

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

Rules of Procedure of the Management Committee

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RULES OF PROCEDURE OVERVIEW

Further to Article 39 of the Articles of Association, these Rules of Procedures (RoP) of the Management Committee are intended to provide guidance and interpretation in respect of the provisions of Articles of Association relating to the Management Committee. These RoP also provide interpretation of the meaning of some of the provisions in these Articles.

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 Management Committee, in addition to the Articles of Association, shall be published on the website of the ICH Association. The Rules of Procedures of the Management Committee are amended in accordance with Article 37(4) and (5).

1. Permanent Management Committee Representatives

1.1. Permanent Management Committee Representatives

Further to Article 27 (2), the Permanent Management Committee Representatives are the two (2) representatives appointed by each of the Founding Regulatory Members, the Founding Industry Members and the Standing Regulatory Members.

1.2. Designation of Lead Representative

If the Permanent Management Committee Representatives of a Member are the same individuals as the representatives of that Member in the Assembly, the Founding Regulatory Members, Founding Industry Members, and Standing Regulatory Members should designate one (1) of their two (2) representatives as the lead representative in the Management Committee (and, if applicable, in the MedDRA Management Committee) respectively, and notify the ICH Secretariat of the name of the lead representatives without undue delay. The lead representative of the Management Committee should not cast the vote on behalf of the Member when the Assembly votes on the discharge of the Management Committee. The lead representatives of the MedDRA Management Committee should not cast the vote on behalf of the Member when the Assembly votes on the discharge of the MedDRA Management Committee.

1.3. Replacement of a Permanent Management Committee Representative

Article 33(1) only applies where the position of a Management Committee Representative becomes vacant but it does not apply where a Management Committee Member has chosen to withdraw altogether from the Management Committee under Article 32(1), i.e., when it no longer wishes to be a Member of the Management Committee.

Where the position of a Permanent Management Committee Representative becomes vacant, the Member should notify the ICH Secretariat of the name of the newly appointed Permanent Management Committee Representative as soon as possible and at the latest within four (4) weeks of the date at which the position became vacant. The Member having appointed the Permanent Management Committee Representative (whose post becomes vacant) will continue to be represented by the other (remaining) Permanent Management Committee Representative. The new Permanent Management Committee Representative will take office immediately upon receipt of the notification to the ICH Secretariat. The ICH Secretariat should immediately inform the Chair of the Assembly and the Chair of the Management Committee of the name. Within two (2) weeks, all Members will be informed of the name by the ICH Secretariat.

2. Elected Management Committee Representatives

2.1. Opening-up of Management Committee to Elected Representatives

As per Article 27(3), no later than 1 January 2018, the Management Committee shall consist of up to sixteen (16) Permanent Management Committee Representatives and twelve (12) Elected Management Committee Representatives. Further to this Article, the total number of

Representatives on the Management Committee will depend on the number of Elected Management Committee Representatives that will be appointed by the Assembly.

2.2. Elected Management Committee Representatives from Regulatory Members

2.2.1. Eligibility Criteria for Elected Management Committee Representatives from Regulatory Members

This section provides guidance and clarification on the eligibility criteria referred to in Article 29.

Criteria 1: Further to Article 29(1)(a) and the criteria for regular participation in all ICH meetings during the previous four (4) years prior to proposing an Elected Management Committee Representative, the past participation will be verified by the ICH Secretariat from the meeting records.

Criteria 2: Further to Article 29(1)(b) and the criteria to have appointed experts that have participated in at least two (2) Working Groups prior to proposing an Elected Management Committee Representative, the appointment of experts and their participation in the Working Groups throughout the process will be verified by the ICH Secretariat from the available records.

Criteria 3: Further to Article 29(1)(c) and the need to have a good record of implementation of ICH Guidelines this will be assessed against the text provided under section 1.1.3. of the RoP of the Assembly which provides guidance on the meaning and interpretation of implementation. The Regulatory Member that puts forward candidates for appointment as Elected Management Committee Representatives should provide a list of those ICH Guidelines that the Regulatory Member has implemented together with the dates of the implementation and a reference to the relevant document (e.g., website links or providing the documents themselves). The stage of implementation of ICH Guidelines will be verified by the ICH Secretariat after the Regulatory Member has put forward the candidates for Elected Management Committee Representative. Given the role of the Management Committee in close oversight of ICH Guideline work, it is very desirable for the Member that is proposing candidate(s) to have implemented all of the “Tier 1” and “Tier 2” Guidelines that are considered particularly foundational. For any of the Tier 1 or Tier 2 Guidelines that have not been implemented, it would be helpful for the Member that is proposing the candidate(s) to explain why that is the case.

2.2.2. Nomination Process for Elected Management Committee Representatives from Regulatory Members

In line with Articles 29(2), nominations for Elected Management Committee Representatives should be submitted in writing by the Regulatory Members to the ICH Secretariat no later than four (4) months before the start of the Assembly meeting at which the election is to take place, specifying the names of the pair, i.e., the two (2) representatives (of a Member), put forward as candidates. Observers do not have the right to put forward nominations.

2.3. Elected Management Committee Representatives from Industry Members

2.3.1. Eligibility Criteria for Elected Management Committee Representatives from Industry Members

This section provides guidance and clarification on the eligibility criteria referred to in Article 30.

Criteria 1: Further to Article 30(1)(a) and the need to have participated as an Industry Member in Assembly meetings during the previous four (4) years prior to proposing the Elected Management Committee Representatives or to have been an Interested Party as defined prior to the establishment of the Association, and to have appointed experts that have participated in the Working Groups during the previous four (4) years prior to proposing the Elected Management Committee Representatives; the past participation will be verified by the ICH Secretariat from the meeting records.

Criteria 2: Further to Article 30(1)(b) and the need to have demonstrated that the organisation and/or its members are regulated or affected by the majority of the ICH Guidelines, the Industry Member that is interested in putting forward candidates as Elected Management Committee Representatives should submit a list of those ICH Guidelines by which it and/or its affiliate members are regulated or affected by and thus be able to show that these represent a majority of the ICH Guidelines.

2.3.2. Nomination Process for Elected Management Committee Representatives from Industry Members

In line with Article 30(2), nominations for Elected Management Committee Representatives should be submitted in writing by the Industry Members, specifying the names of the pair, i.e., the two (2) representatives (of a Member) put forward as candidates to the ICH Secretariat no later than four (4) months before the start of the Assembly meeting at which the election is to take place. Observers do not have the right to put forward nominations.

2.4. Replacement of an Elected Management Committee Representative

Further to Article 33(2), the Member should notify the ICH Secretariat of the name of the substitute Elected Management Committee Representative as soon as possible and at the latest within four (4) weeks of the date at which the position became vacant. The substitute Elected Management Committee Representative will take office immediately upon receipt of the notification to the ICH Secretariat and remain in office until a new Elected Management Committee Representative has been elected by the Assembly. The ICH Secretariat should immediately inform the Chair of the Assembly and the Chair of the Management Committee of the name of the substitute representative. Within two (2) weeks, all Members will be informed of the name of the substitute representative by the ICH Secretariat.

3. Permanent Management Committee Observers

3.1. Participation of Permanent Management Committee Observers

Further to Article 27(4), the participation of the Permanent Observers in the Management Committee meeting is entirely voluntary. WHO and IFPMA respectively should inform the ICH

Secretariat of the names of their Permanent Observer delegates that will participate in the meetings of the Management Committee. Thereafter, the ICH Secretariat should be notified only of any changes in the names of the delegates.

3.2. Replacement of a Permanent Observer Delegate

Where the position of a Permanent Observer delegate becomes vacant, the Management Committee should invite the Standing Observer to appoint a new delegate.

4. Withdrawal or Dismissal from the Management Committee

4.1. Withdrawal from the Management Committee

Further to Article 32(1), a Management Committee Member wishing to withdraw from the Management Committee should send a letter to the ICH Secretariat expressing its intention to withdraw and provide explanation for its decision. The withdrawal takes effect at the end of the calendar month following the calendar month in which the ICH Secretariat was notified about the withdrawal. The ICH Secretariat should immediately inform the Chair of the Assembly and the Chair of the Management Committee of the withdrawal. Within two (2) weeks of receiving the letter, all Management Committee Members will be informed of the withdrawal by the ICH Secretariat and provided with the letter explaining the decision of the withdrawing Member. The Assembly will also be notified of the withdrawal. If the withdrawal is notified less than two (2) months prior to the next Assembly meeting, the election of a new Elected Management Committee Representative can only take place at the subsequent Assembly meeting.

If the withdrawing Management Committee Member is a Regulatory Member that has had Elected Management Committee Representatives on the Management Committee, the subsequent Assembly meeting after the notification of the withdrawal, may elect a pair of two (2) new Elected Management Committee Representatives from amongst the eligible Regulatory Members provided that their nominations have been put forward within the timelines under Article 29(2). If the withdrawing Management Committee Member is an Industry Member that has had Elected Management Committee Representatives on the Management Committee, the subsequent Assembly meeting after the notification of the withdrawal, may elect a pair of two (2) new Elected Management Committee Representative from amongst the eligible Industry Members that have put forward nominations within the timelines under Article 30(2).

Elected Management Committee Representatives elected as a result of replacing the representatives of a Member who has withdrawn before the expiry of the term of office, should serve a four (4) year term in line with Article 27(3).

4.2. Dismissal from the Management Committee

Article 32(2) concerns the exclusion of the individuals, i.e., the Management Committee Representative or the Permanent Observer delegate and not the exclusion of the Member having appointed the Management Committee Representative of the Permanent Observer delegate. Exclusion of a Management Committee Representative or Permanent Observer delegate should only take place in exceptional circumstances and provided the conditions in this Article are met.

Actions or behaviour that seriously impair the proper functioning or reputation of the Management Committee or the ICH Association can take the form of, for example, material or repeated violations of applicable laws, the Articles of Association or any by-laws, such as the RoPs, disclosing confidential or sensitive information to outside parties in violation of the requirement to respect professional secrecy / confidentiality undertaking referred to in RoP 8 below or making insulting or harmful statements in any ICH meeting or publicly regarding the ICH Association, including its bodies, or regarding any of its Members or Observers.

Before taking a decision pursuant to Article 32(2) of the Articles of Association, the Assembly should hear the affected Management Committee Representative of Permanent Observer delegate.

An excluded Management Committee Representative or Permanent Observer delegate should be replaced in accordance with Article 33 of the Articles of Association and RoP 3.2 above.

5. Management Committee Meetings

5.1. Management Committee Meeting Organisation

Further to Article 36(1), the Management Committee will hold its meetings in conjunction with the Assembly meetings. The Management Committee may, when required, hold meetings, if needed, in between the Assembly meetings. In addition, the Management Committee may hold virtual meetings in the form of tele- or videoconferences. The Chair of the Management Committee should propose to the Management Committee the frequency of such virtual or any other meetings for its agreement. The meetings will be set up by the ICH Secretariat at dates and times that are agreed by the Management Committee. In principle, at least one (1) virtual meeting in between the Assembly meetings should be organised. The meeting invitations should be sent out at least two (2) weeks in advance of the virtual meeting, unless there is an urgent need for a meeting in which case it can be organised with at least one (1) week's notice, if agreeable by the Management Committee Chair, based on representatives' availabilities.

5.2. Management Committee Representative Participation in Meetings

Further to Article 34(2)(a), a Member is considered to be present if at least one (1) of its representative(s) nominated in accordance with Articles 28 and 31 of the Articles of Association is present at the meeting of the Management Committee. Additionally, and further to Articles 34(2)(a) and 34(2)(b), the Management Committee Representatives nominated in accordance with Articles 28 and 31 of the Articles of Association should actively participate in the meetings and contribute to the work of the Management Committee.

5.3. Additional Meeting Participants

As regards the attendance at Management Committee meetings, in addition to the two (2) representatives of the Founding Regulatory Members, the two (2) representatives of the Founding Industry Members and the up to two (2) representatives of the Standing Regulatory Members, each of those Members may be accompanied by a maximum of two (2) further participants in addition to these Members' representatives of the Assembly, their representatives of the MedDRA

Management Committee, their Coordinators and Technical Coordinators who can also attend Management Committee meetings. The Permanent Observers of the Management Committee do not have the right to appoint additional participants in addition to their up to two (2) delegates, for the Management Committee meetings. Once the Assembly has appointed Elected Management Committee Representatives to the Management Committee, those Members with up to two (2) Elected Management Committee Representatives may be accompanied by one (1) additional participant excluding these Members' representatives of the Assembly and their Coordinators. Notifications of the number of additional participants should be made to the ICH Secretariat at least four (4) weeks in advance of the Management Committee face-to-face meetings. The ICH Secretariat should also be notified prior to the Management Committee virtual meetings of the number of additional participants.

5.4. Assignment of Vote in Event of non-Participation in Management Committee Meeting

Further to Article 37(2), where a Member or Permanent Observer is unable to participate in a Management Committee meeting, the Member or Permanent Observer concerned should inform the ICH Secretariat in advance. The ICH Secretariat shall inform the Chair and Vice-Chair of the non-attendance as soon as possible and at the latest at the beginning of the meeting and this information shall be recorded in the minutes. In the case of non-attendance, the Member may give a written proxy to another Member. The proxy needs to be submitted to the ICH Secretariat at the latest at the start of the Management Committee meeting. The proxy should specify the Management Committee meeting and the agenda items which the proxy concerns. The Management Committee Member or Permanent Observer may exceptionally delegate its participation to another person/delegate who is well informed of the Management Committee activities, for example the Coordinator/Technical Coordinator or a member of a sub-committee, from that Member or Permanent Observer.

6. Election of Management Committee Chair and Vice-Chair

6.1. Temporary Arrangement

Further to Article 36(2), a temporary arrangement will be in place until November 10, 2016, the chairmanship will rotate as follows: after the end of the chairmanship of FDA on December 10, 2015, the EC ensures chairmanship until June 16, 2016 (and MHLW/PMDA the vice-chairmanship) after which MHLW/PMDA takes over chairmanship (and Health Canada the vice-chairmanship) until November 10, 2016.

As of November 2016, at the Management Committee meeting in conjunction with the ICH meeting in Japan on November 5-10, 2016, the Management Committee should elect a Chair who should take office on November 10, 2016.

6.2. Election Process

The meetings of the Management Committee shall be chaired by one (1) of the Management Committee Representatives appointed by the Permanent Regulatory Members. The Management Committee may also elect a Vice Chair from amongst one (1) of the Management Committee

Representatives appointed by the Permanent Regulatory Members. 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. As of November 2016, the Chair and Vice-Chair will serve for one (1) year from the date of election. The Chair and Vice-Chair may be re-elected.

Nominations for Chair and Vice-Chair should be submitted in writing by the Members, specifying the name of the representative (of a Permanent Regulatory Member) who is put forward as the candidate to the ICH Secretariat no later than the start of the Management Committee meeting at which the election is to take place. Permanent Observers do not have the right to put forward nominations for Chair or Vice-Chair.

The decision shall be adopted by a qualified majority of the votes cast in line with Article 37(4) and by secret ballot. Two (2) tellers shall be designated amongst the Management Committee Representatives or Permanent Observers to assist in the counting of the vote. At each round, the candidate with the lowest number of votes shall withdraw. Rounds will run until one (1) candidate receives simple majority of favourable votes of the Members.

It is at the discretion of the Member whose representative has been appointed as Chair to decide whether or not it wishes to appoint another representative to represent itself in the Management Committee.

7. Management Committee Decision-Making

7.1. General Decision-Making Process

In line with Article 37(3), either of the two (2) Permanent Management Committee Representatives and either of the two (2) Elected Management Committee Representatives (irrespective of which of the two (2) has been designated as the lead representative) have the right to cast the joint vote on behalf of the Member for decisions where the Member has voting rights. The two (2) representatives jointly decide how to dispose of the vote.

Furthermore, decisions are taken by open ballot with the exception of appointment of Chair and Vice-Chair of the Management Committee which should be taken by secret ballot. The Management Committee may upon proposal by the Chair of the Management Committee decide to cast a secret ballot for other matters.

Decisions by majority in accordance with Article 37 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). Management Committee Representatives are free to abstain from voting, i.e., not casting a vote. Abstentions do not count in tallying the vote negatively or positively; when the Management Committee Representative abstains, they are in effect only contributing to a quorum.

Further to Article 37(7), in the event a two-thirds majority of the votes cast is not reached, only the Permanent Management Committee Representatives appointed by the Founding Regulatory Members are entitled to cast a joint vote since this activity, i.e., the selection of topics for ICH Guidelines and the adoption amendment or withdrawal of ICH Guidelines 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.

No written procedures for the adoption of decisions are foreseen. However for simpler matters, such as the adoption of the minutes of the Management Committee meetings or follow-up to teleconferences e.g., submission of documents that require swift action, approval by written procedure is possible.

Where issues or questions arise where the ICH Secretariat considers input from the Management Committee may be needed, the ICH Secretariat shall consult the Management Committee Chair who will use his/her discretion to (a) provide direction to the Secretariat on the course of action where the issue or question is not sensitive or controversial; or (b) decide that an action should be put on the agenda of the next scheduled Management Committee teleconference/meeting; or (c) request the convening of a Management Committee teleconference to decide on the action to be taken. In case of (a), the Management Committee should be informed of the course of action unless the matter is of pure administrative nature.

7.2. Recording and Communication of Management Committee Decisions

The adopted decisions will be recorded in the minutes of the Management Committee meetings that take place face-to-face. Decisions which are adopted by the Management Committee in virtual meetings, such as teleconferences, are recorded in summary reports. The ICH Secretariat is responsible for drafting the minutes and the summary reports. Draft minutes and draft summary reports should be sent to all Management Committee Representatives and Permanent Observers by e-mail. Generally, the draft minutes should be sent within two (2) weeks of the meeting, and draft summary reports within one (1) week unless there are exceptional circumstances. Also the Coordinators/Technical Coordinators that have been appointed by the Permanent Management Committee Members and Elected Management Committee Members should receive the draft minutes and draft summary reports. The Management Committee Representatives and the Permanent Observer delegates (including Coordinators/Technical Coordinators when they attended the meeting on behalf of the Management Committee Representative) should send any written comments on the minutes to the ICH Secretariat as well as to the Management Committee Representatives and Permanent Observer delegates at the latest within two (2) weeks of the receipt of the minutes, and in the case of summary reports, within one (1) week of the receipt of the summary report. Minor and editorial issues should be resolved at the discretion of the Management Committee Chair in consultation with the concerned Management Committee Representative(s) and Permanent Observer delegates. The outcome of these minor and editorial issues should be shared with the Management Committee. Major issues should be forwarded to all Management Committee Representatives and Permanent Observer delegates, together with a proposal from the Management Committee Chair, in consultation with the Management Committee Representative(s) and Permanent Observer delegates, on how to resolve the matter.

This could be either not to accept the concerns raised or propose amendments to the minutes or summary report. In case of amendments to the draft minutes, the revised minutes should be submitted to the Management Committee Representatives and Permanent Observer delegates at the latest within one (1) month from the Management Committee meeting. In case of amendments to the summary reports, the timeline is two (2) weeks from the virtual meeting. The minutes and summary reports should be adopted by written procedure after the Management Committee meeting or, in the case of substantial amendments, at the next Management Committee meeting. The adopted minutes and summary reports by the Management Committee should be published on the website of the ICH Association whilst ensuring the protection of confidential information and personal data.

7.3. Financial Decision-Making in the Transition Period

The ICH Association shall be financed through annual membership fees or financial means under Article 57(2) and (3). Recognising that time is needed to prepare for the introduction of annual membership fees/annual financial contributions payable by all Members of the ICH Association, a transition period has been introduced in the Articles of Association (Article 59). The decision-making of the Management Committee concerning decisions that have a financial impact laid down under Article 37(6) stems from the fact that during this transition period, the Management Committee collectively bears the responsibility for ensuring the necessary funding of the ICH Association. The Management Committee therefore determines the annual membership fees/annual financial contributions for the Founding Regulatory Members, Founding Industry Members and the Standing Regulatory Members under Article 35(2)(j). While the duration of this transition period is not known, the Management Committee endeavours to put forward proposals for annual membership fees/annual financial contributions payable by all Members to the Assembly as soon as possible. Under Article 22(1)(m), it is the competence of the Assembly to approve the membership fees or financial means to be raised. The Assembly should take such a decision as soon as possible in order to ensure a sustainable and solid funding basis for the ICH Association.

8. Maintaining Confidentiality

Further to Article 34(3), the Management Committee Representatives and the Permanent Observer delegates of the Management Committee shall, even after their duties have ceased hold all confidential information they receive or that is otherwise brought to their attention in confidence. The Management Committee Representatives and the Permanent Observer delegates of the Management Committee are entitled to share such confidential information with persons within their respective organization and third parties provided that the recipients (i) must have access to the confidential information to fulfil their duties within their organization 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 Management Committee Representatives and the Permanent Observer delegates of the Management Committee shall not use the confidential information for any purpose other than as necessary to enjoy their rights or perform their obligations within the Association.

9. Management Committee Responsibilities

9.1. Organisation of Assembly Meetings

Article 35(2)(a) relates to the determination of the venue of the Assembly meetings. When considering different options, the Management Committee should take into account in particular the financial aspects to ensure that the meeting costs are kept at a reasonable level. Also the logistical aspects should be taken into account, i.e. accessibility of the venue (vicinity to public transport and to an international airport and good airport connections) as well as safety aspects. Finally, the Management Committee should endeavour to have a broad geographic balance as this will contribute to giving visibility to the ICH Association and demonstrate its global character. ICH meetings can, however, be organised in the same venue more than once particularly if it meets the requirements for ICH meetings and is financially advantageous.

9.2. Submission of Proposals to Assembly

As per RoP 3.4 of the Assembly RoP, the Management Committee is responsible for submitting proposals to the Assembly.

Article 23 provides for the timelines for the Management Committee to submit proposals to the Assembly.

9.3. Oversight of Working Groups

In line with Article 35(2)(f), the role of the Management Committee is to oversee the work of the Working Groups, including in between the ICH meetings, with the assistance of the ICH Secretariat. The Management Committee will at regular intervals receive work plans from the Working Groups to update the Management Committee on progress, in addition to which the Management Committee may request additional reports (written or oral) from the Regulatory Chair and/or the Rapporteur. The Management Committee should give its approval for all face-to-face meetings of the Working Groups. The decision by the Management Committee on which Working Groups will meet face-to-face at the ICH meetings should be taken at the latest at the preparatory teleconference of the Management Committee approximately two (2) months prior to the ICH meetings. The Management Committee also decides on the size of the Working Groups and processes requests from Observers to appoint experts in the Working Groups. The Management Committee teleconference is preceded by the Coordinators teleconference which is held approximately three (3) months prior to the ICH meeting. The Standard Operating Procedures (SOP) of Working Groups provides more details about the role of the Coordinators and the functioning of the Working Groups (*Note: these SOPs are currently under development*). See also RoP 4.2 of the Assembly RoP concerning the appointment of Regulatory Chairs and Rapporteurs as well as the right of the Management Committee to limit the size of the Working Groups. Until the appointment of Elected Management Committee Representatives from Regulatory Members, the Regulatory Chair should be a representative of the Founding Regulatory Members or the Standing Regulatory Members. After Elected Management Committee Representatives from Regulatory Members have been appointed to the Management Committee, the Regulatory Chair may also be a representative of a Regulatory Member that have Elected Management Committee Representatives on the Management Committee provided that

Regulatory Member has had at least one (1) expert that has participated continuously in that Working Group from the moment it was set up. As regards the right of Members that have Elected Management Committee Representatives in the Management Committee to continue acting as Regulatory Chair, the appointed Regulatory Chair will continue his/her work as Regulatory Chair until the Working Group has finalised its work, even if the Member in the meantime no longer has an Elected Representative in the Management Committee. This allows continuity and stability of the Working Groups. The Management Committee may propose to the Assembly the replacement of a Regulatory Chair or Rapporteur before the Working Group has finished its work.

Regarding the recommendation by the Management Committee to invite Observers to appoint experts in Working Groups, see RoP 4.3.7 of the Assembly RoP.

9.4. Recommendations to Assembly on Membership and Observership Applications

See the RoP 1.3.2. of the Assembly RoP regarding the application review process. The ICH Secretariat will carry out the initial assessment of the eligibility criteria provided in Article 11(1) and (2), Article 12(1) and Article 17(1) and provide its considerations to the Management Committee thus assisting the Management Committee to prepare its recommendations.

9.5. Establishment of Subcommittees

In line with Article 35(3), the Management Committee may set up sub-committees and/or working groups for dealing with specific topics to assist the Management Committee, e.g., by carrying out some preparatory work. Working groups would include technical working groups (EWGs/IWGs) to undertake harmonisation activities following the approval by the Assembly of such activities, as well as any other working groups as deemed necessary by the Management Committee.

The following applies to sub-committees: The mandate of the sub-committee should be clearly defined. Sub-committees may be established for an unlimited time period to support recurrent Management Committee activities (e.g., the Financial Sub-committee) or for a limited time period in order to address time-limited needs. The Management Committee will appoint a lead for each sub-committee. The lead should liaise with the Management Committee notably by providing regular updates at every Management Committee meeting on the progress and, as appropriate, seek advice or steering from the Management Committee. Members who have appointed representatives in the Management Committee have the right to appoint up to two (2) members in each sub-committee on a voluntary basis. The aim should be to have members from all regulatory authorities and industry sectors who have representatives on the Management Committee in each sub-committee. Permanent Observers may appoint members in the sub-committees. Sub-committees should be disbanded when they have accomplished their work. Sub-committees may also be temporarily suspended (e.g., during a period when there is little activity) and then re-activated when work resumes. The sub-committees should work primarily remotely but may also hold face-to-face meetings in conjunction with the ICH meetings, particularly if the majority of the members of the sub-committee are present at the meeting. The lead, who may be supported by a member of its own staff, is responsible for the project management and for organising the meetings of the sub-committee (scheduling meetings, drafting agendas, minutes etc...) in consultation with the members of the sub-committee. A staff member of the ICH Secretariat should be invited to attend the

meetings of the sub-committee and the ICH Secretariat should also as far as possible assist the leads of the sub-committees to facilitate the work and endeavour to avoid duplication between the different sub-committees.

9.6. Preparation of Proposals on Financial Matters

[Under Article 58(1), the amount of the annual membership fees and other financial means that are raised for the next Fiscal Year shall be approved by the Assembly at least six (6) months prior to the end of each Fiscal Year.]

Further to Article 35(2)(m), the Financial Sub-committee of the Management Committee should draft an initial budget twenty-four (24) to eighteen (18) months prior to budget implementation.

The Financial Sub-committee should present a first proposal of the budget to the Management Committee during the meeting that occurs in spring, i.e., normally some eighteen (18) months prior to the new Fiscal Year:

- the goal of the Management Committee discussion is to reach agreement on any proposed revisions to the proposed budget that will be taken forward for Assembly review and approval;
- the proposed budget will be accompanied by the corresponding membership fees established in accordance with the agreed mode of calculation. The general principle when developing the proposal for annual membership fees and other financial means is that 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 annual fees and the other financial means that are raised should be based on objective criteria. There may be deviations from this starting point, but they should be justified objectively.

The Management Committee will present the proposed draft budget for the new (future) Fiscal Year to the Assembly for review and approval during the Assembly meeting that occurs in spring approximately eighteen (18) months before the new Fiscal Year.

The Management Committee will develop a proposal of financial budget based on the comments received:

- the Management Committee will disseminate the proposal of Final budget to the Members of the ICH Association, accompanied by a written summary and analysis of any comments received from the Members, along with a rationale for the incorporation/non-incorporation of any proposed changes received from a Member.

The Management Committee will submit the proposal of Final budget including annual membership fees and other financial means that are raised for the new Fiscal Year to the Assembly for approval at the autumn meeting of the ICH (i.e., normally between twelve (12) and fourteen (14) months prior to the beginning of the new ICH Fiscal Year).