INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES

TERMS OF REFERENCE AND RULES OF PROCEDURE

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INTRODUCTION

The Terms of Reference and Rules of Procedure for the International Coalition of Medicines Regulatory Authorities (ICMRA), including those for the Executive Committee (EC) (Appendix I), are intended to provide an operational framework for ICMRA.

1. MANDATE

1.1 In recognition of the pan-global nature of medicinal products and the related supply chains, it was agreed to develop and establish an international, non-political coalition of Heads of Medicines Regulatory Authorities, responsible for the regulation of medicinal products for human use[1]. The COVID-19 pandemic has shown the importance of regulators being able to share and to access information on clinical trials, therapeutics, vaccines, disease progression and post authorisation surveillance. ICMRA is therefore established to better safeguard global public health by facilitating greater co-operation and to enable Heads of Medicines Regulatory Authorities to exercise collective and concerted strategic leadership during a global public health crisis, and over existing and new international initiatives and enablers, as well as over shared regulatory issues and challenges. ICMRA is a non-political organization and members commit that all interactions are based solely on the ICMRA public health mandate.

1.2 ICMRA exists on a voluntary basis supported by these Terms of Reference and Rules of Procedure and the Terms of Reference and Rules of Procedure of the Executive Committee (Appendix I).

1.3 Should the Members decide a more formal legal structure is required; ICMRA can commission the Executive Committee to put in place a mechanism to review the options available to establish a legal structure for the organisation, sufficient to permit it to accomplish its goals.

2. MEMBERSHIP

2.1 Membership of the International Coalition of Medicines Regulatory Authorities (ICMRA) shall be divided into two types of members; Full Members hereafter referred to as “Members” and associate members referred to as “Associate Members”. The term “ICMRA Membership” shall refer to both types of members and the World Health Organisation. The WHO is a permanent observer to ICMRA Members and Associate Members are listed in a membership register maintained and updated by the secretariat. The process for becoming Associate Members is included in Appendix II.

2.2 The Medicines Regulatory Authority listed shall be the member or associate member and shall be represented by the head of the Medicines Regulatory Authority. The head may be accompanied by one senior support colleague and translation services if

[1] The ICMRA’s primary focus is medicines but ICMRA can consider other health care products as appropriate.

required. In the absence of the head and in principle by agreement with the Chair, the head may exceptionally nominate a named senior deputy to represent him/her.

2.3 Medicines Regulatory Authority may be understood to be the regulatory authority of a country or region, with responsibility for authorisation and supervision of medicines. The Head of the Medicines Regulatory Authority shall be the person who is the lead executive for the Medicines Regulatory Authority[2].

2.4 Associate Members

2.4.1 Associate Members shall receive all documents generated by ICMRA and be invited/ volunteer to join working groups.

2.4.2 Associate Members are invited by the Chair to attend whole or parts of plenary meetings of the full membership either in person or by TC, depending on the meeting agenda and in person facilities available.

2.4.3 Associate Members will not have a vote or be a member of ICMRA Executive Committee.

2.4.4 The process for appointing Associate Members is outlined in Appendix II.

2.4.5 The process by which Associate Members who are sovereign countries or are supranational medicines regulatory authorities can become full Members is outlined in section 2.7 below.

2.5. Responsibility of Members and Associate Members

2.5.1 Members shall be responsible for appointing an Executive Committee to manage the activities of the ICMRA under the Terms of Reference and Rules of Procedure and ICMRA strategic documents. The Terms of Reference and Rules of Procedure for the Executive Committee and their appointment are contained in Appendix I.

2.5.2 The Chair and Vice-chair(s) will be appointed by the Members following a proposal from the Executive Committee. The mechanism and term of appointment of the Chair and Vice-chair(s) shall be in accordance with section 2.6 below.

2.5.3 The Members approves and endorses projects according to its strategic aims: The Members, following a proposal of the Executive Committee, will approve and adopt the work plan and projects for the year and where appropriate, on a voluntary basis, provide resources to those projects.

2.5.4 The Members and Associate Members shall commit where appropriate, on a voluntary basis to supporting the activities of ICMRA. To facilitate supporting the network, a commitment to sharing information is included in section 7 below Confidentiality and Sharing of Information. It is also recognised that there is an understanding that information shared among the Executive Committee and ICMRA Membership will be kept confidential, consistent with the laws of their country or region and any other applicable legislation unless the author or the member providing the information and

[2] While it is intended that the regulatory authority shall be the member, it recognised that for some countries/regions, regulation of medicine may be split between the authority and other parts of Government. In such situations, it will be a matter for the country/region to determine the appropriate attendees but with the underlying principle that the country/region has only one member.

the Executive Committee or ICMRA Membership, as appropriate, agree to its disclosure.

2.5.5 Where appropriate the Members can agree, in response to a proposal from the Executive Committee, that ICMRA engage with third parties subject to, where necessary, ensuring that procedures are put place to avoid a conflict of interest. Expectations or outcomes of such engagement should be agreed in advance.

2.6 CHAIR AND VICE-CHAIR(S)

2.6.1 The Chair and Vice-Chairs role is to provide guidance and leadership to both the Executive Committee and the overall membership.

2.6.2 Meetings are chaired by the Chair. In his/her absence, the meeting shall be chaired by the Vice-chair(s) or in their absence, by a person whom the members of the Executive Committee choose from among themselves.

2.6.3 The term of office of the Chair and Vice-chair(s) will be for a period of three years.

2.6.4 The EC shall invite nominees, 6 months before the expiry of the existing term, from the Members to fill the position of Chair and up to a maximum of two Vice-chair(s). The existing Chair / Vice-chair(s) may volunteer at the end of their term for a further term/(s) [Maximum 2 terms / 6 years]

2.6.5 Where feasible, it is desirable that the Chair and vice Chair posts are filled from different geographical regions.

2.6.6 The proposed nominees who volunteer for the position of Chair or Vice-Chair are presented to the Executive Committee and ICMRA Members for approval by consensus. Every effort should be made to reach consensus. If consensus is not achieved the nominees are put to a vote by secret ballot. Nominees must receive a two-thirds majority of the members in attendance (either in person or virtually) at the ICMRA Summit to be appointed. In the event that no nominee receives the desired majority after two rounds of votes, the candidate with the greatest number of votes at the end of round two is appointed.

2.6.7 The Chair or secretariat will provide summary updates of the activity of the Executive Committee and the activities under the work plan to the ICMRA Membership at a minimum twice yearly. One update will be at the annual ICMRA Summit and the other updates will be by electronic means.

2.7 Procedure for Associate Members to Become Full Members

2.7.1 Associate Members who are medicines regulatory authorities of sovereign countries or supranational regulatory authorities and are eligible to apply for full Membership may submit a request in writing demonstrating how they meet the criteria outlined in Appendix III.

2.7.2 The Executive Committee (EC) reviews the application and if they are satisfied that the application meets the criteria outlined in Appendix III of the TOR, they will make a recommendation to the full membership outlining the basis on which the recommendation is made.

2.7.3 The review by the EC, the recommendation to the membership and the review by the membership can be either at a face-to-face meeting, during a virtual meeting or by written procedure.

2.7.4 The decision by the membership will be by consensus, or in the absence of consensus, by a 2/3 majority.

3. ICMRA MEETINGS

3.1 ICMRA meetings can be either face to face or by teleconference (TC). ICMRA shall have a plenary meeting a minimum of two times per year and where circumstances allow, one or more meetings shall be face-to-face, one of which can be the ICMRA Summit meeting (3.2 below). Where additional meetings[3] are held in person, regardless of the location, the host shall be the ICMRA Chair.

3.2 An ICMRA Summit will be held annually. It will be hosted by one of the Members on a voluntary basis and will, where feasible be hosted sequentially in each of three global parts of the world[4]. In addition to ongoing ICMRA work, the Summit can include any topic (Summit themes) of relevance to ICMRA. The host with the Chair, Vice Chairs and EC will agree the summit themes and the list of invitees to the meeting. Where the host of the ICMRA Summit is not a member of the EC they shall be invited to attend EC meetings prior to the Summit.

3.3 Where facilities exist at face-to-face meetings, Members and associates who cannot attend may participate in meetings by telephone or videoconference. Members so participating are considered to be present at the meeting. The quorum for ICMRA meetings is half the Members plus one member.

3.4 The agenda for ICMRA meetings, other than the Summits, is established by the Chair and is circulated by the secretariat with related papers in advance of the meeting.

3.5 Where an attendee considers that they may have a conflict of interest in relation to a topic on the agenda, they should declare it to the Chair and absent themselves from the meeting for the duration of the topic being discussed.

3.6 ICMRA decisions are made by consensus or in the absence of a consensus by a two-thirds majority of attendees. Every effort should be made to reach a decision by consensus. When a vote is taken, the view of the minority should be noted.

3.7 Participation in the ICMRA work programme and initiatives is voluntary and the individual members may exclude themselves from projects and work streams regardless as to whether they voted for or against those projects, initiatives or work streams.

3.8 Any third party attending an ICMRA meeting, including those attending the ICMRA Summit meeting may be invited to attend part or all of the meeting at the discretion of the Chair but they are not entitled to vote. All members of the EC will be notified in advance of any proposed invited attendees and will have the opportunity to raise any concerns. The Chair and Vice-chair(s) will review these concerns and take the final decision.

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[3] The second meeting has traditionally been held on the margins of the DIA alternating between US and Europe.

[4] The Americas, Europe and Africa, Asia, Australia and New Zealand

3.9 A brief record summarising the decisions taken will be prepared by the secretariat on behalf of the Chair or the Vice-chair(s) and circulated to the ICMRA Membership and other attendees as appropriate. Unless agreed by the EC, meeting records shall be published on the ICMRA website.

4. WRITTEN PROCEDURE

4.1 The Chairperson or the ICMRA Secretariat may, between plenary sessions, initiate a written procedure for decision.

4.2 Draft written proposals, including the background to the proposal, are sent to all the Members who are requested to respond with their agreement or comments within a specified period of time, usually 10 working days.

4.3 The quorum (two thirds of the appointed Members) must be reached for any decision taken by written procedure.

4.4 A full report on the outcome of the procedure and any decision taken is shared with the ICMRA Membership following the finalisation of the procedure and is noted at the next ICMRA plenary meeting.

5. SUSPENSION OF MEMBERSHIP

5.1 The ICMRA mandate recognises that it is established to safeguard global public health. In certain situations, a country or regulator's actions may be so detrimental to public health or to the reputation and mission of the Coalition that it becomes incompatible with membership of ICMRA. Where such a situation arises, the Executive Committee may temporarily suspend the participation of a regulator in ICMRA activities with immediate effect and issue a recommendation together with reasons to the ICMRA plenary on a suspension of membership of the concerned Member. The decision on suspension of the membership is voted on by the Members at the next ICMRA plenary session. The suspension will be for an indefinite period, but it will be up to either the regulator to apply to have the suspension lifted or the Executive Committee to propose lifting the suspension. In both cases, the lifting of the suspension will be voted on by Members following a proposal from Executive Committee.

6. FUNDING

6.1 The costs associated with ICMRA will be funded by the Members and Associate Members who will pay for their own cost and any services that they may provide to the network.

6.2 There is a fee payment system for members to contribute to the cost of hosting and organising the two annual face-to-face plenary meetings (DIA Europe/USA and the ICMRA Summit). The system allows for the registration of attendees and the collection of fees from members. The Health Products Regulatory Authority of Ireland coordinate the fee system utilising an online conference software free of charge. The income received from members is distributed to the meeting host to cover meeting costs or directly to service providers. The details of the fee payment system are outlined in Appendix IV.

7. CONFIDENDIALITY AND SHARING OF INFORMATION

7.1 Members and Associate Members of ICMRA recognise that greater regulatory collaboration and convergence require a commitment in principle to the sharing of information. This sharing of information will be on a voluntary basis, consistent with the laws of their country or region, where sharing of such information will contribute to the better collaboration of regulators and contribute to the safeguarding of public health. In sharing and receiving such information, all the ICMRA Membership will recognise that where information is shared in confidence the Membership should be committed to respecting the confidential nature of such information.

In addition, all Members and Associate Members commit to respect as confidential, consistent with the laws of their country or region and any other applicable legislation or other requirements, any information shared and identified as confidential by the ICMRA Membership under any of the projects or as part of an ICMRA meeting. This commitment does not take precedence or replace any existing confidentiality agreements nor does it place any obligation on members to share information other than on a voluntary basis. Where countries have existing bilateral confidentiality agreements, confidential information shared between those countries will remain subject to those agreements.

8. REVISION OF THE TERMS OF REFERNCE

8.1 The Terms of Reference and Rules of Procedure can be revised at any time and presented to the Members for adoption. Notwithstanding this provision, the Terms of Reference and Rules of Procedure will be formally reviewed every two years.

APPENDIX I: TERMS OF REFERENCE AND RULES OF PROCEDURE OF THE EXECUTIVE COMMITTEE

1. AUTHORITY

1.1 The Executive Committee (EC) is established by the Members of ICMRA.

2. MEMBERSHIP

2.1 The Executive Committee (EC) will have a minimum of 6 members and a maximum of 8 members, comprised of the Chair, up to two Vice Chairs and 5 others. Membership of the Executive Committee (EC) is at the National/Central Government Agency/ Authority level. In general, the head of the authority shall sit on the EC. In the absence of the head and in principle by agreement with the Chair, the head may, exceptionally nominate a named senior deputy to represent him/her. Should a head be replaced, their successor will be entitled to replace them on the EC.

2.2 The 5 additional members will be appointed from a pool comprising the previous Chair and Vice Chairs who automatically take a place if they so wish, to ensure continuity, and two other project leads.

2.3 Where there are greater or less than 5 eligible countries wishing to be on the EC and other countries wish to be members, the current Chair and Vice Chair will allocate spaces by consensus based on the members' contribution to ICMRA, considering the following criteria:

- Are they an immediately preceding Chair or Vice Chair?
- Are they a current project lead?
- Are they from an underrepresented region?
- Are they planned to be a project lead / Summit host?
- Are they a historic Chair or Vice Chair?

2.4 In the event that the procedures in 2.3 above do not result in consensus, the members of ICMRA will vote for the nominees put forward by way of a secret ballot with one vote per member attending the ICMRA Summit. Nominees must receive a two-thirds majority of the attendees at the Summit to be appointed. In the event that no nominee or insufficient nominees receives the desired majority after two rounds of votes, the candidates with the greatest number of votes at the end of round two are appointed. In the event of a tie, the Chair of the EC (or in the absence of a Chair of the EC, the Chair of the Summit) will have the deciding vote.

2.5 Project leads not represented on the EC will be invited to regularly update the EC on their project.

2.6 When a member of the EC or their alternative fail to attend four consecutive meetings, their membership will be deemed to have lapsed and a new member will be appointed in accordance with the procedures 2.1-2.5 above.

3. TERMS OF OFFICE OF THE EXECUTIVE COMMITTEE

3.1 The membership term of the EC shall be three years.

4. FREQUENCY OF MEETINGS

4.1 The EC will meet via TC at least once every two months. The Chair/Vice Chairs may invite others as appropriate on an ad-hoc basis, to attend the whole or part of the EC teleconference.

5. MANDATE

5.1 The EC shall manage the activities of ICMRA consistent with the Terms of Reference and Rules of Procedure, founding documents, strategic framework and work plans.

5.2 The EC through the Chair and Vice-chair(s) will manage and co-ordinate day-to-day matters as they arise.

5.3 The EC will evaluate when the engagement of ICMRA with third parties is appropriate and propose, for agreement by the Members, the terms for this engagement – including expected outcomes and where necessary procedures to avoid a conflict of interest.

6. THE ROLE OF THE CHAIR AND VICE-CHAIR(S)

6.1 The Chair and Vice-chair(s) will provide an administrative structure through the secretariat to support the operation of the EC and will have oversight of the annual work plan and projects.

6.2 The Chair will give direction and focus to the meetings of the EC and ICMRA through the preparation of an appropriate agenda and the conduct of the meeting.

7. MEETINGS

7.1 Meetings are chaired by the Chair. In his/her absence, the meeting shall be chaired by the Vice-chair(s).

7.2 The EC may act in the absence of one or more Members. If Members cannot attend all or part of a meeting, they should notify the meeting facilitator in advance of the meeting.

7.3 The quorum for meetings is one half of the membership plus one.

7.4 In the event that a decision is required outside of a meeting, decisions can be agreed in writing.

7.5 The agenda is established by the Chair and circulated with related papers before the meeting.

7.6 Where a member or attendee considers that they may have a conflict of interest in relation to a topic on the agenda, they should declare it to the Chair and absent themselves from the meeting for the duration of the topic being discussed.

7.7 Every Member present has one vote. Decisions are made by consensus or in the absence of consensus a vote will be held and the decision will be by a qualified majority being two thirds of the votes of the Members present.

8. RECORD OF MEETINGS

8.1 A brief record summarising the decisions taken will be prepared by either the Chair, the Vice-chair(s) or the secretariat, and circulated to the attendees and others as appropriate.

9. REPORTING

9.1 The Chair or secretariat will provide summary updates of the activity of the EC after each meeting to the ICMRA Membership and will report on the activities under the work plan to the membership at a minimum twice yearly. Updates will be by electronic means, TC or face-to-face meetings.

10 GOVERNANCE OF PROJECTS

10.1 Projects approved and endorsed by the EC will be consistent with the strategic aims of ICMRA.

10.2 Each project will have a lead who will be responsible for developing the project plan and the delivery of that project. Each project lead will form a project working group to assist with project development, implementation and delivery.

10.3 The project leads shall report as determined by the EC on the project to the EC and annually to the ICMRA Membership.

10.4 The Chair and Vice-chair(s) through the secretariat, will agree to a reporting template for projects.

10.5 The Chair and Vice-chair(s) shall have oversight on the projects and identify any possible overlaps that exist between projects. They shall bring these overlaps to the attention of the project leads, who with their project team will work with the other project (with whom the overlap exists) to agree to a revised or clarified work plan which ensures that work is not duplicated between the projects.

10.6 The Chair and the Vice-chair(s) with the EC will ensure that the project leads report back to the full membership on the projects as they progress.

11. FUNDING

11.1 The costs associated with the EC including the provision of a virtual secretariat, will be funded by the members who will pay for their own cost and any services that they may provide to the network.

12. REVISION OF THE TERMS OF REFERENCE

12.1 The Terms of Reference and Rules of Procedure can be revised at any time and presented to the EC and ICMRA Membership for adoption. Notwithstanding this provision, the Terms of Reference and Rules of Procedure will be formally reviewed every two years.

APPENDIX II: PROCEDURE FOR APPOINTING ASSOCIATE MEMBERS

1. Countries and regions who are interested in their Medicine Regulatory Authority becoming an Associate Member will write to the secretariat indicating their interest in joining ICMRA.
2. The secretariat shall respond asking the authorities wishing to join as an Associate Member to submit a letter (an "expression of interest") to the secretariat.

   This letter should outline a broad description of their authority to include:

   - Competencies.
   - Size of their authority.
   - Areas of international interest and existing international initiatives.
   - Capacity and interest in contributing to ICMRA.
   - Details of any existing bi/multi-lateral MOUs / confidentiality agreements that they may have in place.

3. The secretariat / Governance working group will summarise the expressions of interest, which will be sent initially to the Executive Committee for comment. This summary, including any comments from the EC, will be circulated to the full members.
4. The Members shall confirm the new Associate Members or ask the secretariat to respond seeking further information on how the new authority will meet the existing objectives and the ICMRA strategic framework.

APPENDIX III: PROCEDURE FOR ASSOCIATE MEMBERS TO BECOME FULL MEMBERS

1. Associate Members who are medicines regulatory authorities of sovereign countries and supranational medicines regulatory authorities will be eligible to apply to become full Members after a period of time[5] as an associate member when they can demonstrate that they meet the criteria outlined in point 2 below.

2. To be eligible to become a full member, the Associate Member must demonstrate a minimum level of participation and contribution in the preceding period. A base line measure of participation is attendance at plenary and other meetings to which they are invited at the level of head[6]. In addition to attendance, it is expected that associate members should demonstrate contribution under one or more of the following criteria:

    a. Sustained contribution as a member of one or more working groups, or to have led a working group.
    b. To have presented at one or more plenary meeting on substantive topics of interest to ICMRA.
    c. To have hosted a database / website or otherwise contributed to the IT/ other infrastructure behind ICMRA work.
    d. Development of one or more reflection papers on issues of potential interest or strategic relevance.
    e. Sustained active engagement in ICMRA work through consistently providing timely review and comments on documents shared for comment.
    f. To have made other significant contributions if not covered above.

3. Associate Members wishing to become full members should demonstrate that in addition to attendance, that they have made a significant contribution to ICMRA, in relation to the categories outlined above.

4. As part of the eligibility criteria for membership, associate members should outline their future commitment in relation to participation and contribution to ICMRA using the criteria outlined in point 2 above.

[5] The minimum period is 1 year.
[6] It is expected that attendance will be at the level of head but exceptionally, can be at an appropriate level of seniority.

APPENDIX IV: ICMRA EVENT FEE PAYMENT SYSTEM

BACKGROUND

Since its initiation as a voluntary non-funded organisation, ICMRA activities such as the Secretariat have been provided on a voluntary basis. The Annual Summit meeting has been funded (room hire, AV, refreshments, dinner etc.) by a host Agency and a second annual face-to-face meeting held every year on the fringes of the DIA has been paid for on a voluntary basis by one or two members. As the number of attendees to both the DIA meeting and the Annual Summit has increased over the past years, it is no longer equitable to have a small number of agencies carrying these costs. It was therefore agreed that a funding mechanism be put in place and availed off where required.

PROCESS FOR FEE PAYMENT SYSTEM

ICMRA has two face-to-face meetings per year, which require funding; the ICMRA Summit hosted by an ICMRA member country and a plenary session on the fringes of the DIA EU or USA meetings.

ICMRA Annual Summit

Where the ICMRA Summit host wishes to charge a fee they will carry out cost estimates in order to establish a fee based on the basic running costs of hosting the meeting e.g. room hire, AV, refreshments/lunch and a dinner. Delegate fees should exclude gifts and focus on the basic elements of running the event. While the host has some discretion in how they want to structure and pay for the event, if a host wishes to arrange a tour, provide gifts or a gala dinner that is a matter for the host to fund.

A financial report based on the fees income and expenditure should be submitted by the host to the ICMRA Executive Committee following the Summit.

If restrictions exist under the host agency's procurement policies, which prevent them from collecting funds from another Government agency, the HPRA is in a position to collaborate with the host to utilise the fee collection service. In this instance:

- HPRA would collect the fee from agencies, which will be transferred to an ICMRA bank account separate to HPRA funds.
- HPRA would then transfer the funds to the host upon receipt of copies of invoices paid by the host to suppliers.
- HPRA would not get involved in paying suppliers directly – the host would need to meet the costs upfront and then receive ICMRA funds from HPRA.
- If the host is not in a position to transfer funds this way then any fees would need to be collected from ICMRA members directly, or the host pays all the Summit costs.
- If a delegate fee were to be calculated and charged for the Summit, the fee would be based on the specified costs of the Summit that the host wanted to be funded, (e.g. AV requirements, refreshments lunch / dinner), but anything over and above that would be a matter for the host to fund.

Face to Face plenary at DIA Europe or USA

As the plenary meeting at DIA is hosted by the Chair of ICMRA, the ICMRA secretariat will lead on coordinating meeting logistics and establishing a fee payment system for that event. As for the annual Summit, the HPRA are in a position to assist the Secretariat with fee collection under the conditions outlined about.

APPENDIX V: RECORD OF HOSTS OF THE SUMMIT (WHICH HAS NOW MERGED WITH THE ICMRA SUMMIT)

Year	Authority	Location
2006	The U.S. - FDA	Washington
2007	Ireland - HPRA	Dublin
2008	Singapore- HSA	Singapore
2009	Canada - The HPFB of Health Canada	Ottawa
2010	The UK - MHRA	London
2011	Australia - TGA	Sydney
2012	Brazil - ANVISA	Manaus
2013	The Netherlands - MEB	Amsterdam
2014	China - CFDA	Beijing
2015	México - Cofepris	Mexico City
2016	Switzerland - Swissmedic	Interlaken
2017	Japan – MHLW/PMDA	Kyoto
2018	The U.S. – FDA	Washington
2019	Italy – AIFA	Rome
2020	ICMRA Secretariat (EMA)	Remote
2021	Brazil – ANVISA	Remote
2022	Ireland – HPRA	Dublin