INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES
TERMS OF REFERENCE AND RULES OF PROCEDURE

VERSION DATE: 5 APRIL 2018

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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 II), are intended to provide an operational framework for ICMRA.

1. MEMBERSHIP

1.1 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 IV.

1.2 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 required. In the absence of the head, the head may nominate a named colleague to represent him/her.

1.3 Medicines Regulatory Authority may be understood to reflect only the national/state regulatory authority of each sovereign country[1] such as, but not exclusively, agency, authority, government department, government division etc. The Head of the Medicines Regulatory Authority shall be the person who is the lead executive for the Medicines Regulatory Authority[2].

2. MANDATE

2.1 In recognition of the pan-global nature of medicinal products and the related supply chains, it was agreed to develop and establish an international coalition of Heads of Medicines Regulatory Authorities, responsible for the regulation of medicinal products for human use[3]. ICMRA is established to better safeguard public health by facilitating greater co-operation and to enable Heads of Medicines Regulatory Authorities to exercise collective and concerted strategic leadership over existing and

[1] Medicines Regulatory Authority is understood also to include the Medicines Regulatory Authority of the European Union (European Medicines Agency), who will determine the appropriate attendees.

[2] While it is intended that the regulatory authority shall be the member, it recognised that for some countries 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 to determine the appropriate attendees but with the underlying principle that the country has only one member.

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

new international initiatives and enablers, as well as over shared regulatory issues and challenges.

2.2. MANDATE OF MEMBERS

2.2.1 Members shall be responsible for appointing an Executive Committee to manage the activities of the ICMRA consistent with the Terms of Reference and Rules of Procedure, founding documents, strategic framework and annual work plan. The Terms of Reference and Rules of Procedure for the Executive Committee and their appointment are contained in Appendix II.

2.2.1 The Chair and Vice-chair(s) will be appointed by the Members following a proposal from the Executive Committee. The appointment of Chair and Vice-chair(s) in the absence of consensus, requires a two thirds majority of Members present when the appointments are being made. The mechanism and term of appointment of the Chair and Vice-chair(s) shall be in accordance with section 2.3 below.

2.2.2 The membership 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.

2.2.3 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 Appendix I. 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 and any other applicable legislation unless the author or the member providing the information and the Executive Committee or ICMRA Membership, as appropriate, agree to its disclosure.

2.3 CHAIR AND VICE-CHAIR(S)

2.3.1 The term of office of the Chair and Vice-chair(s) will be for a period of three years.[4]

2.3.2 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]

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

2.3.4 Where more than one country volunteers for the position of Chair or vice Chair; the EC passes all nominees to the ICMRA Members.

[4] As the organisation matures, consideration should be given to structuring the terms of office so that at least one of the chair / Vice-chair(s) carries forward into the new EC.

2.3.5 The proposed nominees are presented to the 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 attendees 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.

2.4 ASSOCIATE MEMBERS

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

2.4.2 Associate Members may be invited by the Chair to attend meetings of the full membership either in person or by TC as appropriate.

2.4.3 Associate Members will not have a vote, be a member of ICMRA Executive Committee or be automatically entitled to attend meetings.

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

3. ICMRA MEETINGS

3.1 ICMRA meetings can be either face to face or by teleconference (TC). ICMRA shall meet a minimum of 4 times per year of which two meetings shall be face to face, one of which can be the ICMRA Summit meeting (3.2 below). Associate Members shall be invited to all TCs and at least one of the face to face meetings.

3.2 Annually an ICMRA Summit will be held. It will be hosted by one of the Members and will, where feasible be hosted sequentially in each of three global parts of the world[5]. 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.

3.3 Where facilities exist at face to face meetings, Members and associates who can't attend may participate in meetings by telephone or videoconference. Members so participating are considered to be present at the meeting.

3.4 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.

3.5 The quorum for ICMRA meetings is half the Members plus one member.

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

3.6 The agenda for ICMRA meetings is established by the Chairperson in consultation with the Executive Committee and is circulated by the secretariat with related papers in advance of the meeting.

3.7 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 Chairperson and absent themselves from the meeting for the duration of the topic being discussed.

3.8 Each member of ICMRA present has one vote. Where an associate member is invited they shall not be entitled to vote. ICMRA decisions are made by consensus or in the absence of a consensus by a two thirds majority. Every effort should be made to reach a decision by consensus.

3.9 When a vote is taken, the view of the minority should be noted. Participation in the ICMRA work programme and initiatives is voluntary and the ICMRA Membership can exclude themselves from projects and work streams regardless as to whether they voted for or against those projects, initiatives or work streams.

3.10 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 an objection. The Chair and Vice-chair(s) will review the objections and take the final decision.

4. RECORD OF MEETINGS

4.1 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.

5. REPORTING

5.1 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.

6. STRUCTURE

6.1 Initially the ICMRA will exist 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 II).

6.2 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 form[6] of organisation sufficient to permit it to accomplish its goals.

7. FUNDING

7.1 The costs associated with ICMRA will initially 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.

7.2 Should the Members decide a more formal funding structure is required, ICMRA can commission the Executive Committee to put in place a mechanism to review the options available to establish a funding model for the future to ensure the sustainability of ICMRA.

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.

[6] It is recognised that ICMRA currently operates on a voluntary basis and that any change will have to be carefully considered as to the impact on participating countries

APPENDIX I: CONFIDENDIALITY AND SHARING OF INFORMATION - FRAMEWORK

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, 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 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.

APPENDIX II: 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, Vice Chairs and up to 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. Each head may appoint an alternative delegate to represent them in exceptional circumstances. 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 Chairs and Vice Chairs and project leads.

2.3 Where there are more than 5 eligible countries wishing to be on the EC, the immediately preceding Chair and Vice Chairs will have priority in taking three of the spots (to ensure continuity).

2.4 Where there are less than 5 eligible countries wishing to be on the EC and other countries wish to be members, spaces will be allocated on the basis of contribution to ICMRA e.g. new planned project etc. or geographical balance if the EC does not have global coverage.

2.5 In the event that there are more countries eligible/wishing to be on the EC than spaces, the current Chair and Vice Chairs will be tasked with finding consensus 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?

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

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 membership will meet via a bimonthly teleconference; the Chair / Vice Chairs may invite others as appropriate on an ad-hoc basis, to attend the whole or part of the EC teleconference, depending on the Agenda. Members will be able to nominate appropriate deputies/replacements as and when required.

4.2 After the term of office expires of the EC, or a member resigns from the Committee, replacement members will be appointed on a voluntary consensus basis. Existing members may put themselves forward for re-appointment. In the event that more countries (represented by regulatory agencies) volunteer than the available spaces as outlined in 2.3 and consensus cannot be found based on the criteria under 2.5 , the members of ICMRA will vote for the nominees put forward by way of a secret ballot with one vote per country 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.

4.3 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.

4.4 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 point 4.3 above.

5. MANDATE

5.1 The EC shall manage the activities of ICMRA consistent with the terms of reference, founding documents 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.

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 appropriate agenda and the conduct of the meeting.

7. MEETINGS

7.1 Meetings are chaired by the Chair person. In the absence of the Chair, one of the Vice-chair(s) is nominated by him/her to chair the meeting.

7.2 The committee 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 considers that they may have a conflict of interest in relation to a topic on the agenda, they should declare it to the Chairperson 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 REFERNCE

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

Year	Country /Authority	Location
2006	The U.S. - FDA	Washington
2007	Ireland - The Irish Medicines Board	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 - Swismedic	Interlaken
2017	Japan – MHLW/PMDA	Kyoto
2018	The U.S. – FDA	Washington

APPENDIX IV: PROCEDURE FOR APPOINTING ASSOCIATE MEMBERS

1) Countries 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 / 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.