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

Rules of Procedure of the MedDRA Management Committee

Version 7.0

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

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MedDRA MC RoPs
Document History

Version number	Action	Date
V7.0	The MedDRA MC approved revisions related to: extending the term of office of the MedDRA MC Chair for one year from November 2022 and two years from November 2023; electing a Vice-Chair to also serve for a two-year term from November 2022, with the terms of the Chair and Vice-Chair staggered by 1 year; and to be effective from the MC elections in November 2022; and self-funded MHRA, UK participation to MedDRA Management Committee Meetings from 2024.	**November 2022**
v6.0	The MedDRA MC approved revisions related to virtual meetings in extraordinary circumstances, removing outdated text on temporary arrangements, process for press release, principles for 5-year budget planning and for periodic adjustment of MedDRA subscription fees.	**May 2021**
v5.0	The MedDRA MC approved revisions related to cooperation with other organisations and to the approach for decision-making and approval of minutes and reports.	**June 2019**
v4.0	The MedDRA MC approved revisions to clarify the policy regarding use of the MedDRA logo.	**June 2018**
v3.0	The MedDRA MC approved revisions to the MedDRA MC RoP to align with the ICH Articles of Association, Assembly RoP and ICH MC RoP, and provide clarity regarding the roles of the ICH MC, MedDRA MC and Assembly with respect to MedDRA financial matters.	**April 2018**
v2.0	The MedDRA MC approved a couple of minor amendments to the MedDRA MC RoP regarding MSSO and JMO participation to MedDRA MC meetings, as well as rotation of Chairmanship under the temporary arrangement.	**August 2017**
v1.0	The MedDRA MC approved the first version of the MedDRA MC RoPs.	**November 2016**

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RULES OF PROCEDURE OVERVIEW

MedDRA, the Medical Dictionary for Regulatory Activities, is an ICH product. The ICH Association is the owner of the intellectual property rights to MedDRA in all languages. The MedDRA Management Committee acts independently of the ICH Management Committee, and reports to the ICH Assembly.

Further to Article 53 of the Articles of Association, these Rules of Procedures (RoP) of the MedDRA Management Committee are intended to provide guidance and interpretation in respect of the provisions of Articles of Association relating to the MedDRA Management Committee.

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 MedDRA 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 MedDRA Management Committee will be adopted and amended in accordance with Article 49(2).

1. MedDRA Management Committee Representatives

1.1. MedDRA Management Committee Representatives

In line with Article 44(1), and noting also the right permitted by Articles 8(3c), 9(3d) and 10(3c), Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA, UK) each have the right to appoint in their sole discretion up to two (2) MedDRA Management Committee Representatives.

1.2. Nomination Process for MedDRA Management Committee Representatives

Further to Article 44(2), the Founding Regulatory Members, Founding Industry Members and Standing Regulatory Members as well as the MHRA, UK shall notify the MedDRA Secretariat of their choice to appoint any MedDRA Management Committee Representative. The opportunity to appoint any MedDRA Management Committee Representatives can be taken at any time and not necessarily at the time of the establishment of the MedDRA Management Committee. The names of the appointed MedDRA Management Committee Representatives will be notified to the MedDRA Secretariat one (1) month after the notification of the choice to appoint Representatives.

Representatives appointed to the MedDRA Management Committee by Founding Regulatory Member MHLW/PMDA, Japan, and by Founding Industry Member JPMA are currently represented by at least one Representative from each of these Members who is also a Representative on the Japanese Management Board (JMB) which is responsible for overseeing the operations of the Japanese Maintenance Organisation (JMO), which is the organisation provided with the right to distribute MedDRA to organisations headquartered in Japan and their affiliates.

1.3. Designation of Lead Representative

Where a Member has appointed two MedDRA Management Committee Representatives and these MedDRA Management Committee Representatives are the same individuals as the Representatives of that Member in the Assembly, that Member should designate one of their two (2) MedDRA Management Committee Representatives as the lead representative in the MedDRA Management Committee, and notify the MedDRA Secretariat of the name of the lead representative. The lead representatives in 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. In such a case, the MedDRA Secretariat should ensure the ICH Secretariat is informed on who is the lead representative for the MedDRA Management Committee. Where a Member has appointed only one MedDRA Management Committee Representative, this MedDRA Management Committee Representative should also not cast the vote on behalf of the Member when the Assembly votes on the discharge of the MedDRA Management Committee.

1.4. Replacement of a MedDRA Management Committee Representative

Article 46 only applies where the position of a MedDRA Management Committee Representative becomes vacant but it does not apply where the Member who had previously chosen to appoint up to two (2) Representatives in line with Article 44(1) decides it no longer chooses to appoint Representatives.

Where the position of a MedDRA Management Committee Representative becomes vacant, the Member should notify the MedDRA Secretariat of the name of the new MedDRA Management Committee Representative as soon as possible and at the latest within four (4) weeks of the date at which the position becomes vacant. The new MedDRA Management Committee Representative will take office immediately upon receipt of the notification to the MedDRA Secretariat. The MedDRA Secretariat should immediately inform the Chair of the Assembly and the Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee of the name of the new MedDRA Management Committee Representative. Within two (2) weeks, all Members of ICH and the MedDRA Management Committee will be informed of the name by the ICH Secretariat.

2. MedDRA Management Committee Observers

2.1. Participation of MedDRA Management Committee Observers

In line with Article 43(3), the World Health Organization (WHO) shall have observer status on the MedDRA Management Committee without any voting rights. The WHO may nominate up to two (2) delegates to participate in the meetings of MedDRA Management Committee and shall notify the MedDRA Secretariat of the names of such delegates. The participation of WHO in the MedDRA Management Committee meeting is entirely voluntary.

The MedDRA Management Committee may invite other parties to attend the MedDRA Management Committee meetings as non-voting observers.

2.2. Replacement of a MedDRA Observer Delegate

Where the position(s) of the WHO MedDRA observer delegate(s) becomes vacant, the MedDRA Management Committee should invite WHO to appoint a new delegate.

3. Withdrawal or Dismissal from the MedDRA Management Committee

3.1. Withdrawal from the MedDRA Management Committee

Further to Article 45(1), a MedDRA Management Committee Representative wishing to withdraw from the MedDRA Management Committee should send a letter to the MedDRA Secretariat expressing its intention to withdraw and provide explanation for its decision. The withdrawal takes effect at the end of any Fiscal Year by prior written six (6) months' notice to that effect to the MedDRA Management Committee. The MedDRA Secretariat should immediately inform the Chair, and Vice-Chair in the absence of the Chair, of the MedDRA Management Committee of the withdrawal.

3.2. Dismissal from the MedDRA Management Committee

Article 45(2) concerns the exclusion of the individuals, i.e., a MedDRA Management Committee Representative or WHO observer delegate, and not the exclusion of the Member having appointed the MedDRA Management Committee Representative or the WHO Observer.

Exclusion of a MedDRA Management Committee Representative or observer delegate should only take place in exceptional circumstances and provided the conditions in Article 45(2) are met. Actions or behaviour that seriously impair the proper functioning or reputation of the MedDRA 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 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 45(2) of the Articles of Association, the Assembly should hear the affected MedDRA Management Committee Representative or WHO Observer delegate.

An excluded MedDRA Management Committee Representative or WHO Observer delegate should be replaced in accordance with Article 46.

4. MedDRA Management Committee Meetings

4.1. MedDRA Management Committee Meeting Organisation

Further to Article 48(1), the MedDRA Management Committee will hold its regular meetings in conjunction with the Assembly meetings.

While such Assembly meetings are usually face-to-face, in line with Article 24(1) and Article 24(2) of the Articles of Association, in extraordinary circumstances a decision may be taken to replace an Assembly face-to-face meeting by a virtual meeting. In such case, the MedDRA Management Committee meetings which would occur in conjunction with the Assembly meeting as per Article 48(1) may also be replaced by virtual meeting(s) as necessary.

When the MedDRA Management Committee RoP provide specific procedures that could only practically be carried out physically (i.e. at face-to-face meetings), for example on the appointment of tellers to physically count the votes for the election of the MedDRA Management Committee Chair and Vice-Chair (MedDRA MC RoP 5.1), the MedDRA Management Committee Chair, or Vice-Chair in the absence of the Chair, with support from the ICH Secretariat, will determine how to adapt the procedures for a virtual meeting whilst maintaining the purpose and spirit of the procedure.

In addition, the MedDRA Management Committee may hold meetings as required in between the Assembly meetings, either in the form of face-to-face meetings or virtual meetings (e.g., tele- or videoconferences).

The Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee should propose to the MedDRA Management Committee the frequency of such virtual meetings for its agreement. The meetings will be set up by the MedDRA Secretariat based on the availability of the MedDRA Management Committee Representatives. In principle, at least one 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 notice, if agreeable by the MedDRA Management Committee Chair, or Vice-Chair in the absence of the Chair, based on the availability of the MedDRA Management Committee Representatives.

Ordinarily MedDRA Management Committee meetings, including virtual meetings, will be composed of an executive session for Member Representatives only, followed by a session which includes participation from WHO Observer delegate(s). The MedDRA Management Committee shall

determine the invitation of representatives of the MSSO and JMO to its meetings. The MedDRA Management Committee may also invite other parties to participate in its meetings as non-voting observers.

Executive sessions of the MedDRA Management Committee shall be organised to allow discussion of items including, but not limited to: contract management (e.g., MSSO contract); MSSO financial oversight (e.g., MSSO budget, financial reports); and MSSO performance oversight (e.g., audit reports).

The Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee shall be responsible for determining other topics appropriate for discussion in the executive session on a case-by-case basis and may as appropriate invite the MSSO or JMO to report to the MedDRA Management Committee in an executive session on matters of a confidential nature.

Exceptionally the Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee may convene a meeting of the MedDRA Management Committee for Representatives only.

The MedDRA Secretariat will attend MedDRA Management Committee meetings, including executive sessions without voting rights.

In view of the principle of self-funded participation to ICH meetings for all ICH Members, from 2018 the MedDRA Management Committee Representatives of the ICH Members will cover their costs for participating to MedDRA Management Committee Meetings. As a non-ICH Member and for historical reasons, MHRA, UK's cost for participating to MedDRA Management Committee meetings was still covered from 2018 by the MedDRA budget, with a decision taken subsequently for MHRA, UK to be self-funded starting from 2024 in view of it becoming an ICH Member in 2022.

4.2. Additional Meeting Participants

A maximum of two (2) additional participants may attend MedDRA Management Committee meetings for the Founding Regulatory Members, Founding Industry Members, Standing Regulatory Members, and MHRA, UK, in addition to their up to two (2) Representatives. The WHO Observer does not have the right to appoint additional participants further to their up to two (2) delegates for the MedDRA Management Committee meetings.

To meetings MSSO and JMO are invited to attend, the MSSO Program Manager should attend with up to two (2) other key MSSO personnel, and the JMO Director should attend with one key JMO personnel. Any requests for additional MSSO or JMO personnel to attend meetings should be directed to the Secretariat who will consider such requests on the basis of justification and available meeting space. The Secretariat will also consult the MedDRA MC and/or JMB as necessary regarding any additional participant requests.

Notifications of any additional participants should be made to the MedDRA Secretariat at least four (4) weeks in advance of MedDRA Management Committee face-to-face meetings. The MedDRA Secretariat should also be notified prior to the MedDRA Management Committee virtual meetings of any additional participants at least one (1) week in advance of MedDRA Management Committee virtual meetings.

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

Further to Article 49(1), where a Representative or WHO observer delegate is unable to participate in a MedDRA Management Committee meeting, the Representative or observer delegate concerned should inform the MedDRA Secretariat in advance. The MedDRA Secretariat shall inform the Chair or Vice-Chair, in the absence of the 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 case non-attendance results in a party not being represented at a meeting, the party having appointed the Representative(s) may give a written proxy to another participating party's Representative(s). The proxy needs to be submitted to the MedDRA Secretariat at the latest at the start of the MedDRA Management Committee meeting. The proxy should specify the MedDRA Management Committee meeting and the agenda items which the proxy concerns. The MedDRA Management Committee Representative or WHO observer delegate may also exceptionally delegate participation to another person from their party who is well informed of the MedDRA Management Committee activities.

5. Election of MedDRA Management Committee Chair and Vice-Chair

5.1. Election Process

As per Article 48(2), the meetings of the MedDRA Management Committee shall be chaired by one (1) of the MedDRA Management Committee Representatives. The MedDRA Management Committee should elect a Chair. The MedDRA Management Committee may elect a Chair from amongst the MedDRA Management Committee Representatives appointed by the Founding Regulatory Members, the Standing Regulatory Members and the MHRA, UK. The MedDRA Management Committee may also elect a Vice-Chair from amongst the MedDRA Management Committee Representatives appointed by the Founding Regulatory Members, the Standing Regulatory Members and the MHRA, UK. The Chair and Vice-Chair will serve for a two (2) year term from the date of election.

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, particularly when the Chair is unavailable.

From November 2022, a Chair will be elected for a one (1) year term from the date of election and a Vice-Chair for a two (2) year term. From November 2023, a Chair will be elected for a two (2) year term. This approach will allow staggering of the terms of the Chair and Vice-Chair and an overlapping of mandates to ensure the continuity of knowledge between the Chair and Vice-Chair.

Nominations for Chair and Vice-Chair should be submitted in writing by the Members, specifying the name of the Representative who is put forward as the candidate to the MedDRA Secretariat no later than the start of the MedDRA Management Committee meeting at which the election is to take place. The WHO observer does not have the right to put forward nominations for Chair and Vice-Chair. The decision shall be adopted by consensus. Only when consensus cannot be reached, decisions shall be adopted by qualified majority of the votes cast and by secret ballot. Two (2) tellers shall be designated amongst the MedDRA Management Committee Representatives or WHO Observer delegates 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 candidate receives the qualified majority of favourable votes of the Members.

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

Although the Chair and Vice-Chair may be re-elected, when feasible, consideration should be given to transitioning the Vice-Chair to the position of Chair, either at the end of the two year term or in the event of resignation of the Chair. This is intended to ensure continuity in the management of MedDRA Management Committee. Until a new Chair has been elected at the subsequent Management Committee meeting, the Vice-Chair should act as Chair. The new Chair would serve the remaining period of the term of office of the previous Chair. In the event the Vice-Chair resigns, a new Vice-Chair can be elected at the subsequent Management Committee meeting. The new Vice-Chair would serve until the remaining period of the term of office of the previous Vice-Chair.

In case of resignation, the Chair and/or Vice-Chair should notify the ICH Secretariat of their 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 MedDRA Management Committee, the ICH Management Committee and the Assembly of the notification.

6. MedDRA Management Committee Decision-Making

6.1. General Decision-Making Process

In line with Article 49(2), either of the two (2) MedDRA Management Committee Representatives have the right to cast the vote on behalf of the Member. The two (2) Representatives jointly decide how to dispose of the vote.

Decisions are taken by open ballot with the exception of appointment of the Chair and Vice-Chair of the MedDRA Management Committee which should be taken by secret ballot when consensus cannot be reached. The MedDRA Management Committee may upon proposal by the Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee decide to cast a secret ballot for other matters.

In cases where it is necessary for the MedDRA Management Committee to provide direction to the MSSO between meetings, or where it is important to the progress of an activity, the MedDRA Management Committee may take decisions via written (electronic) procedure.

Decisions by two-third majority in accordance with Article 49(2) should be passed if consensus is not reached. Prior to voting, the MedDRA Management Committee 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). MedDRA 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 a MedDRA Management Committee Representative abstains, they are in effect only contributing to a quorum.

In line with Article 41, Representative(s) to the MedDRA Management Committee may abstain from decision-making on items which would be in conflict with the rules of their organisation.

6.2. Recording and Communication of MedDRA Management Committee Decisions

The adopted decisions will be recorded in the minutes of the MedDRA Management Committee meetings that take place face-to-face. Decisions which are adopted by the MedDRA Management Committee in virtual meetings, such as teleconferences, are recorded in summary reports. Separate summary reports will be developed for executive sessions of the MedDRA Management Committee which occur either face-to-face or virtually. The MedDRA Secretariat is responsible for drafting the minutes and the summary reports. With the exception of draft summary reports of executive sessions which should only be shared with the MedDRA Management Committee Representatives, the draft minutes and draft summary reports should be sent by e-mail to all MedDRA Management Committee Representatives and WHO Observer delegate(s). The draft minutes and draft summary reports of meetings attended by MSSO and JMO representatives will also be shared with these representatives, unless determined otherwise by the Chair, or Vice-Chair in the absence of the Chair. Generally, the draft minutes should be sent within three (3) weeks of a face-to-face meeting, and draft summary reports within one (1) week of a virtual unless there are exceptional circumstances.

An abbreviated summary of the main decisions taken at the MedDRA Management Committee meetings held in conjunction with ICH Assembly meetings will be shared within the ICH press release This summary will be put forward by the MedDRA Management Committee although the final press release will be approved by the Assembly Chair before being published on the website of the ICH Association preferably within one (1) week of the Assembly meeting.

The MedDRA Management Committee Representatives and WHO Observer delegates, as well as MSSO and JMO representatives, as appropriate, should send any written comments on the minutes/summary to the MedDRA Secretariat 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. If no comments are received by the time of the close of the comment period, the minutes and summary reports shall be considered as adopted provided these reports have received the express approval of the MedDRA Management Committee Chair, or Vice-Chair in the absence of the Chair. Minor and editorial issues should be resolved by the MedDRA Secretariat in consultation with the concerned MedDRA Management Committee Representative(s) and WHO Observer delegate(s). Major issues should be forwarded to all MedDRA Management Committee Representatives and WHO Observer delegates, together with a proposal from the MedDRA Management Committee Chair, or Vice-Chair in the absence of the Chair, in consultation with the MedDRA Management Committee Representative(s) and WHO Observer delegate(s), on how to resolve the matter. This could be either not to accept the concerns raised or to propose amendments to the minutes or summary report. In case of amendments to the draft minutes, the revised minutes should be submitted to the MedDRA Management Committee Representatives and WHO observer delegates at the latest within six (6) weeks of the MedDRA Management Committee meeting. In case of amendments to the summary reports, the timeline is two (2) weeks from the virtual meeting. In the case of revised minutes, MedDRA Management Committee Representatives and WHO observer delegate should send their approval or written objections or comments during a period of two (2) weeks of the receipt of the revised minutes, and in the case of revised summary reports within one (1) week. If no comments are received by the time of the close of the comment period, the minutes and summary reports shall be considered as adopted provided these reports have received the express approval of the MedDRA Management Committee Chair, or Vice-Chair the of absence of the Chair.

7. Declaration of Conflicts of Interest

MedDRA Management Committee Representatives and Observer delegates shall not have any conflict of interest which may negatively affect their participation in the MedDRA Management Committee to the extent allowed by their organisation's rules. An example of a conflict of interest would be having a personal financial interest in a service provider with which the MedDRA Management Committee authorises ICH to contract. If a MedDRA Management Committee Representative or Observer delegate considers they have a conflict of interest, they should inform the MedDRA Management Committee.

8. Maintaining Confidentiality

The MedDRA Management Committee Representatives and WHO Observer delegates of the MedDRA 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 MedDRA Management Committee Representatives and WHO Observer delegates of the MedDRA Management Committee are entitled to share such confidential information with persons within their respective organisation and third parties provided that the recipients (i) must have access to the confidential information to fulfil their duties within their organisation, and (ii) executed a confidentiality agreement or arrangement that has corresponding confidentiality obligations or that such persons or third parties are otherwise bound to confidentiality obligations. The MedDRA Management Committee Representatives and the WHO Observer delegates of the MedDRA 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.

The aforegoing requirements regarding confidential information shall also be respected by any additional participants in attendance of MedDRA Management Committee meetings as per the RoP for Article 48(1), as well as any person to whom participation in a MedDRA Management Committee is delegated as per the RoP for Article 49(1).

9. MedDRA Management Committee Responsibilities

9.1. Oversight of MedDRA

In line with Article 42(1), the role of the MedDRA Management Committee is to manage, support and facilitate the maintenance, development and dissemination of MedDRA.

Further to Article 42(2), the MedDRA Management Committee reports directly to the Assembly and acts independently of the ICH Management Committee as regards the ordinary management of MedDRA. A Member may appoint the same individual to both the ICH Management Committee and the MedDRA Management Committee.

With respect to the oversight of the MedDRA Secretariat, the Chair, or Vice-Chair in the absence of the Chair, of the MedDRA Management Committee should ensure coordination with the Chair of the ICH Management Committee (or Chair's delegate for Secretariat matters), since the MedDRA Secretariat is a sub-division of the Secretariat.

9.2. Entering into Agreements with Third Parties

Further to Article 47(1) and in order to fulfil its responsibilities, the MedDRA Management Committee may enter into agreements with third parties e.g., contract to perform the MSSO activities. Further to Article 47(2)(e), the MedDRA Management Committee is responsible for determining the persons with signatory powers who are entitled to represent the Association on matters relating to MedDRA vis-à-vis third parties. The persons provided with such signatory powers may be determined by the MedDRA Management Committee to be the same or different to those identified by the ICH Management Committee for other ICH matters.

As per Article 4, and further to RoP 6.1 of the Assembly RoP, proposals regarding cooperation with other organisations should be submitted to the Management Committee for review due to its responsibility for the general operation of the Association. The Management Committee is responsible for forwarding to the Assembly proposals for cooperation which it considers favorably.

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

9.3. Selection of the Maintenance and Support Services Organisation (MSSO)

In line with Article 47(1), the MedDRA Management Committee is responsible for selecting the contractor which serves as the maintenance and support services organisation (MSSO) and approving the contract for sign-off by the persons which it has determined to have signatory powers and represent the Association on matters relating to MedDRA vis-à-vis third parties. The MedDRA Management Committee is responsible for determining the term of the contract with the MSSO contractor, any amendments or extensions to the contract which has been awarded, as well as the frequency of putting the contract out for tender. In carrying out its activities, the MedDRA Management Committee should adhere to generally recognised good governance practices. In line with RoP 6.1 of the Assembly RoP, the support of the Assembly should however be sought before entering into the contract, introducing amendments thereto or terminating the contract, with the Assembly briefed on obligations or risks for the ICH Association.

The MedDRA Management Committee is responsible for approving contracts with other third parties which are necessary to the maintenance, development and strategic placement of MedDRA, or which are necessary to its oversight of MSSO activities (e.g., contracting an auditor). As above, this however excludes cooperation with other organisations as per Article 4 and RoP 6.1 of the Assembly RoP or other significant/high-profile contracts.

9.4. Oversight of MSSO Operations

Further to Article 47(2)(a), the MedDRA Management Committee has the following responsibilities in line with its role to manage, support and facilitate the maintenance, development and dissemination of MedDRA and exercise oversight of MedDRA activities including MSSO operations. Further to Article 52(1), the MedDRA Secretariat shall be responsible for the day-to-day management of MedDRA

related activities and supporting the MedDRA Management Committee in its exercising of oversight of MedDRA activities. MedDRA Management Committee responsibilities include but may not be limited to:

9.4.1. *Overseeing MSSO Performance*

- Reviewing and approving the annual MSSO business plan and budget, based on Assembly approval of the overall annual work plan and annual budget for MedDRA in accordance with Article 23(1)(q);
- Reviewing quarterly financial reports, as well as quarterly reports on MSSO activities;
- Organising external audits of the MSSO (e.g., financial, systems etc…);
- Ensuring that the MSSO is meeting the various needs of those individuals and groups using MedDRA;
- Assessing any problems encountered in the provision of normal service by the MSSO;
- Reviewing and approving the MSSO Annual Report.

9.4.2. *Reviewing and Approving MSSO Subscription and Sub-licensing Agreements*

- Reviewing and approving amendments to MSSO subscription agreements developed by the MSSO;
- Reviewing and approving amendments to the MSSO sub-licensing agreement with the JMO.

9.4.3. *Overseeing MedDRA's Development*

- Tasking the MSSO to investigate certain terminology development opportunities for further planning and scoping;
- Prioritising and formally approving all MedDRA developmental changes prior to their implementation;
- Discussing MedDRA's use with regulatory authorities, major stakeholders or subscribers and whether MedDRA meets their needs;
- Approving the distribution of the MedDRA terminology to other entities which propose to use the terminology for purposes that are not in conflict with the intended use for human healthcare purposes;
- Taking action to promote the use of MedDRA while maintaining its granularity and integrity;
- Ensuring the MSSO interacts with and provides the appropriate support to the ICH MedDRA Points-to-Consider Working Group, including participating in meetings (both face-to-face & virtual) of this Working Group;
- Recommending to the Assembly for approval, after consultation of the ICH Management Committee, that the MSSO interacts with other ICH Expert Working Groups when this is deemed appropriate;
- Ensuring the protection of MedDRA's intellectual property, including directing the ICH Secretariat to register MedDRA trademarks in various countries and ensuring MSSO secure distribution of MedDRA;
- Providing recommendations on further harmonisation of issues related to MedDRA to the ICH Assembly.

9.4.4. *JMO*

- Ensuring that there is a good working relationship between the MSSO and the JMO which ensures that the needs of MedDRA users in Japan are met;

- Ensuring harmonisation in the offerings made to MSSO and JMO subscribers;
- Providing input on urgent issues raised in relation to the MSSO/JMO contract and the support of MedDRA users in Japan;
- Ensuring the JMO interacts with and provides the appropriate support to the ICH MedDRA Points-to-Consider Working Group, including participating in meetings (both face-to-face & virtual) of this Working Group;
- Recommending to the Assembly for approval, after consultation of the ICH Management Committee, that the JMO interacts with other ICH Expert Working Groups when this is deemed appropriate.

9.4.5. *Other*

- Approving new MedDRA language translations;
- Approving training classes to MSSO subscribers and the regions/countries in which training is offered;
- Approving the provision of MSSO support to regulators beyond the authorities represented on the MedDRA Management Committee;
- Reviewing any MSSO press releases.

9.5. Setting MedDRA Subscription Fees

9.5.1. *MSSO Subscription Fees*

Further to Article 50(2) and (3), the MedDRA Management Committee is responsible for setting and submitting to the Assembly for approval the annual subscription fees, at a level that corresponds to the cost of all MedDRA activities anticipated in the multi-annual budget. This will include costs for the activities of the MedDRA Management Committee and the MedDRA Secretariat in relation to their support of MedDRA, as well as the overall cost of the MSSO Contractor for its support of MedDRA. The subscription fees shall be included in the annual budget for MedDRA which is submitted to the Assembly for approval.

In the event that higher subscriber numbers in a given year result in a greater contribution of subscriber fees than is necessary to cover costs in such year, such surplus will be assessed by the MedDRA Management Committee who may propose its use for contingencies, or to offset the MedDRA budget in line with Article 50(3). The use of any such surplus should be for the benefit of the Association, including MedDRA, in line with Article 2(2) which states that as a non-profit organisation any funds are exclusively and irrevocably assigned to the purposes of the ICH Association. Proposals for the use of the surplus should be submitted to the Management Committee for review due to its responsibility for the general operation of the Association and specifically for financial matters before issuing proposals or recommendations to the Assembly for approval (referred to in Article 36(2)(m) of the ICH Articles of Association.

The MedDRA Management Committee should, on the basis of 5-year budget planning, make best efforts towards a 5-year adjustment of MedDRA subscription fees, to allow MedDRA subscribers to better plan for changes in subscription fees.

In line with Article 50(1), whilst non-profit or non-commercial organisations are exempt from paying subscription fees for MedDRA, a small fee may be charged for access to some translations depending on the need to recover costs related to the development and maintenance of a particular translation.

The MedDRA Management Committee may also grant MedDRA Special Licenses which are fee waivers for small and medium-sized companies to use MedDRA in non-downloadable form in data collection and presentation systems.

9.5.2. *JMO Subscription Fees*

With respect to Japan, the MedDRA Management Committee shall approve the sub-licensing fee paid by the Japanese Maintenance Organisation (JMO) to MSSO for the right to distribute MedDRA to Japanese headquartered organisations. The Japanese Management Board (JMB), after consultation of the MedDRA Management Committee, shall determine the subscription fees paid by Japanese MedDRA users to the JMO. These fees shall correspond to the sub-licensing fee and the JMB anticipated cost for its support of MedDRA taking into account possible income received in excess by the JMB in the previous years.

9.6. Reporting to the Assembly

The Assembly is responsible for approving the annual work plan of the MedDRA Management Committee, the annual budget of MedDRA, the annual report on the activities regarding MedDRA, and approval of policy relating to MedDRA.

In line with Article 47(2)(b), the MedDRA Management Committee will submit to the Assembly a proposal for the following year's work plan at the latest by the second Assembly meeting of the year. At the same meeting, the following year's budget for MedDRA will also be presented to the Assembly by the MedDRA Management Committee Chair, or Vice-Chair in the absence of the Chair. This will include the cost for the activities of the MedDRA Management Committee and the MedDRA Secretariat in relation to their support of MedDRA, the overall cost of the MSSO Contractor for its support of MedDRA, as well as the estimated income from the MedDRA subscription fees.

Since the annual work plan of the MedDRA Management Committee and the annual budget for MedDRA must take into account the MSSO's business plan and budget for the respective year, the timeframe for submission of these items to the Assembly is based on the timeframes for the MedDRA Management Committee's approval of these MSSO deliverables in line with the MSSO contract.

Further to Article 47(2)(c), a report on the previous year's MedDRA activities will be submitted to the Assembly for approval at the first Assembly meeting of the year. This report may be provided to the ICH Management Committee for inclusion in the annual report on the activities of the ICH Association. Based on this report the Assembly will be asked to discharge the MedDRA Management Committee.

The MedDRA Management Committee will furthermore maintain a 5-year budget plan in line with MedDRA strategic and administrative multi-year planning which will be shared with the Assembly annually to support Assembly approval of the annual budget, including subscription fees.

9.7. Use of the MedDRA Logo

Apart from official use of the MedDRA logo by the MedDRA Management Committee, the ICH Association and its bodies, or in conjunction with the MedDRA Management Committee meetings, use

of the logo is restricted and requires the express permission of the MedDRA Management Committee. This restriction applies not only to third parties, but also to ICH Members and Observers. Permission should be granted by the MedDRA Management Committee based on a recommendation by the MedDRA Secretariat.

As a general rule, permission shall only be granted for use of the MedDRA logo on materials which have undergone review by the MedDRA Management Committee and which the MedDRA Management Committee supports, or for use in the promotion of events that the MedDRA Management Committee has expressly agreed collaboration on. The MedDRA Management Committee may itself undertake such reviews or may delegate to a dedicated MedDRA expert review group. In no event shall MedDRA's logo be permitted for use in or in connection with the certification of a product, organisation or person.

Notwithstanding the provision of permission by the MedDRA Management Committee, users of the logo shall acknowledge that, access to the logo is provided "as is" without warranty of any kind. The MedDRA Management Committee shall limit or exclude the liability of the MedDRA Management Committee and the ICH in connection with the use of the MedDRA logo by users to the maximum extent permitted by applicable law.

It should be noted that this restriction regarding the use of the MedDRA logo extends to the use of the MedDRA presentation template which carries the MedDRA logo, with such presentations being subject to the same review and permission process stated above. An exception is in the case of presentations made by the MSSO and the JMO in the context of its usual training and outreach activities.

10.MedDRA Secretariat

10.1. Support of MedDRA Management Committee

Further to Article 52(1), the MedDRA Secretariat shall support the MedDRA Management Committee in its work and will take direction from the MedDRA Management Committee in this regard. The MedDRA Secretariat shall be responsible for the day-to-day management of MedDRA and supporting the MedDRA Management Committee in relation to its responsibilities outlined in the RoP for Article 47(2)(a).

The MedDRA Secretariat will raise urgent issues to the attention of the MedDRA Management Committee and will work closely with the MedDRA Management Committee Chair, and Vice-Chair in the absence of the Chair. The MedDRA Secretariat will report regularly on its activities to the MedDRA Management Committee, at least at the time of face-to-face meetings, and will request MedDRA Management Committee input as necessary between meetings.

MedDRA Secretariat staff shall take part in meetings of the MedDRA Management Committee without voting rights. The MedDRA Secretariat will prepare an agenda to be circulated two (2) weeks prior to each scheduled meeting and will capture the decisions taken in minutes or summary reports in line with the RoP for Article 49(2).

In line with Article 52(2), the MedDRA Secretariat shall assist the MedDRA Management Committee to prepare the annual budget for MedDRA for approval by the Assembly and otherwise carry out the directives of the MedDRA Management Committee.

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

10.2. Coordination with the ICH Secretariat

Further to Article 52(3), the MedDRA Secretariat is a sub-division of the ICH Secretariat allowing for the coordination of activities and overall support of the aims of the ICH Association. The MedDRA Secretariat shall follow the rules outlined in the Employee Handbook which is also followed by ICH Secretariat staff, however, objectives, responsibilities, and scope of authority of MedDRA Secretariat staff in relation to support of MedDRA activities is determined uniquely by the MedDRA Management Committee.