Memorandum of Understanding

between

the World Health Organization,
(WHO)

and

the International Association of
Medical Regulatory Authorities, Inc.
(IAMRA)

WHEREAS the World Health Organization (WHO), through its Department of Health Workforce aims to promote the development and implementation of appropriate regulations for health practitioners;

WHEREAS the aims of the International Association of Medical Regulatory Authorities, Inc (IAMRA), a 501(c)(3) non-profit organization (Texas), are to promote effective medical regulation worldwide by guiding the medical profession and supporting best practice, innovation, collaboration, and knowledge sharing in the interest of public safety;

WHEREAS WHO and IAMRA, hereinafter also referred to as "the Parties", believe that technical collaboration between the two organizations will contribute to the shared goals of promoting safe, effective, and affordable systems of health practitioner regulation to the public, including in particular the public sector of developing countries;

WHEREAS the Parties furthermore believe that agreement in advance on certain aspects of individual collaborative projects (as the Parties may identify on a case-by-case basis) will facilitate the early implementation of such projects, in particular by facilitating the conclusion of the agreements to which such projects would be subject;

NOW, therefore, the Parties hereby agree as follows:

1. Areas of collaboration

Where possible and appropriate, the Parties wish to collaborate in the following areas:

- Support for the implementation and uptake of the WHO Guidance on Health Practitioner Regulation.
- Contribute to the identification of priority evidence gaps and related research agenda pertaining to health workforce regulation.
- Contribution of regulatory perspectives to the development of normative statements by WHO and assistance in the identification of technical experts consistent with established WHO processes to develop normative guidance.
- Technical support for capacity building in medical regulation in countries and assistance in the identification of appropriate technical advisors.
- Facilitating conference themes and sponsored participation of low-and middle-income countries (LMIC) at IAMRA global meetings.
- Develop a webinar series with a specific focus on issues for medical regulation in LMIC.

2. Collaborative activities

Any collaborative activity as outlined in Article 1 above shall be subject to the availability of sufficient financial and human resources for that purpose, as well as each Party's programme of work, priority activities, internal rules, regulations, policies, administrative procedures and practices. Each collaborative activity shall thus be agreed on a case-by case basis, subject to a separate exchange of letters or agreement.

3. Funding

3.1 Each Party hereto shall be fully responsible for the funding of its activities under this Memorandum of Understanding (MoU), except as may otherwise expressly be agreed in any subsequent letter of agreement.

3.2 Each Party shall administer the funds handled by it in accordance with its financial regulations, rules and administrative practices.

4. Confidentiality

It is acknowledged that each Party may possess confidential information, which is proprietary to it or to third parties collaborating with it. Any such information shall only be shared between the Parties under a separate confidential disclosure agreement, specifically covering such information.

5. Publications

5.1 Subject to each Party's proprietary rights and/or the proprietary rights of others, and without prejudice to obligations of confidentiality, the results of any collaborative activity under this MoU may be published by either Party. The Parties are encouraged to publish the results of their joint work in a collaborative fashion. Guidelines for authorship of major, international, peer-reviewed journals will be used to establish authorship of collaborative publications. In regard to separate publications, it is agreed that in order to avoid prejudicing proprietary rights and the confidentiality of information, the publishing Party shall transmit to the other party for its review the material intended to be published at least 60 days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by the other Party within that 60 day period, concerning prejudice to proprietary rights or confidentiality of information, the publication may proceed.

5.2 Copyright in any publications resulting from or relating to any of the collaborative activities under this MoU, and prepared by one of the Parties hereto on its own, shall be vested in that Party, provided, however, that any such publication shall be submitted to the other Party for review and comment in accordance with paragraph 5.1 above.

5.3 In the event that any publications are jointly prepared by WHO and IAMRA the Parties shall consult in good faith and designate one of the Parties to act as the lead publishing Party in each case.

- If the Parties designate WHO to act as the lead publishing Party, IAMRA will retain copyright in its contribution to the publication and will grant WHO a non-exclusive, sub-licensable, world-wide, royalty-free licence to deal with the contribution for all purposes, in all manners and in all formats, as part of the publication. In such case, copyright in the final published work will vest in WHO.

- If the Parties designate IAMRA to act as the lead publishing Party, WHO will retain copyright in its contribution to the publication and will grant IAMRA non-exclusive,

sub-licensable, world-wide, royalty-free licence to deal with the contribution for all purposes, in all manners and in all formats, as part of the publication. In such case, copyright in the final published work will vest in IAMRA.

5.4 Both Parties shall be duly acknowledged in any publication resulting from the collaborative activities and the wording of such acknowledgement shall be agreed between the Parties. In addition to review of the content of publications as referred to in paragraph 5.1 above, each Party shall have the right to review the acknowledgement and request reasonable changes to the use of its name, or request that its name be deleted altogether.

5.5 No publication or other work resulting from the collaborative activities under this MoU shall contain commercial advertising or be used for the promotion of any commercial product or service.

6. Products resulting from the collaboration

6.1 The Parties shall make appropriate arrangements to promote that any product which may result from collaborative research and development work undertaken as a result of this MoU, shall be made widely available to the public on reasonable terms, including in particular to the public sector of developing countries on preferential terms. Any possible additional benefits, including royalties, shall be granted to each Party with due account being taken of the relative value of each Party's financial, intellectual and other contributions to the product (provided that priority shall always be given to the objective of the Parties set forth in the first sentence of this paragraph 6.1).

6.2 Ownership of any intellectual property rights arising from collaborative activities under this MoU shall be agreed by the Parties on a case-by-case basis. However, regardless of whether the Parties shall agree that ownership of the intellectual property rights of a particular collaborative activity shall be vested in WHO or in IAMRA alone, or in any third party, the Parties agree that the industrial or commercial exploitation of such rights shall be designed to achieve the objectives set forth in paragraph 6.1 above, and shall be subject to and exercised in accordance with an agreement to be negotiated in good faith between WHO or IAMRA and the third party concerned, as the case may be.

7. Liability

7.1 Each Party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this MoU. Thus, a Party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other Party, or that other Party's staff or sub-contractors, in connection with, or as a result of, the collaboration under this MoU.

7.2 The Parties shall make appropriate arrangements to cover liability risks for any collaborative activities involving product research and development.

8. Compliance with WHO Policies

By entering into this MoU, IAMRA acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing, IAMRA shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by its employees and any other natural or legal persons engaged or otherwise utilized to perform any Project activities under the MoU. Without limiting the foregoing, IAMRA shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which IAMRA becomes aware. For the purposes of this MoU, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy Directive on Protection from sexual exploitation and sexual abuse (SEA); (iii) the WHO Policy on Preventing and Addressing Abusive Conduct; (iv) the WHO Code of Conduct for responsible Research; (v) the WHO Policy on Whistleblowing and Protection Against Retaliation; (vi) the WHO Policy on Prevention, Detection and Response to Fraud and Corruption, and (vii) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

9. Zero tolerance for sexual exploitation and abuse, sexual harassment and other types of abusive conduct

WHO has zero tolerance towards sexual exploitation and abuse, sexual harassment and other types of abusive conduct. In this regard, and without limiting any other provisions contained herein, each Party warrants that it shall: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual exploitation and Abuse Prevention and Response and/or sexual harassment and other types of abusive conduct as described in the WHO Policy on Preventing and Addressing Abusive Conduct by any of its employees and any other persons engaged by it to perform any services under the MoU, and, in the case of the other Party, (ii) promptly report to WHO and respond to, in accordance with the terms of the respective Policies, any actual or suspected violations of either Policy of which the other Party becomes aware.

10. Anti-Terrorism and UN Sanctions; Fraud and Corruption

IAMRA warrants for the entire duration of the MoU that:

(i) it is not and shall not be involved in, or associated with, any person or entity associated with terrorism, as designated by any United Nations Security Council sanctions regime, that it shall not make any payment or provide any other support to any such person or entity and that it shall not enter into any employment or other contractual relationship with any such person or entity;

(ii) it shall not engage in any fraudulent or corrupt practices, as defined in the WHO Policy on Prevention, Detection and Response to Fraud and Corruption, in connection with the implementation of the Project;

(iii) it shall take all necessary measures to prevent the financing of terrorism and/or any fraudulent or corrupt practices as referred to above in connection with the implementation of the Project; and

(iv) it shall promptly report to WHO, through the WHO Integrity Hotline or directly to the WHO Office of Internal Oversight Services (IOS), any credible allegations of actual or suspected fraudulent or corrupt practices, as defined in the WHO Policy on Prevention, Detection and Response to Fraud and Corruption of which the contractor becomes aware and respond to such allegations in an appropriate and timely manner in accordance with its respective rules, regulations, policies and procedures. Furthermore, IAMRA agrees to cooperate with WHO and/or parties authorized by WHO in relation to the response. Relevant information on the nature of any credible allegations of such actual or suspected violations, as well as the details of the intended response and the outcome of any such response, should be communicated and coordinated with WHO, with the understanding that, subject to the terms of the WHO Policy on Prevention, Detection and Response to Fraud and Corruption, confidentiality and the due process rights of those involved will be respected.

11. Breach of essential terms

IAMRA acknowledges and agrees that each of the provisions of article 8 (Compliance with WHO Codes and Policies), article 9 (Zero tolerance for Sexual Exploitation and Abuse), and article 10 (Anti-Terrorism and UN Sanctions; Fraud and Corruption) above constitutes an essential term of this MoU and that in case of breach of this provision, WHO may, in its sole discretion, decide to terminate this MoU and/or any other agreement concluded by WHO with IAMRA, immediately upon written notice to IAMRA, without any liability for termination charges or any other liability of any kind.

12. Use of the Parties' names

Except as explicitly provided in this MoU, neither Party shall, in any statement or material of a promotional nature, refer to the relationship of the other Party to the collaboration pursuant to this MoU, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of the other Party.

13. Relationship of the Parties

For the purposes of this MoU, each Party is an independent contractor and not the joint venturer, agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for in this MoU or authorized in writing by the other Party.

14. Termination

This MoU may be terminated by either Party, subject to three (3) months' advance written notice to the other Party. Notwithstanding the foregoing, it is agreed that any termination of this MoU shall be without prejudice to: (i) the orderly completion of any

ongoing collaborative activity; and (ii) any other rights and obligations of the Parties accrued prior to the date of termination of this MoU.

15. Amendments

This MoU may only be amended in writing by mutual consent of the Parties.

16. Settlement of disputes

Any dispute relating to the interpretation or execution of this MoU, or of any subsequent exchange of letters or agreement with respect to individual collaborative activities shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, in accordance with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.

17. Privileges and Immunities of WHO

Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted:

For the World Health Organization

Dr Tedros Adhanom Ghebreyesus
Director-General

Date: 19 FEB 2024

For the International Association of Medical Regulatory Authorities, Inc.

Joan Simeon
Chair

Date: 19 FEB 2024