appoint one (1) ICH Coordinator for the smooth running of ICH and who acts as the main contact point between the Member and the ICH Secretariat, notably in relation to the work of the Working Groups and to ensure that ICH documents are distributed to the appropriate persons within the area of their responsibility. Considering that Founding Regulators have to appoint experts in all Working Groups, the Founding ICH Regulators may in addition appoint one (1) Technical Coordinator to support the ICH Coordinator. More details about the role of the ICH Coordinators and Technical Coordinators are laid down in the Standard Operating Procedures (SOPs) of the Working Groups.

2. Observer Admission, Termination and Representation

2.1. Standing Observers

Further to Article 16(2)(a), the participation of the Standing Observers in the Assembly and/or the Management Committee meeting is entirely voluntary.

2.1.1. Standing Observer Appointment of Coordinators

Standing Observers may appoint one (1) ICH Coordinator who acts as the main contact point between the Standing Observer and the ICH Secretariat, notably in relation to the work of the Working Groups and to ensure that ICH documents are distributed to the appropriate persons within the area of their responsibility.

2.2. Observers

2.2.1. Eligibility criteria for Observers

This section provides guidance and clarification on the eligibility criteria referred to in Article 17.

Overlapping observership between a Regional Harmonisation Initiative and its individual members

There may be situations where both the Regional Harmonisation Initiative and its individual members are simultaneously Observers in ICH especially because observership is a precursor for membership. In line with Article 11(2)(g), the intention is, however, to avoid that the individual

members of RHIs remain Observers in ICH for a long period of time. The duration of such overlapping observership should therefore be limited in time as the expectation is that the individual members of the RHI will apply for membership in ICH as soon as they meet the eligibility criteria. This calls for coordination between the Regional Harmonisation Initiative and its members about their respective intentions. As regards overlapping observership of a Regional Harmonisation Initiative and one or several of its members, the provisions outlined below should apply to all observership applications submitted after 7 June 2018.

Article 17(1)(a) provides that legislative or administrative authorities, supranational bodies or international organisations with responsibility for the regulation for pharmaceutical products for human use may apply for observership. Supranational bodies are entities that are somewhere between a confederation, i.e., an association of states, and a federation that is a state. Certain powers are delegated to an authority by the member states of the supranational body that possesses competences only to the extent that they are conferred to it by its member states. Within the scope of these competences, the supranational body exercises its powers in a sovereign manner, having its own legislative, executive, and judicial authorities.

As regards legislative or administrative authorities referred to in Article 17(1)(a), different scenarios are outlined below depending on whether or not these applicants are members of a Regional Harmonisation Initiative and whether or not that Regional Harmonisation Initiative is a Member or an Observer in ICH:

A. Application by an individual member of a Regional Harmonisation Initiative that is not a Member or an Observer of ICH should be assessed.
B. Applications by individual members of a Regional Harmonisation Initiative that is itself an Observer of ICH should be assessed. The fact that the RHI is an Observer in ICH should not preclude the individual members of the RHI to become Observers but there should be prior coordination between the Regional Harmonisation Initiative and its members because in line with Article 11(2)(g), the aim is to avoid that the individual members of RHIs remain Observers in ICH for a long period of time. The duration of such overlapping observership should therefore be limited in time in view of the expectation is that the individual members of the RHI will apply for membership in ICH as soon as they meet the eligibility criteria. Once all the individual members of the RHI have become either Observers or Members in ICH, the RHI is expected to withdraw its observership.
C. Application by an individual member of a Regional Harmonisation Initiative that is itself a Member of ICH should not be considered admissible because the Regional Harmonisation Initiative is already in a position to assume rights and obligations on behalf of its individual members and to commit on their behalf to adequately implement ICH guidelines. The application may, however, be assessed if the Regional Harmonisation Initiative commits in writing to withdraw its membership within two (2) months of the admission of the member of the Regional Harmonisation Initiative as a Member of ICH or if the individual member of the RHI intends to leave the RHI. The individual member should include in its application written documentation to support the change in membership representation of the

region in ICH or documentation to support the termination of the membership of the authority in the RHI, e.g., press release or meeting minutes.

Article 17(1)(b) provides that Regional Harmonisation Initiatives may apply for observership. Different scenarios are outlined below depending on whether or not any of the individual members of the Regional Harmonisation Initiative are Members or Observers of ICH:

A. Applications by a Regional Harmonisation Initiative whose individual members are not Members or Observers of ICH should be assessed.

B. Application by a Regional Harmonisation Initiative whose members are Observers in ICH should be assessed. The fact that one or several authorities are Observers in ICH should not preclude the Regional Harmonisation Initiative (of which these authorities are a member) to become an Observer but there should be prior coordination between the Regional Harmonisation Initiative and its members. This is because in line with Article 11(2)(g), the aim is to avoid that the individual members of RHIs remain Observers in ICH for a long period of time. The duration of such overlapping observership should therefore be limited in time in view of the expectation is that the individual members of the RHI will apply for membership in ICH as soon as they meet the eligibility criteria. Once all the individual members of the RHI have become either Observers or Members in ICH, it is expected that the RHI will withdraw its observership in ICH.

C. Applications by Regional Harmonisation Initiatives whose individual member(s) is/are all already Member(s) of ICH should not be assessed unless the individual members of the RHI commit in writing to withdraw their membership in ICH within two (2) months of the admission of the RHI as an Observer in ICH. However, the application from the RHI should be assessed as long as there remains one or more of its individual members that are not yet Members or Observers of ICH. Once all the individual members of the RHI have become either Observers or Members in ICH, it is expected that the RHI will withdraw its observership in ICH.

Eligibility of Industry organisations

Article 17(1)(c) concerns future Industry Members and provides the possibility for the international pharmaceutical industry organisations that do not yet meet all the eligibility criteria under Article 12(1) to get involved in ICH as Observers before applying for Membership. As an illustration of its international character, the industry organisation should have a global constituency. In view of this, it should have affiliates (members or constituents) worldwide and be represented at global level with well-established international offices dedicated to pursuing international interests relating to harmonisation of pharmaceuticals. The organisation should also provide justification of the incremental value of their Membership to unrepresented constituents and to ICH. International pharmaceutical industry organisations whose members of constituents are already represented directly or indirectly by other Members or Observers of ICH are not eligible to become Observers.

Eligibility of International organisations

Article 17(1)(d) requires that the international organisation be represented at global level. As an illustration of its international character, it should have a global constituency and well-established international offices dedicated to pursuing international interests relating to harmonisation of pharmaceuticals. If the organisation that applies for observership is an affiliate organisation of a global umbrella organisation, the applicant organisation would not in principle be considered as an international organisation that is "represented at a global level" within the meaning of Article 17(1)(d). Moreover, the organisation should be directly or indirectly regulated or affected by ICH guideline(s) and be able to demonstrate its interest and expertise and how it can contribute to ICH activities. Being affected by ICH guideline(s) should be interpreted as meaning that the organisation or its members are expected to comply with ICH guideline(s) by the competent regulatory authorities. The organisation should also provide justification of the incremental value of their Membership to unrepresented constituents and to ICH. International organisations whose members of constituents are already represented directly or indirectly by other Members or Observers of ICH are not eligible to become Observers.

2.2.2. Observership Application Process for Observers

Expression of interest (pre-application) of organisations

An international organisation referred to in Article 17(1)(c) and (d) who considers it fulfils the Observership criteria should prior to submitting an application form for Observership, submit a written expression of interest to the ICH Secretariat seeking to exceptionally attend an Assembly meeting as an Ad-hoc Observer, within the meaning of Article 18. Organisations should note that such participation would be at their own expense.

The expression of interest should explain the international organisation's interest in ICH and interest in potentially applying to become an Observer. The Management Committee will decide, whether to extend an invitation to participate in the forthcoming Assembly meeting as an Ad-hoc Observer.

An international organisation invited to participate as an Ad-hoc Observer would be invited to present its organisation to the Assembly and how it is regulated or impacted by ICH Guidelines. The opportunity to participate as an Ad-hoc Observer is intended to be mutually beneficial to both ICH and the organisation in allowing an understanding of each other's activities. International organisations having attended an ICH Assembly meeting as an Ad-hoc Observer following an expression of interest are under no obligation to submit an Observership application.

Application

Further to Article 19(1), an application form is provided for Observership applications to be completed by all parties interested in Observership. The applicants for Observership whose application has been provisionally assessed and considered by the Management Committee as fulfilling the Observership criteria should, in principle, be invited as Ad-hoc Observers within the meaning of Article 18 to the forthcoming Assembly meeting where their application will be dealt with.

Assessment

The ICH Secretariat may reject any expressions of interest/applications where an applicant clearly does not meet the eligibility criteria (e.g., individual person / individual company) and provide the applicant with information about the reasons for the rejection. The applicant may choose to resubmit its expression of interest/application and provide any necessary clarification on its eligibility. The ICH Secretariat will inform the Management Committee of any such rejected expressions of interest / applications.

In assessing applications for Observership from international organisations, the Management Committee should also take into account stakeholder representativeness in ICH with a view to having a balanced representation of different categories of stakeholders and avoid 'over-representation' of any given stakeholder category. The eligibility criteria for Observers referred to in Article 17(1)(d) should therefore be interpreted in a manner so as to facilitate the participation of the main international/global organisations of relevant stakeholder categories that are not yet represented in ICH provided they meet the eligibility criteria and have the adequate expertise to be able to contribute to the work of ICH. The Management Committee may request that additional information is provided by the applicant in order to issue a recommendation.

An RHI that is an Observer should not, as a general rule, be represented by a legislative or administrative authority (DRA) that is already itself a Member or an Observer of the ICH Association.

2.2.3. Decision by the Assembly

As per Article 19(1), the Assembly should take a decision on the Observership admission in any of its subsequent meetings. The Assembly may request that additional information is provided by the applicant in order to take a decision.

The applicant may be present during the Assembly meeting when the Observership admission is being discussed. The Chair may, however, decide on his/her own initiative or on the basis of a proposal from a Member to hold all or part of the discussion without the presence of the applicant. As indicated in section 3.6., the Chair may decide on the basis of a proposal of a Member, provided that proposal is supported by at least one (1) other Member, that the decision be taken on the basis of a secret ballot under Article 26(9).

2.2.4. Representation

Further to Article 17(2), once admitted, the Observer should nominate its delegate and alternate delegate to replace the delegate when he/she is unavailable by notifying the ICH Secretariat of the names of the delegates. Observers participate in the Assembly meeting and have the right to speak and express their opinion. If in the decision-making process, the Assembly resorts to voting, the Observers do not have the right to vote.

In case there is a change of delegate, the Observer should inform the ICH Secretariat without undue delay of the change. In addition to the delegates, there should be no additional participants (including possible translators) from the Observer in the Assembly meetings. For the avoidance of doubt, this rule applies to face-to-face as well as virtual Assembly meetings. Any request for

additional participants should be properly justified. In applying this rule, it is important to ensure equal treatment and equivalent level of representation of all Observers.

2.2.5. Observer Name

All Observers of ICH will be referred to using the name of the entity as listed in the official Observer list maintained by the ICH Secretariat and posted on the ICH website. This includes the names as they will appear on slides featuring the ICH logo, ICH documents, publications, name tags, name tents, table cards, and all other instances in ICH.

2.3. Ad-hoc Observers

Further to Article 18(1), the invited parties can be natural or legal persons (i.e., individuals or entities/organisations). If the invited parties accept the invitation, they are expected to cover their own meeting expenses (unless specified otherwise, see RoP 3.5.6). In terms of entities or organisations to be invited, one can envisage those that have not applied for or do not fulfil the criteria for Observership. See also section 2.2.2 on the Observership application process. The invitations are likely to be submitted to those who have shown interest in ICH activities or who are deemed to have an interest in ICH.

The number of invited Ad-hoc Observers should be kept reasonable for reasons of meeting logistics, e.g., to keep the size of the Assembly manageable.

As a result, and in line with Article 18(2), Ad-hoc Observers need an invitation for each meeting. The invitation can either concern one specific meeting or can concern more than one meeting (but with specifications of the meeting(s) concerned). In addition to the one (1) delegate, there should be no additional participants from the Ad-hoc Observer in the Assembly meetings. For the avoidance of doubt, this rule applies to face-to-face as well as virtual Assembly meetings. This rule should be interpreted strictly in order to ensure equivalent level of representation of all Ad-hoc Observers.

2.4. Termination of Observership

Further to Article 20(3), exclusion of a Standing Observer or an Observer should only take place in exceptional circumstances and provided the conditions in this Article are met. Actions or behaviour which seriously impairs the proper functioning or reputation of the ICH Association can take the form of insulting or harmful statements made publicly or at the meetings of any of the bodies of the ICH Association, in respect of the ICH Association, including its bodies, or in respect of any of its Members or Observers. This can take the form of engaging in political, nationalist, propagandist, private profit-oriented or other behaviour which is extraneous and detrimental to the technical scientific scope and mission of ICH. It includes intimidating behaviour and other uncivil or disrespectful treatment of the ICH Secretariat or ICH Members, Observers, and their staff and expert representatives. It can also include seeking to exert pressure and undue influence on the ICH Secretariat, ICH Members or Observers by pursuing financial, political, diplomatic, or other channels outside of ICH.

The affected Standing Observer or Observer may be present during the Assembly meeting when the Observership exclusion is being discussed. The Chair may, however, decide on his/her own initiative or on the basis of a proposal from a Member to hold all or part of the discussion without the presence

of the affected Standing Observer or Observer. As indicated in section 3.6, the Chair may decide on the basis of a proposal by a Member, provided that proposal is supported by at least one (1) other Member, that the decision be taken on the basis of a secret ballot under Article 26(9).

3. The Assembly

3.1. Election of Assembly Chair and Vice-Chair

Further to Article 24(6), nominations for Chair and Vice-Chair should be submitted in writing by the Members, specifying the name of the representative (of a Member) who is put forward as the candidate as well as a brief résumé in support of the candidature, to the ICH Secretariat no later than the start of the Assembly meeting at which the election is to take place. Standing Observers and Observers do not have the right to put forward nominations for Chair or Vice-Chair.

The decision should be adopted by simple majority of the votes cast and by secret ballot in accordance with Articles 26(7) and (9). Two tellers should be designated amongst the Members, Standing Observers or Observers to assist in the counting of the vote. At each round, the candidate with the lowest number of votes should withdraw. Rounds will run until one candidate receives simple majority of favourable votes of the Members.

From the date of election, the Member whose representative has been appointed as Chair or as Vice-Chair should appoint another representative to represent itself at the Assembly until the termination of the chairmanship or vice-chairmanship. From the date of election, the Chair and Vice-Chair lose their voting rights.

3.2. Role of Assembly Chair and Vice-Chair

In line with Article 26(2), the Chair should do his/her utmost to reach consensus amongst the Members. The Chair should ensure that all Members, as well as Standing Observers and Observers, have been given the opportunity to express their views and should try to reconcile any divergent views. The discussion may be prolonged in the interest of reaching consensus. The Chair should ensure the proper conduct of the Assembly meetings and intervene if a Member representative or an Observer delegate makes insulting or harmful statements regarding the ICH Association, its bodies or its Members or Observers. The discussions in the ICH Association should be related to technical and scientific issues of regulatory harmonisation and any attempt to discuss matters outside the remit of the Association should be avoided.

The Vice-Chair should deputise for the Chair when the latter is unable to chair either all or part of a meeting. The Chair may also delegate the chairing to the Vice-Chair e.g., for specific topics. The Chair and Vice-Chair should agree on how they will work together and generally, the role of the Vice-Chair is to provide support and assistance to the Chair. In the absence of the Vice-Chair, the most experienced representative from amongst the Founding Regulatory Members and Standing Regulatory Members (in terms of number of attended ICH meetings, including those that took place prior to the establishment of the ICH Association) should deputise for the Chair. In the event of resignation of the Chair, the Vice-Chair should take the chair until a new election takes place. The

Chair should notify the ICH Secretariat of his/her intention to resign without delay and the resignation should take effect two (2) months after the date of the notice. The ICH Secretariat should without delay inform the Management Committee and the Assembly of the notification. After the taking of effect of the resignation or in the case of a resignation with immediate effect and until a new Chair has been elected at the subsequent Assembly meeting, the Vice-Chair should act as Chair. In the event the Vice-Chair resigns, the Member from which the Vice-Chair was appointed may, with the support of the Assembly, propose that one of its Representatives act as interim Vice Chair until a new Vice Chair is elected.

The host Regulatory Member where the meeting of the Assembly takes place may appoint an associate Vice-Chair for that meeting. The associate Vice-Chair should assist the Chair and the Vice-Chair, especially in respect of the meeting logistics.

3.3. Calling of Assembly Meetings

3.3.1. Regular Assembly Meetings

Further to Article 24(1), it is foreseen to have regular, bi-annual meetings in spring and autumn as it has been the case for ICH meetings in the past. Assembly meetings will take place as face-to-face meetings except in extraordinary circumstances where the holding of a face-to-face meeting is not possible. This may be due to either the meeting venue becoming inaccessible or a significant number of Members or the ICH Secretariat being prevented from travelling for extraordinary or unforeseen events beyond the control of the Management Committee including, but not limited to, pandemics, natural disasters, terrorism, wars, and government regulations with impact for the meeting or government-imposed travel restrictions. In such event, the Management Committee shall endeavour to take a decision on the need to replace a face-to-face meeting with a virtual meeting as early as possible and prior to the decision, keep the Assembly updated of relevant developments. Further to Article 24(2), the Management Committee shall inform the Assembly of its decision to replace a face-to-face meeting with a virtual meeting together with the date and duration of the virtual meeting at the latest one (1) month prior to the date on which the virtual meeting was scheduled to commence. Should an unforeseen situation occur less than one (1) month before the scheduled start of the face-to-face meeting, the meeting should either be cancelled or rescheduled (either face-to-face or virtually) within a timeframe which respects the 3-month notification period in line with Article 24(2) in the Articles of Association. Assembly RoP 3.3.1.1. provides further information on Assembly virtual meetings.

Further to Article 24(2) and Article 53, in exceptional cases concerning documents that contain sensitive or confidential information, the Chair of the Assembly, after consultation of the Management Committee or the MedDRA Steering Committee, may decide that such documents are only provided to the Members.

In exceptional cases, the timelines referred to in Article 24(2) may not be adhered to. In case of delays, explanations for the delay should be provided to the Members, Standing Observers and Observers.

Further to Article 24(3), any proposals by a Member, or any issues that a Member wishes to discuss, should equally be submitted in writing no later than two (2) months before the date of the Assembly meeting. This will enable the Management Committee to adequately prepare the Assembly meeting.

3.3.1.1. Virtual Assembly Meetings

As per Article 24(1), Article 24(2), Article 36(2)(a) and Assembly RoP 3.3.1, in extraordinary circumstances, the MC may decide to replace an Assembly face-to-face meeting with a virtual meeting. In such case, the provisions in the Assembly RoP that relate to Assembly (face-to-face) meetings are applicable also to Assembly virtual meetings.

However, when the Assembly RoP provide specific procedures that could only practically be carried out physically (i.e. at face-to-face meetings), for example on the appointment of tellers to physically count the votes for the election of the Assembly Chair and Vice-Chair (Assembly RoP 3.1) and the election of Elected Management Committee Representatives (Assembly RoP 3.6.4), the Assembly Chair and Vice-Chair, with support from the ICH Secretariat, will determine how to adapt the procedures for a virtual meeting (for example by selecting appropriate IT tools to carry out the procedure virtually), whilst maintaining the purpose and spirit of the procedure.

3.3.2. Extraordinary Assembly Meetings

Further to Article 24(5), such extraordinary meetings of the Assembly should only take place in urgent situations where this is essential for the functioning of the Association. Examples are situations where there are internal or external serious threats to the existence of the Association, such as a risk of dissolution of the Association or critical external actions, e.g., initiation of court proceedings against the Association with significant potential financial implications for the Association that require an urgent response from the Assembly.

3.4. Preparation for and Conduct of Assembly Meetings

The Management Committee is responsible for submitting recommendations or proposals to the Assembly in preparation of Assembly discussions, as referred to in Articles 24(4) and 36(2)(g). A document or proposal/recommendation may be approved as such, without any amendments, or with amendments or it may be rejected. It is the responsibility of the Chair to decide how to proceed if a given document is not adopted. Many of the documents, such as the ones referred under Article 23(1) points (j), (k), (m), (n), (o), (p) and (q) need to be adopted eventually in order to allow the continued operations of the ICH Association. Should the Assembly not approve the Membership fees, this would have a negative financial impact on the annual budget for the ICH Association. Therefore, and if no other solution can be found in the meantime, the previous year's Membership fees or relevant budgets should automatically be carried over, at least for the recurring expenditures, to the following Fiscal Year as an interim measure until the approval is given.

If the proposed amendments to a given document are not substantial and straightforward, they may be approved by the Assembly at the same meeting, in which case the revised document is adopted. However, in case of substantial amendments, the Management Committee should revise the document in the light of comments and concerns expressed at the Assembly meeting. In its request,

the Assembly may provide a timeline by which the revised document should be submitted to the Assembly. The Assembly should strive to express their concerns clearly and Members may be invited to provide their comments in writing (within a given deadline) to facilitate the preparation of the revised version.

If a Member, a Standing Observer or an Observer put forward proposals to the Assembly during the meeting, the Chair should propose to the Assembly how to handle the proposal (e.g., proceed to a discussion or postpone the discussion to a later meeting). Normally, in order to be dealt with at the Assembly meeting itself, such proposals should be limited without requiring substantial discussions, whereas proposals that require such discussions should be submitted in advance of the meeting in accordance with Article 24(3).

3.4.1. Selection of new topics for harmonisation

Should a Member, a Standing Observer or an Observer suggest a new topic for harmonisation, this request should be submitted to the ICH Secretariat for transmission to the Management Committee. For the development of Concept Papers and the subsequent process of the harmonisation activity, see the SOP on the WGs. In respect of ICH Guideline development, Members of the Assembly should be kept informed of the development process of the various guidelines that are discussed in the Working Groups. This is important particularly for those guidelines developed by Working Groups in which not all Members have appointed experts. Members wishing to have a presentation at the Assembly meeting by the Regulatory Chair or the Rapporteur of a given Working Group regarding the state of play should submit such a proposal within the timelines indicated under Article 24(3). Where the request concerns a Working Group that is not meeting face-to-face in the ICH meeting, the request will be considered by the Management Committee in order to assess whether a remote presentation can be organised. On the basis of recommendations by the Management Committee, the Assembly will review periodically the proposals on new topics in the context of the 5-year plan.

3.4.2. Development and Review of Reflection Papers

Reflection Papers are used to make a proposal for areas where future harmonisation work may be desirable, including identifying specific future topics for harmonisation.

Should a Member/Observer be interested in developing a Reflection Paper, the Member/Observer should first ascertain the Management Committee interest in the subject area of the Reflection Paper. For this purpose, the Member/Observer should first submit a Reflection Paper Proposal, i.e., a high-level summary of the subject area which would be presented in the Reflection Paper. Reflection Paper Proposals should be submitted to the ICH Secretariat following the same timeline as the New Topic Selection Process (see SOP of the WGs).

If the Management Committee supports the Reflection Paper Proposal, the Member/Observer may proceed with developing the Reflection Paper, and it should be submitted to the ICH Secretariat 5 months prior to an Assembly meeting. The Management Committee will review the Reflection Paper against criteria similar to that considered in the review of the Reflection Paper Proposal (refer to the Management Committee RoP 9.2.2), and should provide comments within 2 months of receiving the Reflection Paper.

For more information on the process for development and review of Reflection Papers, see the Management Committee RoP 9.2.2.

3.5. Participation in Assembly Meeting

The names of the Members and Observers as well as their representatives should be published on the website of the ICH Association.

3.5.1. Member Participation in Assembly Meeting

The Member is considered to be present if at least one (1) of its representative(s) nominated in accordance with Article 25 is present at the Assembly.

Further to Article 25, the representatives should be acting upon a written proxy of the Member. The proxy needs to be submitted to the ICH Secretariat at the latest at the start of the Assembly meeting. The proxy does not need to specify the Assembly meeting as the same proxy will continue to be valid until any (or both) of the representatives indicated on the proxy change. When the representative(s) change, a new proxy should be provided. If the Member has appointed two (2) representatives, either of the two (2) representatives nominated by the Member may cast the vote under Article 26(2). This is the general rule. For those Members who have appointed two (2) representatives, the following applies but only in respect of decisions concerning the discharge of the Management Committee: the Members of the Management Committee are requested to designate one (1) of their representatives as the lead representative in the Management Committee, and notify the ICH Secretariat of the name of the lead representative. If this lead representative is also a representative of the Member in the Assembly, the lead representative on the Management Committee should refrain from decision-making and from casting the vote on behalf of the Member (and thus leave this to the other representative).

As regards attendance at meetings, the delegations of the Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members consist of their representatives of the Management Committee (including the Management Committee Chair and Vice Chair), MedDRA Steering Committee, Coordinators and Technical Coordinators. The Chair or Vice-chair of the MedDRA Steering Committee, or in their absence, another representative of the MedDRA Steering Committee, is expected to attend the Assembly meeting for the agenda items relating to MedDRA.

The delegations of the Regulatory Members and Industry Members consist of their representatives of the Management Committee, Coordinators and Technical Coordinators.

Founding Regulatory Members, Founding Industry Members, Standing Regulatory Members, Regulatory Members and Industry Members may, in addition, include one (1) additional participant in their delegation, subject to prior approval of the Management Committee. For the avoidance of doubt, this rule applies to face-to-face as well as virtual Assembly meetings.

Notification of any additional participants to an Assembly meeting should be made to the ICH Secretariat within a month after the opening of the registration. A representative that has been appointed by a Member to attend the Assembly meeting may give a proxy to any of the additional

participants of that Member for a part of the Assembly meeting that the representative(s) are unable to attend.

Attendance at the Assembly meeting should be in-person participation. However, in case of exceptional circumstances, remote participation could be considered. Exception for remote participation should be approved by the Assembly Chair and Vice-Chair and should be communicated to the Secretariat, in advance of the meeting.

It should be noted that the rules on confidentiality, set out in clause 7.3, apply to additional participants in face-to-face and virtual meetings.

3.5.2. Standing Observer and Observer Participation in Assembly Meeting

Further to Articles 16(3) and 17(2), the Standing Observer and Observer are considered to be present if one (1) delegate of the Standing Observer and one (1) delegate or alternate delegate of the Observer is present at the Assembly.

As indicated in Articles 16(2)(a) and 17(2), Standing Observers and Observers have the right to attend the Assembly meeting (without voting rights). Standing Observers and Observers have the right to fully participate in the discussion and to express their opinion. Standing Observers have the right to appoint one (1) additional Coordinator in the Assembly meetings. Observers have no right to appoint additional participants in the Assembly meetings. For the avoidance of doubt, this rule applies to face-to-face as well as virtual Assembly meetings.

3.5.3. ICH Secretariat Participation in Assembly Meeting

The ICH Secretariat staff should also attend the Assembly meetings and provide support notably to the Chair and Vice-Chair, notably on procedural aspects.

3.5.4. Notification of Non Participation in Assembly Meeting

Where a Member, Standing Observer or Observer is unable to participate in an Assembly meeting, the Member, Standing Observer or Observer concerned should inform the ICH Secretariat in advance.

3.5.5. Assignment of Vote in Event of Non Participation in Assembly Meeting

The vote of a Member unable to participate may be assigned by a written proxy to another Member. The ICH Secretariat should inform the Chair and Vice-Chair of the non-attendance and of the proxy of the Member as soon as possible and at the latest at the beginning of the meeting and this information should be recorded in the minutes. In addition to the Member's own vote, each Member may receive a maximum of one vote by proxy.

Although Observers do not have voting rights, if an Observer is unable to participate in a particular Assembly meeting, the Observer may provide a written one-time proxy to another Observer or Member to represent their views. Despite the proxy, the Observer would however not be recorded as having attended the meeting. The ICH Secretariat should inform the Chair and Vice-Chair of the

non-attendance and of the proxy of the Observer as soon as possible and at the latest at the beginning of the meeting and this information should be recorded in the minutes.

In exceptional circumstances when an Observer is unable to attend the Assembly meeting on a regular basis, an Observer can request to be represented by another Observer (subject to ICH Management Committee approval), by providing a written proxy and so long as there is, in addition, a point of contact (e.g., a secretariat) for the Observer which would be copied on all Assembly communications.

3.5.6. Funding of Participation in Assembly Meeting

All meeting participants are participating in the Assembly meetings at their own expense, unless otherwise specified. However, in respect of certain Ad-hoc Observers that are invited to an Assembly meeting, the Assembly or Management Committee may exceptionally decide to provide some funding to allow for their participation.

3.6. Assembly Decision-Making Process

The Assembly is expected to take its decisions by consensus. However, when it is not possible to reach consensus, the Assembly will adopt decisions by voting. According to Article 26(2), each Member has one vote, with the exceptions referred to in Articles 9(2)(a) and 12(2)(b). Votes may be cast by either of the two (2) representatives as it is assumed that both have the right to cast the vote for the Member which they represent. The two (2) representatives jointly decide how to dispose of the vote. To avoid ambiguity (i.e., that the vote of one Member is counted twice due to the fact that each Member may have two representatives), each Member should be given one voting card with the name of the Member. As mentioned under RoP 3.5.1, if one of the two representatives of a given Member in the Assembly is also the lead representative of the Member in the Management Committee, the lead representatives should refrain from casting the vote on behalf of the Member in the Assembly, in respect of the discharge of the Management Committee.

Decisions by majority in accordance with this Article should be passed if consensus is not reached. Prior to voting, the Chair may allow for several rounds of discussions in order to reach consensus, including postponing the voting to a later stage (especially if there is no urgency). Members are free to abstain from voting, i.e., not casting a vote. Abstentions do not count in tallying the vote negatively or positively; when Members abstain, they are in effect only contributing to a quorum.

With the exception relating to matters referred to under Article 26(3) and (4), the Assembly may in accordance with Article 26(8) adopt decisions by written procedure through electronic means, such as the adoption of the minutes of the Assembly meetings. Decisions on ICH Guidelines referred to under Article 26(5) and (6), i.e. the selection of topics (including outlines of Concept Papers) and the adoption of ICH guidelines (*Step 4)*, and decisions under Article 26(7) relating to the intermediate steps prior to the adoption of the final guideline, such as the adoption of the technical document (Step 2a) and the draft ICH guideline (Step 2 b) may be endorsed by written procedure. The decisions by written procedures should be taken by consensus. For the decisions regarding the adoption of the draft ICH guideline (Step 2b), only ICH Regulators' views are considered for the consensus as outlined under section 3.6.2. If consensus cannot be reached, the matter should be postponed for

decision to the next Assembly meeting. The ICH Secretariat should keep record of the approvals given by the Members under the written procedure.

Regarding changes or corrections to ICH Guidelines, see the SOP.

Under Article 26(9), some decisions shall be taken by the Assembly on the basis of secret ballot, however, on the basis of a proposal by a Member, and provided the proposal is supported by at least one (1) other Member, the Chair may decide to take a decision by secret ballot for other matters.

3.6.1. Decisions on Selection of ICH topics

Article 26(5) concerns decisions on the selection of topics on the basis of an outline of a Concept Paper. All the Members have the right to participate in the initial discussions and in the consensus-building on the selection of topics for ICH Guidelines and should thus be given the opportunity to express their views on all topics. The regulatory authorities that are Members of the ICH Association (ICH Regulators) are required in good faith to consider the opinions expressed by the Members representing industry and others. The discussion will be reflected in the minutes. If at the end of the discussion there is consensus amongst all Members, this will be recorded in the minutes of the Assembly meeting.

If there is no consensus, the Chair will request the ICH Regulators to express their views and explain their position in the presence of all Members. The Chair may propose to postpone the discussion or propose to proceed to voting if it appears that further discussions are unlikely to lead to consensus. In the case of voting, only the ICH Regulators have the right to vote on the selection of topics for harmonisation considering that regulators have the ultimate responsibility to ensure the protection of public health and have the responsibility to issue regulatory guidelines. The voting results should be recorded in the minutes of the Assembly meeting. Where an ICH Regulator voted against the decision to select a topic that was selected by the Assembly meeting, that Regulatory Member may request that a note is added to the minutes explaining the reasons for its objection. Notably an explanation should be provided in case an ICH Regulator considers that it will not be in a position to implement the envisaged Guideline.

3.6.2. Decisions on Adoption, Amendment or Withdrawal of ICH Guidelines

Further to Article 26(6), to facilitate the discussion on the adoption, amendment or withdrawal of those ICH Guidelines which are being discussed in Working Groups at the ICH meeting, (during their different development steps), the Regulatory Chair and/or the Rapporteur of the Working Group, accompanied by all the experts of the Working Group concerned, should be invited to the Assembly for this particular agenda item in order to present the results of the Working Group together and put forward proposals e.g., for next steps of the Working Groups to the Assembly.

All the Members have the right to participate in the initial discussions and in the consensus-building on the adoption, amendment or withdrawal of ICH Guidelines. In respect of the development process of ICH Guidelines for the adoption of new ICH Guidelines and amendment of existing guidelines, the views of all Members are considered for the consensus on decisions to endorse the Technical Document (*Step 2a*). However, subject to Articles 9(2)(a) and 12(2)(b), in the subsequent stages, i.e. the endorsement of the draft ICH Guideline (*Step 2b*), the adoption of the final ICH

Guideline (*Step 4*) as well as the withdrawal of an existing ICH Guideline, only ICH Regulators' views are considered for the consensus as this activity is the prerogative of the regulators, considering that they have the ultimate responsibility to ensure the protection of public health and have the responsibility to issue regulatory guidelines. In the case of consensus, the decision will be considered adopted and this will be recorded in the minutes of the Assembly meeting.

If there is no consensus regarding the adoption, amendment or withdrawal of a Final ICH Guideline, the Chair may propose to postpone the discussion or propose to proceed to voting if it appears that further discussions are unlikely to lead to consensus. Also, in the case of voting, only ICH Regulators may cast a vote. Where an ICH Regulator voted against the decision that was adopted by the Assembly meeting, that Regulatory Member may request that a note is added to the minutes explaining the reasons for its objection. Notably an explanation should be provided in case an ICH Regulator considers that it will not be in a position to adhere to the adopted decision.

3.6.3. Granting of Discharge by the Assembly

Further to Article 23(1)(k), the granting of "discharge" amounts to stating that all actions of those bodies that have taken decisions (the Management Committee, and to some extent, the ICH Secretariat) have been in compliance with the Articles of Association. Through the act of discharging, the representatives on these bodies are exempted from liability towards the ICH Association.

3.6.4. Appointment of Elected Management Committee Representatives

Further to Article 23(1)(g), the Assembly is responsible for the appointment of Elected Management Committee Representatives. The Assembly shall review the proposals put forward for Elected Management Committee Representatives from Regulatory Members and Industry Members as per Articles 30 and 31 respectively. As per Article 32, the Assembly shall then take a decision on the appointment of the Elected Management Committee Representatives.

The decision by the Assembly should be adopted by simple majority of the votes cast and by secret ballot under Article 26(7) and (8) of the Articles of Association. Two tellers should be designated amongst the Members or Standing Observers to assist in the counting of the vote. Candidates that receive a simple majority of favourable votes of the Members will be appointed. In case the number of candidates that receive simple majority of the favourable votes exceeds the maximum number of representatives of Regulatory Members or of Industry Members laid down in Article 28(2), a new round of voting will be conducted amongst those candidates within that category that received simple majority. At each round, the candidate(s) with the lowest number of votes should withdraw. Rounds will run until the maximum number of candidates has been reached (and having received simple majority of favourable votes of the Members).

Further to Article 28(3), the term of office of the Elected Management Committee Representatives is three (3) years, and commencing with the first election held in June 2018, new elections for the up to twelve (12) Elected Management Committee Representatives representing the up to eight (8) Regulatory Members and the up to four (4) Industry Members will be held every three (3) years. Interim elections may be held if, following a resignation of an Elected Management Committee Member from the Management Committee or an exclusion of an Elected Management Committee

Member from the Association, a proposal for appointment of a new Elected Management Committee Member has been submitted. If elected at an interim election, the Elected Management Committee Representatives will hold office only for the remaining period of the three (3) year term of office.

3.7. MedDRA Policy

Further to Article 23, as regards MedDRA Steering Committee policy relating to MedDRA, the Assembly is responsible for approving:

- Annual budget, annual work plans and annual reports for MedDRA as part of the Annual budget, work plans and reports of the ICH Association;
- Management Committee recommendations relating to changes to current MedDRA access policy which currently sees MedDRA made available through enterprise-wide subscriptions for commercial users based on a sliding fee scale, and free subscriptions for regulators and other non-profit or non-commercial organisations;
- MedDRA Steering Committee recommendations relating to the policy under which it grants special licenses;
- Management Committee recommendations, informed by recommendation of the MedDRA Steering Committee, to appoint or establish a Maintenance and Support Services Organisation (MSSO) and any additional national maintenance organisations for the purpose of distributing MedDRA in a particular region, in accordance with the Management Committee Rules of Procedures and MedDRA Steering Committee Rules of Procedures.

3.8. Communication of Assembly Discussions

3.8.1. Minutes of Assembly Meetings

The Minutes of the Assembly meetings should as a general rule indicate in respect of each item on the agenda:

- Documents submitted to the Assembly;
- A summary record of the proceedings; at the request of Members or the Standing Observers or Observers, the minutes may also provide further details of the discussion of any dissenting views. If a Member wishes to abstain from participation in the discussion and decision-making on a given agenda point, this should also be recorded in the minutes;
- The decisions taken or the conclusions reached by the Assembly. All decisions are expected to be taken by consensus, and the Chair and Vice-Chair should make all their endeavours to try to reach consensus. Should, however, consensus not be reached in a given matter, the minutes should reflect the discussions, particularly the divergent views and the efforts of trying to reach consensus, in addition to the results of the voting. The minutes should normally indicate how the individual Members have voted (with the exception of elections which are done by secret ballot);
- The list of attendees.

The ICH Secretariat is responsible for drafting the minutes. As regards the adoption of the draft minutes:

- Draft summary of decisions taken and agreed actions, prepared by the ICH Secretariat, should be agreed by the Assembly at the end of the meeting as this will also facilitate the swift communication of the outcome of the meeting, e.g., the press release;
- Draft minutes (prepared in English) should be sent to all Members, Standing Observers and Observers by e-mail within two (2) weeks of the meeting following review by the Assembly Chair and Vice-Chair, unless there are exceptional circumstances;
- Members, Standing Observers and Observers should send either their approval or written objections or comments on the minutes to the ICH Secretariat during a period of one (1) week of the receipt of the draft minutes. A Member, Standing Observer or Observer may request the ICH Secretariat for an extension to the commenting period and should submit a justification for the request. If no comments are received at the end of the extended commenting period, the minutes shall be considered as adopted.
- Minor and editorial issues should be resolved at the discretion of the Chair in consultation with the concerned Member(s), Standing Observer(s) or Observer(s);
- Major issue should be forwarded to all Members, Standing Observers and Observers, together with a proposal from the Chair, in consultation with the Member(s), Standing Observer(s) or Observer(s), on how to resolve the matter. This could be either not to accept the concerns raised by a Member, Standing Observer or Observer or propose amendments to the minutes. In case of amendments to the draft minutes, the revised minutes should be submitted to the Members, Standing Observers and Observers at the latest within two (2) months from the Assembly meeting;
- In case of revised minutes, Members, Standing Observers and Observers should send either their approval or written objections or comments on the revised minutes to the ICH Secretariat during a period of one (1) week of the receipt of the revised minutes, to be determined on the basis of ICH Secretariat consultation with the Chair and Vice-Chair. If no comments are received by the time of the close of the comment period, the minutes shall be considered as adopted. If there are opposing comments, the Chair may decide to postpone the adoption of the minutes until the next meeting.

The adopted minutes should be published on the website of the ICH Association.

3.8.2. Press Release Following Assembly meetings

The ICH Secretariat should be responsible for ensuring the development of the draft press release after the Assembly meeting. This ICH Secretariat may directly undertake this activity itself or identify a volunteer(s) to support this (e.g., Communication expert(s) in attendance of meeting). The draft should be approved by the Assembly Chair, after consultation of the Management Committee for any views, before being published on the website of the ICH Association preferably within one (1) week of the Assembly meeting.

3.8.3. Photography

Participants to ICH meetings, including Members, Observers and *Ad hoc* Observers, acknowledge that photographs may be taken of them during the meeting for use in ICH communications (e.g., ICH website and other social media) unless a participant explicitly requests prior to the start of the meeting that their photograph not be used. All such requests must be made to the ICH Secretariat.

4. Working Groups

Further details about the working of the Working Groups are provided in the Standard Operating Procedure ('SOP') for the Working Groups.

4.1. General

4.1.1. Procedure for the appointment of experts in Working Groups

As regards Working Groups that are established as of 6 June 2019, the procedure outlined in this section 4.1.1. will apply. Shortly after the Assembly has taken a decision to set up a Working Group, the ICH Secretariat will issue a call for expression of interest to all ICH Members and Observers to nominate experts to the Working Group. ICH Member and Observers should submit nominations for experts to Working Groups when the ICH Member and Observer deem that they are in a position to devote the necessary level of effort to participate actively in the activities of the Working Group. This call for expression of interest may also provide an alternative option to nominate experts to a Plenary Working Party as referred to in section 4.1.4. There will be a deadline of 3-weeks from the launch of the call for expression of interest. The MC will then consider all expressions of interest and if needed decide on the prioritisation amongst the requests, as referred to in section 9.3 of the Management Committee RoP. After the requests to nominate experts in Working Groups have been approved by the MC, the Members and Observers should notify the ICH Secretariat of the name of the expert and specify the Working Group to which the expert is appointed. The Members and Observers should inform the ICH Secretariat of any change of experts or the withdrawal of experts.

For further information on the establishment of Working Groups, see the SOP of the Working Groups Sections 1.2.1 and 1.4.

4.1.2. Number of experts in the Working Groups[1]

4.1.2.1. Informal Working Groups, Expert Working Groups, Implementation Working Groups

Excluding the Regulatory Chair and the Rapporteur, ICH Members may appoint maximum up to one (1) expert for each Working Group, with the exception of the Founding Regulatory Members who

may appoint up to two (2) experts per Working Group. In the event a Member elects not to appoint an expert or is not eligible to do so in line with the applicable procedures, the "unused position" is not transferable to another Member unless in exceptional situations where such a transfer is considered justified by the Management Committee and subject to its explicit approval.

Furthermore, Founding Industry Members, Industry Members, Industry Standing Observer and Industry Observers of ICH, may collectively as a group nominate up to 3 additional experts, by coordinating amongst themselves the nomination from a pool of designated industry experts. For further information, see section 1.5.1.2 of the SOP of the Working Groups. In this coordination, efforts should be made to identify the best possible experts across concerned industry sectors while at the same time make efforts to have experts from regions outside of the 3 Founding Members to achieve appropriate diversity in representation of industry perspectives. Industry as a group should provide information in writing to the MC by the deadline for expressions of interest (see Assembly ROP section 4.1.1), outlining which (eligible) industry Members/Observers were approached, including any who declined the possibility to have their expert in that Working Group through this process. The additional experts that would be appointed in this process would subsequently report to the appropriate ICH Founding Industry Member / Industry Member / Industry Standing Observer for their respective industry sector(s). If Industry collectively as a group cannot reach an agreement on which expert(s) to appoint, the additional industry expert position(s) would remain unfilled. If Industry as a group would wish to nominate experts to a Working Group after the deadline for expression of interests to nominate experts, the nomination and supporting information would be reviewed by the MC following the bi-annual process described in section 1.4.1.2 of the SOP of the Working Groups, and in consideration of factors including the then size of the Working Group.

Standing Observers otherwise have the right to appoint maximum one (1) Standing Observer expert. Following a positive decision by the MC under Article 17(3), Observers have the right to appoint maximum one (1) Observer expert.

Members and Observers with one (1) expert in a Working Group may appoint an alternate expert to replace the expert when they are unavailable to ensure continued representation of that Member/Observer in the WG.

4.1.2.2. Discussion Groups

In exceptional circumstances, the ICH Management Committee may decide to establish a Discussion Group to serve as a technical forum for exchange of scientific views around areas for potential future harmonization under ICH. The Assembly Members may nominate a maximum of two (2) experts for each Discussion Group excluding the Regulatory Chair and the Rapporteur. Standing Observers have the right to nominate a maximum of one (1) Standing Observer expert and one (1) alternate expert to replace the Standing Observer expert when he/she is unavailable. Following a positive decision by the MC under Article 17(3), Observers have the right to nominate a maximum of one (1) Observer expert and one (1) alternate expert to replace the Observer expert when he/she is unavailable.

4.1.3. Limiting the number of experts in Working Groups

To ensure the effectiveness and efficiency of **Working Group** operations, the size of ICH Working Groups will be no greater than 25-30 experts; and while some Working Groups established prior to 6 June 2019 may exceptionally be larger, the consideration is that the maximum size of a Working Group should remain at or below 30 experts. There may be an exception to this size limit in the case of Discussion Groups, the membership of which may be larger than a normal WG per the Management Committee's purview. Further details are provided in section 1.4.1. in the SOP. For any Working Group where the interest to appoint experts by Members exceeds the group size limit, or there is interest in appointing experts among Observers, a **Plenary Working Party** (as referred to in section 4.1.4) may be established.

It should also be noted that, for Regulatory Members and for Industry Members, the right to appoint experts is not an absolute right (e.g., as the Industry Member concerned needs to explain how it or its affiliates will be affected or regulated by the guideline in question). The appointment of Observer experts by Observers needs the approval of the Management Committee under Article 17(3).

4.1.4 Plenary Working Party

As of 6 June 2019, a Plenary Working Party may be established for each Working Group which follows the formal ICH Procedure further to approval of its Concept Paper, unless otherwise determined by the Management Committee. The Plenary Working Party includes the Working Group membership, plus additional experts from other ICH Members and Observers who do not have an expert in the Working Group and wish to follow more closely the work on a particular guideline topic. The Plenary Working Party is established based on need and interest, with up to one (1) experts per Member and Observer who is either unable to (1) participate in the Working Group due to the limitations referred to in 4.1.2 and 4.1.3, or (2) devote the necessary level of effort to participate actively in Working Group activities, but still want to follow more closely the progress of the Working Group. In the latter scenario, ICH Members and Observers will be given the alternative option at the time of establishment of a Working Group, as referred to in 4.1.1, to nominate an expert to the Plenary Working Party rather than to the Working Group.

Further information on Plenary Working Parties, including on the scope of activity of these groups, is provided in section 1.6 of the SOP of the Working Groups.

4.2. Appointment of Rapporteurs

Following the establishment of a new Working Group, the Assembly will appoint a Rapporteur. The Rapporteur may be a representative of any Member. The Rapporteurships should as much as possible be attributed in a way to ensure the widest possible geographical distribution. However, if an ICH Member proposed a selected topic, that Member should generally be provided the opportunity to appoint the Rapporteur. Furthermore, in the case of a preceding informal Working Group for that topic, the same representative who led the informal Working Group (generally also the Member who proposed the topic) would be expected to continue in this position for reasons of continuity. Following *Step 2*, the Rapporteurship will rotate to a Regulatory Member if formerly held by an Industry Member. Typically, the Rapporteurship will rotate to the Regulatory Member from

the same region; however, the Assembly may decide to appoint a Regulatory Member from another region to serve as the Rapporteur.

As soon as a new topic is up for adoption on the agenda of the Assembly meeting, and in the event that an Observer proposed the new topic, or that the Member who proposed the topic would not for whatever reason wish to assume the role of Rapporteur, the Members (who are eligible) are invited to confirm to the ICH Secretariat in advance of the meeting their expression of interest to provide a Rapporteur if the new topic is approved. The eligible Members who express such interest should put forward the name of their candidate. In addition to possible expressions of interest submitted prior to the Assembly meeting, and before appointing the Rapporteur, the Chair of the Assembly should at the Assembly meeting request Members (who are eligible) to put forward their expression of interest and put forward the name of their candidate, including his / her résumé. Where more than one candidate has volunteered for the role of Rapporteur, the Assembly will take a decision based on consideration of each candidate's experience.

The appointed Rapporteurs should enjoy the confidence of the Assembly as well as of the Management Committee that is exercising oversight of the Working Groups. Should a Rapporteur no longer enjoy the confidence of the Assembly, it should appoint a new Rapporteur.

In the event that an appointed Rapporteur, for whatever reason, is unable to continue in this position, the Member, which the Rapporteur is a representative of, will be responsible for ensuring there is an Acting Rapporteur, until such time that the Assembly can appoint a new Rapporteur in line with the process outlined above. Such Member will ensure the Rapporteurship, in the first instance by making one of its other experts already participating in the Working Group Acting Rapporteur, and if this is not possible, the Member will instead ensure that the Management Committee identifies an Acting Rapporteur from amongst the other experts in the Working Group. Either way the Management Committee will be informed of the need to appoint an Acting Rapporteur through a notification to the ICH Secretariat.

4.3. Expert Appointment and Participation

All experts appointed to a Working Group by a Member or Observer are expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis to ensure continuity and efficiency of the Working Group process. Any experts appointed to a given Working Group should have the necessary and adequate expertise in the area concerned. Should the appointed expert in a Working Group be unable to participate in a given meeting (face-to-face or via teleconference), that expert should be replaced by the alternate expert and in the absence of an appointed alternate expert, with another qualified expert for that meeting.

If an ICH Member/Observer's expert has an unexplained absence from two or more consecutive meetings of the Working Group, the Rapporteur should inform the Secretariat. The Secretariat will notify the Member or Observer that they may appoint another qualified expert. If the Member or Observer's replacement expert is absent from two or more consecutive meetings, the Rapporteur should again inform the Secretariat and the Member or Observer will lose its right to appoint experts in that particular Working Group. The Secretariat will notify the Member or Observer of the loss of

Working Group membership, offering the option for participation in the PWP for that Working Group.

Before appointing an expert to a Working Group, an Industry Member should provide information to the Management Committee, via the ICH Secretariat about how it or its affiliate members will be affected or regulated by the guideline in question in line with Article 12(2)(d). The Management Committee may invite further clarification on this point.

The approved experts from the Industry Members will fully participate in the development of a Technical Document (under *Step 2a*) in the Working Group. After *Step 2b* is reached, the experts appointed by the Industry Member will remain members of the Working Groups and will continue participating in the meetings of the Working Groups.

Observers wishing to request to appoint an Observer expert in a given Working Group (subject to MC approval), should inform the ICH Secretariat of their interest and providing explanations for their interest in this Working Group, information about their available expertise and how they expect to contribute to the work of the Working Group. Separate requests should be made for each Working Group. The experts that are appointed to a given Working Group should have the necessary and adequate expertise in the area concerned.

4.4. Working Group Quorum

Quorum for meetings (face-to-face or virtual) of the Working Groups:

- If Founding Industry Members and/or Standing Regulatory Members have not appointed experts in a Working Group, the presence of an expert from at least two (2) of the Founding Regulatory Members, including the Founding Regulatory Member that holds the position of Regulatory Chair or Rapporteur, is required for the quorum of the Working Group;
- For a Working Group to which Founding Industry Members and/or Standing Regulatory Members have appointed experts, the presence of at least one expert from each of those Members that have appointed experts, including an expert from at least two (2) of the Founding Regulatory Members, including the Founding Regulatory Member that holds the position of Regulatory Chair or Rapporteur, is required for the quorum of that Working Group.

5. Financing of ICH

5.1. Member Responsibility to Finance ICH Association

Further to Article 50(2), and the raising of the necessary financial means, Members are required to contribute to the financing of the ICH Association. Members are normally expected to pay an annual Membership fee but where the payment of an annual Membership fee is not possible due to the laws and regulations that apply to the Member, it may instead pay an annual financial contribution. No Member should be required to pay both an annual Membership fee and an annual financial contribution and the amounts of the annual payment should not depend on the form of the payment

(i.e., whether it is referred to as a Membership fee or a financial contribution). Regional flexibility is allowed regarding how and when the payments are made for the Fiscal Year concerned.

5.2. Determination of Annual Fees / Contributions

General principles: In line with Article 51(2), the amounts should be fair and proportionate so that Members that bear similar rights and duties within the same Membership category pay similar amounts. The amount of the fees should be based on objective criteria. There may be deviations from this starting point, but they should be justified objectively.

The starting point is equal treatment of Members within the same Membership category. However, as per Article 51(3) when the type of Member is very different, distinguishing between Members should be possible under objective criteria.

5.3. Non-Payment of Annual Fees / Contributions

Members are expected to contribute to the funding of the ICH Association on an annual basis. Further to Article 50(1), the manner and format in which the Member is able to provide such contribution will depend largely on the applicable laws and regulations applicable to the Member.

However, it should be recognised that particularly regulatory authorities that are Members of the ICH Association are dependent on their respective competent budgetary authority for obtaining their annual budget. Each Member is likely to have different budgetary approval processes.

In the unlikely event that the budgetary authority of a Member concerned will not grant the necessary budget for the following Fiscal Year as a result of which the Member is unable to pay its annual Membership fee or financial contribution, the Member should notify the ICH Secretariat of this without undue delay. The Member should provide explanations for the non-payment, notably confirming that this is beyond the control of the Member and provide an estimation as to whether the Member is expected to be able to provide the payment later (i.e., after the payment deadline) and whether the non-payment is expected to be a one-off situation.

The non-payment of the annual Membership fee or the annual contribution for the following Fiscal Year needs to be considered by the Management Committee in the preparation of the budget for the following Fiscal Year, e.g., by cutting down or reducing some activities. If needed, the shortfall in income may be compensated by the use of any existing reserve fund.

As regards possible consequences, the non-payment for one Fiscal Year is not a sufficient reason in itself to exclude a Member from the Association as the exclusion requires the continuous failure to comply with the Member's responsibilities under Article 14(2). It should also be taken into account that if the non-payment is beyond the control of the Member itself. However, in the case of non-payment by the Member of its annual Membership fee or annual financial contribution for the second, consecutive Fiscal Year, the Member's status within the Association may be reviewed. The decision on the exclusion is taken by the Assembly on the basis of the proposal of the Management Committee (Article 23(1)(e)). The decision on the exclusion should take into account the reasons for the non-payment, e.g., whether this is likely to be a temporary issue that is expected to be resolved or whether it represents a non-commitment to the ICH Association. The Member itself may naturally

also voluntarily withdraw from the Association as referred to in Article 14(1). Regional flexibility is allowed regarding how and when the payments are made for the Fiscal Year concerned.

5.4. Support by Other Means

5.4.1. Additional Financial Means

In line with Article 50(3) additional financial means can be raised in case the ICH Association needs additional funding sources to cover its budget and where an increase in the annual Membership fees or annual financial contributions is not considered as an appropriate alternative. It may also be considered worthwhile to diversify the funding sources in order not to depend entirely on annual Membership fees or annual financial contributions.

Examples of participation fees could be fees charged to participants in the ICH meetings.

It may be decided to organise specific meetings and/or events, possibly including issuing a publication, with the purpose of raising additional funds, if necessary, in order to cover the costs of the Association.

5.4.2. Non-Financial Means

Further to Article 50(5), examples of such means could be:

a. Organisational support for meetings and/or workshops and the provision of documents for the topics to be discussed in the course of such meetings;
b. Production and circulation of publications about ICH-related activities, as well as other informative material relating to ICH activities;
c. Providing expertise in kind.

5.4.3. Other Means

The purpose with the provision in Article 50(4) is to keep options open for other possible sources of funding. Where the budget is fully covered by the foreseen annual Membership fees / financial contributions, there will be no pressing need to introduce additional forms of funding. A sustainable funding model is necessary to guarantee the continued functioning of the ICH Association, and such a model should be based on annual Membership fees or corresponding annual financial contributions.

See Annex 2 for ICH Policy regarding additional financial contributions.

6. Cooperation

6.1. Cooperation with Other Organisations

As per Article 4, the ICH Association may cooperate with another organisation e.g., for the purposes of sharing a common office in order to achieve cost savings. Other forms of cooperation can be envisaged with other international organisations with which there are common interests, for

example to pursue training activities, or with organisations with similar or related activities, such as IPRP, VICH and PIC/S. The agreement on cooperation should be captured in written form, e.g., through an exchange of letters or other written agreement clearly spelling out the interest in the cooperation, its scope and duration. Expected resource (both in terms of human and financial) implications, as well as any other obligations or risks for the ICH Association should also be analysed by the Management Committee before putting forward a proposal to the Assembly for a decision on entering into such cooperation.

The Assembly should be requested to approve such cooperation on the basis of a written proposal provided by the Management Committee, including such proposals related to MedDRA as recommended by the MedDRA Steering Committee.

For the avoidance of doubt, excluded from the concept of cooperation are contracts related to general operations of the ICH Association for which budget has been approved by the Assembly (e.g., Secretariat office rental, staff contracts and operational support contracts, website development etc…). Other contracts, which are significant/high-profile for the Association, for example in view of significant multi-year costs, obligations or risks (e.g., MSSO Contractor, Professional Conference Organiser), should be brought to the attention of the Assembly by the Management Committee before being entered into or terminated and the Assembly invited to confirm its support to proceed.

Furthermore, cooperation agreements entered into via third parties that have been engaged by ICH (e.g., by the MSSO Contractor) are also excluded from this provision on ICH Cooperation provided that such cooperation agreements remain within the remit of the responsibilities entrusted to the third party engaged by ICH.

7. Supporting ICH

7.1. Supporting Aims

In line with Articles 8(3)(e), 9(3)(e), 10(3)(d), 11(4)(a) and 12(3)(c), all Members should act in the interest of the Association. As a Member of the ICH Association, the Member is accepting the aims and purposes of the Association, with protection of public health being at the forefront, and should act in accordance with these.

7.2. Promoting ICH Guidelines

The Founding Regulatory Members, Standing Regulatory Members and Regulatory Members are expected to actively promote the use and understanding of the ICH Guidelines. A policy or strategy should be put in place to promote the use and understanding of the ICH Guidelines by all relevant staff of the authority. This is particularly important for an RHI in order to promote the use and understanding of the ICH Guidelines amongst all the members of the RHI.

In line with Articles 9(3)(b) and 12(3)(a) respectively, Founding Industry and Industry Members which have individual pharmaceutical companies as their affiliate members, are expected to actively promote the compliance of its affiliate members with the ICH Guidelines. A policy or strategy should be put in place to provide for the dissemination and understanding of the ICH Guidelines amongst

the affiliate members. In particular, participation in regional public meetings on ICH as well as in other events, such as conferences, where ICH Guidelines are on the agenda is encouraged.

7.3. Maintaining Confidentiality

Further to Article 53, the representatives of the Members, Standing Observers, Observers and Ad-hoc Observers should be required, even after their duties have ceased, not to disclose sensitive, confidential information of the kind covered by the obligation of professional secrecy. The representatives of the Members, Standing Observers, Observers and Ad-hoc Observers are entitled to share such confidential information with persons within their respective organisation and third parties provided that the recipients (i) must have access to the confidential information to fulfil their duties within their organisation and (ii) executed a confidentiality agreement or arrangement that has corresponding confidentiality obligations or that such persons or third parties are otherwise bound to confidentiality obligations. The representatives of the Members, Standing Observers, Observers and Ad-hoc Observers shall not use the confidential information for any purpose other than as necessary to enjoy their rights or perform their obligations within the Association. For the avoidance of doubt, confidential information includes draft documents and proposals pending Assembly approval, in addition to other information not in public domain. For the avoidance of doubt, this clause applies to all representatives of the Members, Standing Observers, Observers and Ad-hoc Observers, including, but not limited to, the official Representatives, Delegates, Coordinators, Technical Coordinators, and any additional participant to the face-to-face meetings and virtual meetings, as well as any support staff who have been requested by a Member, Standing Observer, Observer or Ad-hoc Observer to have access to information shared by ICH, whether through email or otherwise. It is the responsibility of the official Representatives and Delegates of the Member, Standing Observer, Observer or Ad-hoc Observer to ensure that all those supporting them and with access to information shared by ICH at their request are asked to take note of and abide by this ICH provision on confidentiality.

8. Legal Considerations

8.1. Member Conflicts with Governing Laws

As per Article 55, each Member will continue to be bound by the (national, supranational etc.) laws and regulations that are applicable to that Member. Therefore, in the unlikely case of a conflict between the applicable law of the Member and the Articles of Association of the ICH Association, the Member will not be required under the Articles of Association (or under the Rules of Procedure) to take any action that would breach those laws.

In any event, the Members are free to choose how they exercise their rights and deal with the requirements under these Articles of Association. When submitting an application for Membership, it is presumed that the applicant has examined the Articles of Association and concluded that they are not in conflict with the applicable laws of that applicant. After having become a Member and in participating in the discussions and decision-making in the Association, the Members are expected to ensure that they comply with the applicable laws of that Member. Any Member may always abstain from participating in the discussions and/or decision-making on any topic. Ultimately, a

Member, Standing Observer and Observer may also decide to withdraw its Membership or Observership in the ICH Association.

8.2. Conflict of interest

Further to Article 54, to ensure the highest integrity of and public confidence in ICH's activities, the representatives, including experts of ICH Members and Observers are expected to act not only in the interest of their appointing organisations, but also in accordance with the mission of ICH in achieving global harmonization. When it comes to experts, the need to strike the right balance between finding the best expertise and conflict of interest should also be recognized. In general, there are two categories of activity where this balance is a particular concern: ICH harmonized guideline development on a particular topic, and ICH activities influencing or determining services procurement or other contract awards. Actual or perceived conflicts of interests (hereinafter 'CoI') of individual representatives and experts should not interfere with the primary interest of the ICH Members and Observers that are appointing these representatives and experts or with ICH's mission. The provisions outlined below are intended to provide general guidance for these two categories.

I. Experts appointed to Working Groups

A. Experts appointed by the Industry Members/Observers

In accordance with the applicable Articles of Association and Assembly Rules of Procedure, only international pharmaceutical industry organisations that have a global constituency are eligible for membership and observership in ICH. The experts appointed by the Industry Members/Observers who participate in the Working Groups are therefore representing their respective industry organisations and not the individual, pharmaceutical companies where they may be employed. In the interest of parity and transparency, it is expected that these experts provide information about their interests to the appointing Industry Member/Observer organization for their awareness (see general guidance below under point B). It is up to each Industry Member/Observer to ensure that their experts adhere to the applicable (internal) rules pertaining to these organisations and that the experts act within the mission of ICH.

B. Experts appointed by the Regulatory Members/Observers

Experts appointed by the Regulatory Members/Observers who participate in Working Groups are subject to the applicable (internal) rules on CoI that pertain to the appointing Regulatory Member/Observer. Experts are expected to disclose their interests to the appointing Regulatory Member/Observer. It is up to the ICH Regulatory Members/Observers to ensure that the experts they appoint in ICH WGs adhere to the applicable (internal) rules and that they act within the mission of ICH. However, some general guidance is useful in order to strengthen the integrity of and public confidence in ICH and its activities, by reiterating what is generally considered to be perceived or actual competing financial interests in the pharmaceutical industry or commercial entities with an interest related to the subject of the work in the WG:

(a) Regarding employment and consulting, receiving remuneration from the pharmaceutical industry or from a commercial entity with an interest related to the subject of the work of the WG; or

(b) Investment interests in a pharmaceutical industry or in a commercial entity with an interest related to the subject of the work of the WG (shares, stocks, bonds, stock options…) or commercial business interests (proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company).
(c) Receiving research support, including grants, collaborations, sponsorships and other funding from the pharmaceutical industry or from a commercial entity with an interest related to the subject of the work;
(d) Having intellectual property rights (patents, trademarks or copyrights, including pending applications) that may be enhanced or diminished by the outcome of the work of the WG.

II. Experts appointed by ICH Members or Observers to working groups, sub-committees, task forces etc. that are involved in procurement ('procurement-related working groups')

Identification of CoI should be made at the point of establishing the procurement-related working group, which includes the preparatory stage e.g. preparing requests for information, developing terms of reference. Experts involved should not have any actual or perceived conflict of interest i.e. a personal interest in the outcome of the procurement process. A conflict of interest generally arises due to a relationship or an activity that affects, or can be perceived to affect, a person's independence, objectivity and impartiality. Experts should not have any current secondary or competing interests that could materially interfere with the duty to act impartially in the work undertaken. Experts should also not in the past two (2) years from the establishment of the group have any past secondary or competing interests that could materially interfere with the duty to act impartially in the work undertaken. This is essential to ensure the integrity, fairness and transparency of the processes. Each expert should disclose any CoI as defined in the applicable (internal) rules of the appointing Member/Observer and any CoI as described in this section to its appointing Member or Observer before the appointment to the procurement-related working group.

The chair and vice-chair of the procurement-related working group should at the first meeting of the group receive confirmation from all experts in the group that they do not have any current or past CoI. If there is a declared CoI or a suspected CoI, the chair and vice-chair should inform the Member/Observer that has appointed the expert concerned. If, after assessing the interest, the Member/Observer considers there to be a CoI as described in this section or a CoI according to the applicable (internal) rules of that Member/Observer, it is recommended that the Member/Observer removes the expert and replaces him/her (in accordance with the ICH procedure). If the Member/Observer considers that the expert has a CoI or suspects a CoI as described in this section, but still wishes to retain this expert in the group and discuss other mitigating options (described below), the Member or Observer should inform the ICH Secretariat that will bring this matter to the Management Committee for its consideration along the lines explained in the section "Managing CoI" in the MC RoP.

8.3. Liability

As per Article 56(1), the ICH Association being a legal entity means that any liability may only be enforced towards the assets of the Association and thus limiting the personal liability of the individuals who are serving on any of the bodies of the Association or in working groups.

Further to Article 56(2), under Swiss law, liability cannot be excluded in the case of intent or gross negligence.

8.4. Dissolution of Association

Further to Article 57(2), in case of a voluntary dissolution and where the Association disposes of any assets, the Assembly should decide on their liquidation in the same meeting. In particular, the Assembly should appoint a liquidator in accordance with Swiss law. The Assembly should decide to which Swiss organisation (that is pursing the same or similar non-profit purpose as the ICH Association) the liquidator should transfer the remaining assets. The ICH Secretariat should make any notifications required under Swiss law.

As indicated under Article 26(3)(c), the decision to dissolve the Association can only be taken by three-quarter (3/4) majority of the Assembly, which must include the votes of each Founding Regulatory Member.

8.5. Dispute Resolution

Further to Article 58, disputes between the Association and its Members or amongst its Members should be referred to the ICH outside legal counsel by the Chair of the Assembly who should provide a written summary of the subject of the dispute. The ICH outside legal counsel should act as a mediator between the parties of the dispute and he/she should in this capacity act in a neutral and objective manner. The ICH outside legal counsel should provide the parties involved in the dispute with the opportunity to put forward their arguments and he/she may set up meetings (virtual or face-to-face) in order to try to resolve the matter. If an amicable settlement cannot be found between the parties, the ICH outside legal counsel prepares a report of his/her mediation to the Assembly. The Assembly should consider whether it is possible to resolve the dispute.

If the latter cannot be resolved, the Assembly, upon a proposal by the Management Committee (unless the dispute involves a Member of the Management Committee, in which case the Management Committee should refrain from making a proposal), should designate three (3) representatives for the Dispute Resolution Board from amongst the regulatory authorities that are Members of the Association, including one Founding Regulatory Member (or Standing Regulatory Member) that should act as Chair. Should the dispute involve one Founding Regulatory Member, a representative of a Standing Regulatory Member should act as Chair. None of the Members may be a party to the dispute.

The ICH outside legal counsel should assist the Dispute Resolution Board by providing legal advice, and should attend all meetings of the Dispute Resolution Board. Also, the Secretary General of the

ICH Secretariat should attend all meetings of the Dispute Resolution Board and keep a register of all the documents and draw up minutes of the meetings and of any oral proceedings.

The dispute Resolution Board should be convened by its Chair who should ensure the quality and consistency of the Board's decisions. The Chair should assign the examination of the dispute to one of the Board's members as Rapporteur. The Rapporteur should carry out a preliminary study of the dispute. The Rapporteur should ensure a close consultation and exchange of information with the parties to the proceedings. For this purpose, the Rapporteur should prepare the necessary communications to the parties and set appropriate procedural time limits. The Rapporteur should prepare the internal meetings of the Board and should draft the decision, with the assistance of the legal counsel of the ICH Association.

Only members of the Board should participate in the deliberations; the Chair may authorise other persons to attend. Deliberations should be secret. During the deliberations between members of the Board, the opinion of the Rapporteur should be heard first and the Chair last.

Decisions of the Dispute Resolution Board should be taken by a majority of its members. Abstentions should not be permitted.

ANNEX 1: Definitions of terms in the context of the implementation of ICH Guidelines

Term	Definition	Comments
Not (yet) implemented	The process for the implementation of an ICH Guideline has not yet started.	a) No guideline exists or b) national/ regional guideline deviating from ICH Guideline or national/regional guideline exists but the process for replacement or amendments for alignment with the ICH Guideline has not started yet.
In the process of implementation	The process for the implementation of the ICH Guideline has started and has reached a specified milestone. The process is monitored by the regulator and the progress is reported to the ICH MC/Assembly on a regular basis.	The process can have different starting points: a) no national/regional guideline exists; the ICH Guideline defines new requirements and b) a national/regional guideline is in the process of development or c) a national/regional guideline exists and is replaced by or is amended to be in line with the ICH Guideline. Generic processes for a) non-electronic and b) electronic guidelines will be defined outlining the milestones that should be followed.
Implemented	The process of implementation is completed. This step is identical to step 5 of the ICH process.	This term refers to the self-declaration of the regulator regarding the conclusion of the implementation process. The regulator makes publicly available the final guideline.
Adequately implemented	All relevant elements, concepts and principles of the ICH Guideline are followed. This is done preferably by referring to/implementing the original ICH Guideline text and/or translating the original guideline text. This may include in	Minimal elements, concepts and principles will be defined and included in the survey to assess the degree of implementation. Additional information to the ICH guideline should only be included in order to provide clarity and facilitate

Term	Definition	Comments
	justified cases implementation of the guideline in a way that may incorporate additional information beyond those defined in the ICH Guideline in circumstances when the Guideline is too high-level and does not provide sufficient guidance.	implementation by industry, but should not increase regulatory burden. Deviations or additional information to help clarify concepts should be communicated (with the justification) to the ICH Management Committee for transparency and possibly assessment.
Not adequately implemented	The ICH Guideline has been implemented in a modified way that a) incorporates additional requirements beyond those defined in the ICH Guideline without objective justification in cases where clear guidance is provided, or b) does not include all relevant elements, concepts and principles of the ICH guideline and does not provide any objective justification for omitting some requirements in the guideline or c) requires application of the guideline for a smaller range of products than outlined in the ICH Guideline.	Lack of adequate implementation means that the ICH guideline has not been adequately implemented following an assessment of the regulatory or administrative step that incorporates the ICH Guideline into the regulatory framework. There may be varying degrees of inadequate implementation and this assessment can only be done on a case-by-case basis. Examples could be taken from the Industry Survey to illustrate this range. It should be noted that according to the Assembly RoP (v. 4.0), deviation from the guideline, in exceptional cases, may be accepted if objectively justified.
Adherence*	In its practice, the regulatory authority consistently adheres to (applies) all identified relevant elements, concepts and	Once an ICH Guideline has been (adequately) implemented by a regulatory authority, experience is gathered on how the regulator applies the guideline in practice. Adherence leads to

* Adherence at this point in time is defined as application of the ICH Guideline by the regulator's view. At a later stage, consideration will be given to the aspect of adherence to the guideline requirements by industry's view.

Term	Definition	Comments
	principles of the ICH Guideline over time.	a stable regulatory environment and to increased sustainability. Adherence may be assessed in regular intervals.
Lack of adherence	Even if the guideline has been adequately implemented, it is not being applied and adhered to in practice.	The regulatory authority does not in practice require industry to adhere to the guideline or does not follow the guideline when assessing the applications; e.g., is in its practice adding requirements beyond what is provided in the (implemented) ICH guideline.
Confirmed implementation/ adherence	Both the implementation of and adherence to the ICH Guideline have been assessed by an independent third party and have been found to be adequate by the Assembly/the MC (see above).	The assessment should be done in two-steps: first assessment of a) adequate implementation and then b) adherence to the ICH Guideline. The implementation should not be considered confirmed even in case of adherence if there is no adequate implementation of the ICH Guideline (i.e., where the regulatory authority in practice accepts submissions that comply with the requirements in the ICH Guideline despite not having adequately implemented it).
Not applicable	The implementation of a specific ICH guideline is not applicable in a country/region. An appropriate justification is provided.	Example: A country may not have its own Pharmacopeia but references internationally recognized Pharmacopoeias. Hence, the ICH Q4B Guideline is not applicable (and does not need to be implemented).

ANNEX 2: ICH Policy Regarding Additional Financial Contributions

Article 50(3) of the Articles of Association identifies financial contributions as a means by which the costs of the Association may be covered.

The ICH Association has the right to accept or refuse donations proposed to cover the costs of the association at its entire discretion.

The ICH Donation policy aims to:

- Inform potential donators on how to formulate proposals for donations and the conditions under which these proposals will be considered and accepted.
- Guide the Association in the examination of donation proposals.

The ICH Donation policy identifies the following circumstances under and steps by which monetary donations to the association be considered eligible for acceptance:

- Review of Donation Proposals:
    - Each donation proposal will be submitted using the template provided by the ICH Secretariat. Proposals will be reviewed on a case-by-case basis by the Financial Subcommittee with respect to the criteria listed below. The Financial Subcommittee will present a recommendation to the Management Committee for decision. The Financial Subcommittee will also inform the Management Committee of the donation proposals that are not considered eligible.
    - After the transition period, the decision will be made by the assembly, following a recommendation by the Management Committee.
- Scope of Donation Proposals:
    - Donations will be used to support the funding of ICH within the purpose of the association.
- Donating party limitation:
    - The donating party will submit a proposal which will cover the rationale as to why the donation is being made. The donating party will not be limited to parties who hold Membership or Observership (regulatory agencies, industry associations, RHIs, NGOs), and may be any external party unless a clear conflict of interest can be identified.
- Conflict of Interest/Reputational risk:
    - Donations will not be accepted if they are considered as presenting a risk for a conflict of interest or a risk to damage the reputation of the Association. For example, external parties will be prohibited from making donations during periods when their Membership or Observership application is under review, and/or they are lobbying the association for direction and/or support on a new or ongoing contentious topic.
- Size and frequency of donations:

    - The maximum donation will not be restricted in the outset but rather reviewed when submitted and assessed against the respective year's budget by the Financial Subcommittee.
- Transparency
    - The donating party will agree to have its name, along with the size of the donation publicly disclosed on the ICH website as part of routine financial reporting by the Association.
- Refundability
    - The ICH Assembly, based on a recommendation from the Management Committee, reserves the right to refund any donation made to the Association by an organisation should it be made aware of any conflict of interest or risk to the Association following the time that the donation has been made.