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

VERSION 8: 28 NOVEMBER 2014

INTRODUCTION

The Terms of Reference and Rules of Procedure for the International Coalition of Medicines Regulatory Authorities (ICMRA), including those for the Management Committee (MC) (Appendix III), are intended to provide a framework for the ICMRA's operations during the interim phase (2013 to 2015) and to advance the ICMRA's development towards implementation. The intent is not to capture a permanent framework for the ICMRA's operations, nor are all issues decided at this stage of development. The Terms of Reference and Rules of Procedure will be refined based on lessons learned from the interim phase and after the ICMRA has discussed and agreed on the governance mechanism (including elements such as structure, membership, representation, legal status and funding).

1. MEMBERSHIP

1.1 Initial Membership of the International Coalition of Medicines Regulatory Authorities (ICMRA) comprises, from December 2013 to December 2015, medicines regulatory authorities who were represented at the 8th International Summit for the Heads of Medicines Regulatory agencies[1]. The initial Membership is listed in Appendix II.

1.2 The Medicines Regulatory Authority listed shall be the 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 During the initial two years, ICMRA will require the Management Committee[2] to develop the mechanism and criteria for membership.

1.4 Medicines Regulatory Authority may be understood to reflect only the national/state regulatory authority of each sovereign country[3] 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[4].

[1] ICMRA was developed and facilitated by attendees at the International Summits and the initial (Membership reflects those Medicines Regulatory Authorities who attended the 8th Summit where it was formally agreed that ICMRA would be established.

[2] See point 2.2 and Appendix III.

[3] Medicines Regulatory Authority is understood also to include the Medicines Regulatory Authority of the European Union (European Medicines Agency).

[4] 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.

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[5]. The 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 new international initiatives and enablers, as well as over shared regulatory issues and challenges.

2.2 The Membership shall be responsible for appointing a Management Committee to manage the activities of the ICMRA consistent with the Terms of Reference and Rules of Procedure, founding documents and annual work plan. The Terms of Reference and Rules of Procedure for the Management Committee and their appointment are contained in a separate document and are included in Appendix III.

2.3 The Chair and Vice-chair(s) will be appointed by the ICMRA Membership following a recommendation from the Management Committee. The appointment of Chair and Vice-chair(s) 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 3 of the Terms of Reference and Rules of Procedure for the Management Committee, see Appendix III.

2.4 The Membership, following a recommendation of the Management Committee, will adopt the work plan and projects for the year and where appropriate, on a voluntary basis, provide resources to those projects.

2.5 The Membership 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 Management Committee and ICMRA Membership will be kept confidential, consistent with the laws of their country and any other applicable legislation, unless agreed otherwise by the Management Committee or ICMRA Membership.

3. MEETINGS

3.1 Meetings of the ICMRA are held at least annually. For the initial two years, the annual meeting will be held in conjunction with the International Summit of the Heads of Medicines Regulatory Authorities.

3.2 Members may participate in meetings by telephone or videoconference. Members so participating are considered to be present at the meeting.

[5] The ICMRA will initially focus on medicines but in the future may consider other health care products.

3.3 Meetings are chaired by the Chair. In his/her absence, or if the office of the Chairperson is vacant, the meeting shall be chaired by the Vice-chair(s) or in their absence, by a person whom the members of the Management Committee choose from among themselves.

3.4 The quorum for ICMRA meetings is half the Membership plus one member.

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

3.7 Each member of ICMRA present has one 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.

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

4. RECORD OF MEETINGS

4.1 A brief record summarising the decisions taken will be prepared by either the Chair or Vice-chair(s).

5. REPORTING

5.1 The Chair or secretariat will provide a summary update of the activity of the Management Committee and the activities under the work plan to the Membership after each management committee meeting, one update will be at the annual meeting of ICMRA held in conjunction with the Annual International Summit. 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 Management Committee (Appendix III).

6.2 Should the membership decide a more formal legal structure is required ICMRA can commission the Management 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.

[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

7. FUNDING

7.1 The costs associated with ICMRA membership will initially be funded by the members who will pay for their own cost and any services that they may provide to the network.

7.2 Should the membership decide a more formal funding structure is required ICMRA can commission the Management 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 and the MC.

8. REVISION OF THE TERMS OF REFERNCE

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

APPENDIX I: CONFIDENDIALITY AND SHARING OF INFORMATION - FRAMEWORK

Members of ICMRA recognise that greater regulatory collaboration and convergence require a commitment in principle to 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 Members of ICMRA will recognise that where information is shared in confidence that Members should be committed to respecting the confidential nature of such information.

In addition all 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 ICMRA members 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: MEMBERSHIP OF ICMRA AND OBSERVERS

Membership - Country and Regulatory Authority
Australia: Therapeutic Goods Administration (TGA)
Brazil: National Health Surveillance Agency (ANVISA)
Canada: Health Products and Food Branch Health Canada (HPFB-HC)
Europe: European Commission - Directorate General for Health and Consumers (DG – SANCO) and European Medicines Agency (EMA)
France: French National Agency for Medicines and Health Products Safety (ANSM)
Germany: Paul-Ehrlich-Institute (PEI)
Ireland: Health Product Regulatory Authority (HPRA)
Italy: Italian Medicines Agency (AIFA)
Japan: Pharmaceuticals and Medical Devices Agency (PMDA), and the Ministry of Health, Labour and Welfare (MHLW)
Korea: Ministry of Food and Drug Safety (MFDS)
Mexico: Federal Commission for the Protection against Sanitary Risks (COFEPRIS)
Netherlands: Medicines Evaluation Board (MEB)
New Zealand: Medsafe, New Zealand Medicines and Medical Devices Safety
Nigeria: National Agency for Food Drug Administration and Control (NAFDAC)
China: China Food and Drug Administration (CFDA)

Singapore: Health Sciences Authority Singapore (HSA)
South Africa: Medicines Control Council (MCC), Department of Health
Switzerland: Swissmedic
United Kingdom: Medicines and Healthcare Products Regulatory Agency (MHRA)
United States: Food and Drug Administration (FDA)

Note: the Medicines Regulatory Authority in the respective country is the Member.

Observers
World Health Organization (WHO)
Sweden: Medical Product Agency (MPA)

APPENDIX III: TERMS OF REFERENCE AND RULES OF PROCEDURE OF THE MANAGEMENT COMMITTEE

1. AUTHORITY

1.1 The Management Committee (MC) is established by the Members of ICMRA.

2. MEMBERSHIP

2.1 The membership term shall be a period of three years.

2.2 The Membership of the first MC shall be initially for a period of two years (2014 and 2015) renewable for one further year by agreement of the ICMRA Membership at the Summit. This agreement to renew will be by consensus or in the absence of consensus by a 2/3 majority. In the event that the ICMRA Membership chooses not to renew the interim MC membership for one further year the procedures in 2.7 apply.

2.3 Membership of the Management Committee (MC) is at the National/ Central Government Agency / Authority level. In general the head of the agency shall sit on the MC. 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 MC.

2.4 The Membership shall be not more than 13 members for the first two years, renewable by a further year. Thereafter the membership shall be 12 members (subject to point 2.8 below)

2.5 At least three members will be appointed from each of the three geographical regions i.e. The Americas, Europe Africa and Asia Australia with the balance coming from any region.

2.6 At least one member will be from a country with a developing regulatory framework.[7]

2.7 After the term expires of the existing MC (following the procedure outlined in 2.2), or a member resigns 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, the membership of ICMRA shall vote

[7] The Membership should decide which countries are considered to have a "developing regulatory framework" for purposes of this provision.

for the members of the MC by way of a secret ballot with one vote per country attending the ICMRA meeting held during the Summit of the Heads of Medicines Agencies (The 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 MC (or in the absence of a Chair of the MC, the Chair of the Summit) will have the deciding vote.

2.8 Where the host of the Summit is not a member of the MC they shall be co-opted onto the committee for 18 months (12 months before and 6 month after) the date of their Summit.

2.9 Where a member of the MC and their alternative fail to attend two consecutive meeting, their membership will be deemed to have lapsed and a new member will be appointed in accordance with point 2.7 above.

3. CHAIR AND VICE-CHAIR(S)

3.1 The term of office of the Chair and Vice-chair(s) will be for a period of three years.[8]

3.2 The term of office of the first Chair and Vice-chair(s) will be for a period of two years renewable by one year in accordance with 2.2.

3.3 The MC shall invite nominees, on a voluntary basis, from the MC 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).

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

3.5 Where more than one country volunteers for the position of Chair or vice Chair; the MC passes all nominees to the ICMRA membership who vote in accordance with 3.6.

3.6 The proposed nominees are presented to the ICMRA membership for approval by 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 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.

[8] 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 MC.

4. MANDATE

4.1 The MC shall manage the activities of ICMRA consistent with the terms of reference, founding documents and annual work plan.

4.2 The MC will prepare an annual work plan for adoption by the ICMRA membership at the annual meeting of ICMRA held in conjunction with the Summit.

4.3 The MC will appoint leads to projects agreed by the ICMRA membership, have oversight of those projects and report back to the ICMRA membership on the progress of the projects.

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

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

5.1 The Chair and Vice-chair(s) will provide an administrative structure (in the absence of a secretariat which is to be developed) to support the operation of the MC and will have oversight of the annual work plan and projects (see point 9 on the governance of projects).

5.2 The Chair will give direction and focus to the meetings of the MC and ICMRA though the preparation of appropriate agenda and the conduct of the meeting.

6. MEETINGS

6.1 Meetings will be held as required subject to a minimum of 4 meetings per year. Ideally one meeting, in addition to the meeting at the Summit, will be face to face.

6.2 Members may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting.

6.3 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.

6.4 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.

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

6.6 In the event that a decision is required either by a non quorate meeting or outside of a meeting, decisions can be agreed in writing in accordance with point 6.8.

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

6.8 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.

6.9 Any third party including those outside of ICMRA may be invited to attend for particular items at the discretion of the Chair but they are not entitled to vote. All members of the MC 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.

7. RECORD OF MEETINGS

7.1 A brief record summarising the decisions taken will be prepared by either the Chair, the Vice-chair(s) or the secretariat, when developed.

7.2 The record of the meeting will be circulated to all ICMRA members when finalised.

8. REPORTING

8.1 The Chair will provide a summary update of the activity of the MC and the activities under the work plan to the Membership at a minimum twice yearly by way of email and/or presentation at the annual summit.

9. GOVERNANCE OF PROJECTS

9.1 Projects approved and endorsed by the MC will be consistent with the strategic aims of the founding documents.

9.2 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.

9.3 The project leads shall report as determined by the MC on the project to the MC and annually to the ICMRA membership.

9.4 The Chair and Vice-chair(s) will agree a reporting template for projects.

9.5 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 a revised or clarified work plan which ensures that work is not duplicated between the projects.

10. FUNDING

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

10.2

11. REVISION OF THE TERMS OF REFERNCE

11.1 The Terms of Reference and Rules of Procedure can be revised at anytime and presented to the MC and ICMRA membership for adoption. Notwithstanding this provision the Terms of Reference and Rules of Procedure e will be formally reviewed every two years.