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

Rules of Procedure of the Assembly

Version 1.0
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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

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Assembly RoPs
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RULES OF PROCEDURE OVERVIEW

Further to Article 26 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 25(2) and 25(4) of the Articles of Association.

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 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 regulation without any political connotation, e.g., a country, a constituent state, or even a community.

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 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. 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 will be verified by the ICH Secretariat from the available records.

Criteria 5: As per Article 11(1), second sub-paragraph, implementation of ICH Q1, Q7 and E6 Guidelines – see the section on implementation of Guidelines under RoP 1.1.3 below***.***

1.1.2. Eligibility Criteria for Regional Harmonisation Initiative (RHI)

This section provides guidance and clarification on the eligibility criteria referred to in Article 11(2).

Criteria 1: Further to 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 a 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 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 11(2)(d), the past participation will be verified by the ICH Secretariat from the meeting records. 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 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 implemented by all the members of the RHI.

Criteria 7: As per Article 11(2) second sub-paragraph, implementation of ICH Q1, Q7 and E6 Guidelines – see the section on implementation of Guidelines under RoP 1.1.3.

1.1.3. Implementation of ICH Guidelines

As per Article 11(5), the aim and intention is that all ICH Regulators should implement 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 implementation in the different jurisdictions is a responsibility of the competent regulator in each jurisdiction. Therefore, the notion that ICH Regulators are "expected to 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 implemented 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 implementing 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 implementation is included amongst the membership criteria under 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 implement 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 in full or may choose to implement it only partially. 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 fully implement this particular guideline. ICH Guidelines should be 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 implemented consistently 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 arbitrarily adding further requirements based on national or regional considerations if these are not based on objective grounds as this may lead to disharmony. Regulatory Members should also refrain from 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.

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 fully 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 is present, i.e., that it has affiliate members in the regions of the three Founding Regulatory Members.

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.

Criteria 5: In line with Article 12(1)(e), the appointment of experts 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.

1.3.3. Decision by the Assembly

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

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 affect 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 57 (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 behaviour which seriously impairs the proper functioning or reputation of the ICH Association can 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.

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.

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 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 (*Note: these SOPs are currently under development)*.

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.

2.2. Observers

2.2.1. Observership Application Process

Further to Article 17(2), an application form is provided for Observership applications. The eligibility criteria for Observership are broad and general and should be interpreted in a flexible manner in order to be inclusive. 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.

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

As per Article 17(3), those parties who were former Global Cooperation members are exempt from applying for Observership and can become Observers immediately upon submission of a confirmation letter within three months of the establishment of the Association. This approach is intended to avoid unnecessary administrative burden both for the applicants and for the ICH Management Committee and the Assembly. Considering the great interest that the Global Cooperation members have shown in the ICH Association prior to its establishment, this procedure facilitates their smooth, straightforward and swift participation in the Assembly.

2.2.2. Representation

Further to Article 17(4), once admitted, the Observer should nominate its delegates that will attend the Assembly meeting 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. The Observer is considered to be present if at least one (1) delegate of the Observer is present at the Assembly.

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 maximum of two (2) delegates, there should be no additional participants (including possible translators) from the Observer in

the 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.

2.3. 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. 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 maximum of two (2) delegates, there should be no additional participants from the Ad-hoc Observer in the 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 19(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.

3. The Assembly

3.1. Election of Assembly Chair and Vice-Chair

Further to Article 23(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 25(7) and (8). 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 have the right to appoint another representative to represent itself at the Assembly until the termination of the chairmanship or vice-chairmanship.

3.2. Role of Assembly Chair and Vice-Chair

In line with Article 25(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 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 and until a new Chair has been elected at the subsequent Assembly meeting, the Vice-Chair should act as Chair.

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 23(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.

Further to Article 23(2), 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 Management Committee, may decide that such documents are only provided to the Members.

In exceptional cases, the timelines referred to in Article 23(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 23(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.

3.3.2. Extraordinary Assembly Meetings

Further to Article 23(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 23(4) and 35(2)(g). A document or proposal/recommendation may be approved as such, without any amendments, or with amendments or it may 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 22(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 or the annual budget for MedDRA referred to in points (m), (p) and (q). Therefore, and if no other solution can be found in the meantime, the previous year's membership fees or relevant budgets should be 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 23(3).

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. 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. If the topic is

generally supported by the Assembly, a document (Concept Paper) should be submitted, normally to be developed by the Member, Standing Observer or Observer who proposed the topic. Such a draft Concept Paper drafted by a Member, Standing Observer or Observer should first be assessed by the Management Committee to ensure that it complies with all the requirements laid down in the SOP of the Working Groups before it is submitted to the Assembly. If the Member, Standing Observer or Observer does not wish to develop a Concept Paper, the Assembly may also request the Management Committee to assess the matter and, if the Management Committee is supportive of the topic, put forward a proposal for a Concept Paper. 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 23(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.

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 24 is present at the Assembly.

Further to Article 24, 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 25(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 and the MedDRA Management Committee: the Members of these respective committees are requested to designate one (1) of their representatives as the lead representative in the Management Committee and in the MedDRA Management Committee. If this lead representative is also a representative of the Member in the Assembly, the lead representative on the Management Committee or the MedDRA 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 consisting of the two (2) representatives of each of the Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members may, in addition, include a maximum of two (2)

additional participants, excluding their representatives of the Management Committee, representatives of the MedDRA Management Committee, Coordinators and Technical Coordinators.

The delegations consisting of the two (2) representatives of each of the Regulatory Members and Industry Members may, in addition, include one (1) additional participant, excluding their representatives of the Management Committee, Coordinators and Technical Coordinators.

Notification of the number of additional participants should be made to the ICH Secretariat at least four (4) weeks in advance of the Assembly meeting. 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.

3.5.2. Standing Observer and Observer Participation in Assembly Meeting

Further to Articles 16(3) and 17(4), the Standing Observer and Observer are considered to be present if at least one (1) delegate of the Standing Observer and of the Observer is present at the Assembly.

As indicated in Articles 16(2)(a) and 17(4), 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 and should also submit a proxy. Standing Observers and Observers have no right to appoint additional participants in the Assembly meetings in addition to the two (2) delegates.

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.

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

According to Article 25(2), each Member has one vote. 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 and/or in the MedDRA 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 and/or the MedDRA 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.

No written procedures for the adoption of decisions are foreseen. However for simpler matters, such as the adoption of the minutes of the Assembly meetings, approval by written procedure is possible. As regards ICH Guidelines referred to under Article 25(5) and (6), the following applies: For any minor changes or corrections needed to a Guideline prior to its publication which are editorial in nature, the ICH Secretariat will consult with the Working Group which developed the Guideline and the ICH Coordinators. Where the Working Group and the ICH Coordinators agree with the change, the Members will be informed of the change / correction. However, if the Working Group and/or the ICH Coordinators consider the change to be more than editorial, the ICH Guideline with the change / correction should be put for adoption at the subsequent Assembly meeting. In case of doubt as to whether the change requires adoption at the next Assembly meeting, the ICH Secretariat should consult the Management Committee.

3.6.1. Decisions on Selection of ICH topics

Article 25(5) concerns decisions on the selection of topics and also applies to the adoption of Concept Papers (outlining the topics that have been selected) by the Assembly. 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 25(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.

Subject to Articles 9(2)(a) and 12(2)(b), 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, 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 22(1)(k), the granting of “discharge” amounts to stating that all actions of those bodies that have taken decisions (the Management Committee, the MedDRA

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.

3.7. Communication of Assembly Discussions

3.7.1. 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, unless there are exceptional circumstances;
- Members, Standing Observers and Observers should send written objections or comments on the minutes to the ICH Secretariat during a period of two (2) weeks of the receipt of the draft minutes;
- 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;
- The minutes should be adopted by written procedure after the Assembly meeting or, in the case of substantial amendments (apart from editorial), at the next Assembly meeting.

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

3.7.2. Press Release Following Assembly meetings

The ICH Secretariat should be responsible for preparing a draft press release after the Assembly meeting. The draft should be approved by the Chair, after consultation of the Management Committee, before being published on the website of the ICH Association preferably within two (2) weeks of the Assembly meeting.

4. Working Groups

Further details about the working of the Working Groups are provided in the SOP for the Working Groups (*Note: these SOPs are currently under development)*.

4.1. General

Members should appoint maximum two (2) experts for each Working Group excluding the Regulatory Chair. For the Member holding the Rapporteurship of a Working Group, that Member may appoint one (1) additional expert, in addition to the Rapporteur. In exceptional cases and where justified, this rule can be applied with some degree of flexibility in respect of the number of experts appointed by the Founding Regulatory Members and Founding Industry Members to ensure the adequate level of expertise and the appropriate functioning of all Working Groups. Standing Observers and Observers should appoint maximum one (1) Observer expert and one (1) alternate expert to replace the Observer expert when he/she is unavailable.

The Members that wish to appoint experts in Working Groups should notify the ICH Secretariat of the names of the experts and specify the Working Group to which the experts are appointed. The Members should inform the ICH Secretariat of any change of experts or the withdrawal of experts.

4.2. Appointment of Regulatory Chairs and Rapporteurs

When setting up a new Working Group, a Regulatory Chair should be appointed. The Regulatory Chair should be a representative of the Founding Regulatory Members or the Standing Regulatory Members (at least initially until the moment in time when there will be Elected Management Committee Representatives in the Management Committee).

In addition, a Rapporteur should be appointed for each Working Group. 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.

As soon as a new topic is up for adoption on the agenda of the Assembly meeting, 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 Regulatory Chair or 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 Regulatory Chair and 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.

4.3. Expert Appointment and Participation

4.3.1. Founding Regulatory Member Experts

The experts appointed by the Founding Regulatory Members in all Working Groups are expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis to ensure continuity.

The experts that are appointed to a given Working Group should have the necessary and adequate expertise in the area concerned as they are expected to actively contribute to the work of the Working Group until the work is completed.

The appointment of experts by the Founding Regulatory Members in all Working Groups is a requirement. Should the appointed expert be unable to participate in a given meeting (face-to-face or via teleconference), this expert should be replaced by another qualified expert for that meeting.

4.3.2. Founding Industry Member Experts

Irrespective of Article 9(2)(a), the Founding Industry Members will fully participate in the development of a Technical Document (under *Step 2a*) in the Working Group. After *Step 2b*, the experts appointed by the Founding Industry Members will remain members of the Working Groups and may continue participating in the meetings of the Working Groups.

The Founding Industry Members may also appoint experts in Working Groups that are developing guidelines by which the Founding Industry Member (or its affiliate members) is not affected for which it has appropriate experts in the field.

Once the Founding Industry Member has appointed an expert to a Working Group, this expert is expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis to ensure continuity. All experts that are appointed to a given Working Group should have the necessary and adequate expertise in the topic concerned as they are expected to actively contribute to the work of the Working Group until the work is completed.

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 another qualified expert for that meeting.

4.3.3. Standing Regulatory Member Experts

Once the Standing Regulatory Member has appointed an expert to a Working Group, this expert is expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis to ensure continuity. All experts that are appointed to a given Working Group should have the necessary and adequate expertise in the topic concerned as they are expected to actively contribute to the work of the Working Group until the work is completed.

Should the appointed expert be unable to participate in a given meeting (face-to-face or via teleconference) of the Working Group, that expert should be replaced by another qualified expert.

4.3.4. Regulatory Member Experts

The experts that have been appointed by the Regulatory Members in Working Groups are expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis to ensure continuity. The experts that are appointed to a given Working Group should have the necessary and adequate expertise in the area concerned as they are expected to actively contribute to the work of the Working Group.

Once an expert has been appointed to a Working Group, the Regulatory Member expert is expected to continue participating in the work of this Working Group until the work is completed. If the appointed expert is absent from two consecutive meetings of the Working Group, the Regulatory Member should appoint another qualified expert. After the Regulatory Member's expert has been absent from two consecutive meetings, and if no other qualified expert from that Regulatory Member participates in the subsequent meeting of the Working Group, the Regulatory Member loses its right to appoint experts in that particular Working Group. Such interruption of participation will be noted by the ICH Secretariat and will also be mentioned in the report of the Working Group. If the Regulatory Member wishes to withdraw from participating in a Working Group, it should notify the ICH Secretariat without undue delay.

The right to appoint experts is not an absolute right because the Management Committee can exceptionally limit the number of participants in the Working Groups for meeting logistics reasons, i.e. to avoid that a Working Group becomes too big. In addition to those experts whose presence is required for the quorum, any limitation for the Regulatory Members should be introduced in a fair and objective manner, e.g., by giving preference to the experts that have been appointed earlier (on a first-come-first-served basis). Currently, the average size of ICH Working Groups is in the range of 25-30 experts; however, larger Working Group may exceptionally be established. Therefore, the Management Committee should determine the appropriate size of Working Group.

4.3.5. Industry Member Experts

Irrespective of Article 12(2)(b), 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.

The experts that are appointed to a given Working Group should have the necessary and adequate expertise in the area concerned as they are expected to actively contribute to the work of the Working Group.

Before appointing an expert to a Working Group, the Industry Member should provide information to the ICH Secretariat about how it or its affiliate members will be affected or regulated by the guideline in question.

Once the Industry Member has appointed an expert to a Working Group, this expert is expected to actively participate in and contribute to the work of the Working Group on a continuous and regular basis until the work is completed to ensure continuity. If the appointed expert is absent from two consecutive meetings, the Industry Member should appoint another qualified expert. An initially appointed expert to a Working Group can only be replaced once during the time in which the Working Group is active (i.e. until the finalisation of the work of the Working Group). After the Industry Member's expert has been absent from two consecutive meetings, and if no other qualified expert from that Industry Member participates in the subsequent meeting of the Working Group, the Member loses its right to appoint experts in that particular Working Group. Such interruption of participation will be noted by the ICH Secretariat and will also be mentioned in the report of the Working Group. If the Industry Member wishes to withdraw from participating in a Working Group, it should notify the ICH Secretariat without undue delay.

If, however, in the meantime the Industry Member wishes to withdraw from participating in a Working Group, it should notify the ICH Secretariat without undue delay.

4.3.6. Standing Observer Experts

Further to Article 16(2)(b), the appointment of experts by the Standing Observers is entirely voluntary and it is the choice of each of them to decide whether to appoint experts and to which Working Groups. The experts that are appointed to a given Working Group should have the necessary and adequate expertise in the area concerned as they are expected to actively contribute to the work of the Working Group until the work is completed.

4.3.7. Observer Experts

Further to Article 17(5), when considering the recommendation by the Management Committee regarding the invitation to Observers to appoint Observer experts, the Assembly should treat all Observers fairly and make the decision objectively, e.g., on the basis of the type of activity or available expertise of the Observer.

Observers may also request to appoint an Observer expert in a given Working Group by informing 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. The appointment is subject to a favourable decision of the Assembly.

Once the Observer has appointed its experts, these experts are expected to fully participate as Observer experts in the work of the Working Groups.

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 each of the Founding Regulatory Members 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 each of the Founding Regulatory Members, is required for the quorum of that Working Group.

5. Financing of ICH

5.1. Member Responsibility to Finance ICH Association

Further to Article 57(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. Financing of ICH Association in Transition Period

The purpose of the provision in Article 59(1) regarding a transition period is to guarantee the continued funding and operation of the ICH Association. While the Assembly is required to introduce membership fees for all Members, it is unknown how long this will take until a decision is taken. In the meantime, it is important to ensure the continued operations of the ICH Association and therefore, the Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members bear the responsibility for the intermediate funding during a transition phase until annual membership fees or corresponding annual financial contributions have been introduced for all Members.

5.3. Determination of Annual Fees / Contributions

General principles: In line with Article 58(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 58(3) when the type of Member is very different, distinguishing between Members should be possible under objective criteria.

5.4. 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 57(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 22(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.

5.5. Consideration of Members Organising ICH Meetings

The purpose of the provision in Article 59(2) is to avoid that any of the Founding Regulatory Members, Founding Industry Members or Standing Regulatory Members that is hosting the meeting will have to pay both for the meeting costs relating to the organisation of the meeting as well as the annual membership fee / financial contribution (which included the meeting costs), i.e., to avoid double payment. In case any of these Members has agreed to host (organise and finance the meeting), those meeting costs will be deducted from the annual membership fee or corresponding annual financial contribution either of that particular Fiscal Year or the following year. The Member should submit to the ICH Secretariat proof of the expenses related to the organisation of the meeting.

5.6. Support by Other Means

5.6.1. Additional Financial Means

In line with Article 57(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.

5.6.2. Non-Financial Means

Further to Article 57(4), 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.

5.6.3. Other Means

The purpose with the provision in Article 59(3) 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.

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 organisations with similar or related activities, such as IPRF, VICH and PIC/S. The cooperation should be laid down in written form, e.g., through an exchange of letters or an agreement clearly spelling out the interest in the cooperation, its scope and duration. Expected resource (both in terms of human and financial) implications 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 by the Management Committee. This Article is not intended to cover cooperation relating to MedDRA activities, as this will be covered in the Rules of Procedures of the MedDRA Management Committee.

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

The representatives of the Members, Standing Observers and 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.

8. Legal Considerations

8.1. Member Conflicts with Governing Laws

As per Article 60, 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. Liability

As per Article 61(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 61(2), under Swiss law, liability cannot be excluded in the case of intent or gross negligence.

8.3. Dissolution of Association

Further to Article 62(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 25(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.

8.4. Dispute Resolution

Further to Article 63, 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 Director 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.