

MEMORANDUM OF UNDERSTANDING

between

THE MINISTRY OF HEALTH REPUBLIC OF INDONESIA

and

MEDICINES PATENT POOL

on

**STRATEGIC COLLABORATION ON IMPROVING ACCESS
TO VACCINES AND MEDICINES IN INDONESIA**

This **Memorandum of Understanding** (hereinafter referred to as “**MOU**”) is made on 27 May 2024 (hereinafter “the Effective Date”) by and between **the Ministry of Health of the Republic of Indonesia** (hereinafter referred to as “**MoH**”), based at Jl HR Rasuna Said Kav .4-9, Jakarta 12950, Indonesia, and **Medicines Patent Pool**, a public organisation based in Switzerland having its registered office at Rue de Varembe 7, fifth floor 1202 Geneva, Switzerland (hereinafter referred to as “**MPP**”);

Hereinafter each of MoH or MPP referred to as a “**Party**” and both together as “**the Parties**”.

In accordance with the prevailing laws and regulation, policies and procedures of the Government of Indonesia;

1. RECITALS

WHEREAS, MoH is a government body responsible for public health affairs, with a mission to improve and protect public health, empower communities (including the private sector and civil society), and address the equitable availability of quality health efforts and required resources in Indonesia; and

WHEREAS, MPP is a public health organisation with a mission to increase equitable access to innovative medicines and other health technologies in low- and middle-income countries through public health-oriented voluntary licensing and technology transfer; and

WHEREAS, both MoH and MPP recognize the unique and unprecedented opportunity that presently exists to further the role and impact of vaccines and medicines in public health, to fully realize their potential in addressing major health security threats and decreasing disease burdens by ensuring equitable access to affordable and quality vaccines and medicines; and

WHEREAS, to successfully address this opportunity, both MoH and MPP recognize the need to work together and to develop a strategic approach to support Indonesia with improved access to such cutting-edge vaccines and medicines.

THE PARTIES AGREE as follows:

2. THE GOAL AND OBJECTIVES

- 2.1 The Parties agree to facilitate the cooperation and collaboration in areas of common interest by focusing on mutually agreed activities and specific projects.
- 2.2 The Goal of the cooperation and collaboration is to seek to strengthen the health system for the purpose of enhancing access to essential vaccines and medicines, and more broadly within the context of the MoH scope of responsibilities and activities and the mandate and mission of MPP.
- 2.3 The primary purpose/objective of this MOU is to set forth the collaboration between the Parties for projects to strengthen the capacity and capabilities of the Indonesian Health system, including the improvement of access to and uptake of selected, prioritized medicines, and the enhancement of local manufacturing efforts, leverage domestic

resources in order to ensure an impactful and sustainable investment outcome, and ultimately seek to contribute, where possible, to reducing major medicine access gaps at the country level.

- 2.4 As such, this MOU sets out the framework for strategic cooperation to ensure close collaboration and exchange of information between the Parties in a manner that can create a synergistic relationship and partnership.

NOW, THEREFORE, the Parties agree to collaborate as follows:

3. AREAS OF COLLABORATION

3.1 The Parties agree to collaborate in the following areas:

(i) Strengthen access to vaccines and medicines in Indonesia

- Assess current access gaps to recommended innovative vaccines and medicines in Indonesia, with a view to prioritizing product(s) (i.e. medicine(s), including monoclonal antibodies, and/or vaccine(s)) that could be the focus of the collaboration that are considered important by the MoH and that could be important for the broader region;
- Support introduction of innovative medicines for which MPP has a licence or for which MPP may be able to contribute to access and/or local production through licensing and/or technology transfer.

(ii) Technical assistance on local manufacturing of vaccines and medicines

- Identify possible manufacturing partner(s) for local manufacturing of prioritized product(s) in Indonesia and undertake a gap/needs assessment of such manufacturer(s) for the product(s) in question
- Identify possible sources of technology for the prioritized product(s), explore opportunities for supporting technology transfer to Indonesian manufacturer(s) and possible incentives that could facilitate technology transfer from international technology providers
- If resources permit, work with the identified Indonesian manufacturer(s) to increase the ability to develop, produce, and deliver high-quality, affordable versions of the prioritized product(s) that meet stringent/international regulatory requirements, including through technical assistance, technology transfer agreements, and linkages to global manufacturers interested in supplying the relevant technology.
- Contribute to strengthening quality management systems development and documentation in relation to prioritized product(s), including design of required verification and validation plans.
- Support the development of capabilities in Indonesia for the development and manufacture of medicines or vaccines relying on new technology, starting with mRNA vaccine technology, in the context of the ongoing mRNA Technology Transfer Programme.

(iii) Enhancing Health Talent Capacity

- Provide opportunities for learning in various fields related to MPP's areas of work and fields of expertise, and consider opportunities for providing training and capacity building for MoH personnel in such areas, as appropriate
 - Where appropriate, explore opportunities to include MoH personnel in relevant global health activities MPP is involved in thus contributing to exposing MoH personnel to global health discussions and contribute to the development of the future public health leaders within MoH by enriching their knowledge and experience in the global health areas thereby contributing to the advancement of public health
- (iv) Collaboration for licensing and for uptake of MPP-licensed products:
- Support MPP in making the case to innovators for licensing of innovative medicines and/or vaccines through:
 - exchange of market and health-related information and data that can contribute to making the case
 - exploration of possible incentives or commitments for future procurement of priority products
 - Explore opportunities to accelerate access to MPP-licensed products through:
 - consideration of possible inclusion of the product(s) in the national formulary for national procurement
 - consideration of possible mechanisms for fast-tracking regulatory processes in relation to such product(s)
 - identification of other possible access barriers that the MoH may be able to address in relation to such products in order to support uptake in Indonesia
- 3.2 The performance of the above activities will be dependent on the availability of needed resources
- 3.3. The Parties further agree to cooperate in any other areas of mutual interest as may be necessary to achieve the objectives of this MOU and to this end may be subject to supplementary agreements.
- 3.4. A Joint Strategic and Action Plan (the "JSAP") for the operationalization of this MOU may be developed and agreed between the Parties that may include, but is not limited to:
- (i) Specific joint or separate projects and activities that focus on the impactful interventions or models; and
 - (ii) Time frames and funding for all activities; and
 - (iii) Mechanisms for review and evaluation of implemented activities and progress made; and
 - (iv) Formulate the strategies for future interventions and/or models that will further support a successful strategic collaboration and project outcomes.
 - (v) Develop specific budgets for implementing these activities and work with the Indonesia MoH, bi- and multilateral donors, to ensure funding is available to fully implement the vision and activities.

4. FORMS OF COLLABORATION

4.1 Subject to 3.4 above, the JSAP shall be agreed by the Parties and reviewed annually which will be formed as an integral part of this MOU to elaborate on the agreed activities to be implemented by the Parties.

4.2 The activities under the Memorandum shall be subject to the availability of funds and personnel of the Parties.

4.3 Unless otherwise agreed in this Memorandum, each Party shall be responsible for its own expenses occurred for the implementation of this Memorandum.

4.4 If it is deemed necessary, the Parties may conclude a specific arrangement for the implementation of activities under this Memorandum. Such arrangement shall be in conformity with this Memorandum and shall form an integral part of it.

5. EXCHANGE AND CONFIDENTIALITY OF INFORMATION

5.1 The Parties agree to share relevant information as deemed appropriate relating to the activities of both organizations, subject to confidentiality obligations of trade secret protection, contractual or otherwise.

There shall be no obligation of confidentiality or restriction on use where:

- (i) the information is publicly available, or becomes publicly available otherwise than by action of the receiving Party in violation of this Article 3; or
- (ii) the information which is or was already known to the receiving Party (as evidenced by its written records) prior to its receipt; or
- (iii) the information was independently developed by the receiving Party without reference to the information disclosed hereunder (as evidenced by contemporaneous written records); or
- (iv) the information was received from a third party without indication that such disclosure was in breach of an obligation of confidentiality owed to the disclosing Party.

5.2 The Parties undertake to exchange information on matters of common interest subject to Section 4.1 above, and to consider proposals made by either Party that relate to the JSAP. Each Party shall, to the extent feasible and appropriate, use all reasonable efforts to keep the Steering Committee (referred to in Section 6.1 below) informed of its activities with any third parties that may have a direct impact on the Strategic Collaboration or individual projects as contemplated under this MOU.

5.3 If either party to this MOU receives access to any confidential information of the other party, the receiving Party shall maintain the confidentiality of such confidential information, subject to applicable law, policy and procedures, including (without limitation) legal, regulatory and administrative process. For the purposes of this clause,

“confidential information” means private or secret information that is marked as confidential, classified confidential based on regulation of the parties and that is customarily kept private and closely held by the party who owns or controls such information. Any health information or data concerning to this MOU is classified as confidential information based on regulation and shall not be subject of cross border data transfer and exchange without appropriate data protection procedure

- 5.4 For the avoidance of doubt, this MOU does not constitute confidential information and may be published on the website of either Party.

6. IMPLEMENTATION MECHANISM

- 6.1 The Parties agree to hold regular consultations and review meetings on all matters arising from this MOU that may be necessary for the smooth running of the Strategic Collaboration. The mechanism for such meetings shall be mutually agreed by the Parties, and may include the establishment of a Strategic Collaboration Steering Committee, the composition and working modus of such committee to be mutually agreed, at an appropriate juncture.
- 6.2 The Parties may take ancillary mutual or individual administrative measures that may be deemed necessary for the implementation of this MOU.

7. SUPPLEMENTARY ARRANGEMENTS AND AMENDMENTS

The Parties to this MOU may, by exchange of letters agreed by both Parties, enter into supplementary arrangements within the scope of this MOU or amend any provision contained herein.

8. ASSIGNMENT OR TRANSFER TO THIRD PARTIES

The Parties will pursue the Goal of this MOU on the basis of non-exclusivity. Neither Party, nor its affiliates, employees or agents, shall be restricted from making any arrangements or entering into any agreement with any third party.

9. DURATION AND EARLY TERMINATION

- 9.1 This MOU shall come into effect on the Effective Date subject to signature by The Parties hereof and shall have a duration of three (3) years, unless terminated in accordance with Section 10.2 of this MOU.
- 9.2 Either Party may terminate this MOU by giving three (3) months prior notice to the other Party. Such termination shall take effect as of the date specified in the termination notice, provided that the provisions contained herein shall remain in effect to the extent necessary to permit an orderly, efficient, equitable, responsible, and ethical manner of winding down operations, and settlement of all arrangements made with respect to ongoing cooperation activities.

10. STATUS OF THE MOU

The Parties agree to be bound by the provisions of paragraph 5, 10 and 11 and agree that the remaining parts of this MOU are not intended to be binding and represent the framework for collaboration between the Parties. The provisions of paragraph 5, 10 and 11 will survive expiration or termination of this MOU.

11. NOTICES

Any notices required to be given or which shall be given under this MOU shall be in writing and delivered by electronic means for a copy, and by recognized overnight courier service, personal delivery, or by certified or registered mail (with return receipt requested) addressed to the Parties as shown below and shall be deemed to have been given or made as at the date received:

For MoH	Director General of Pharmaceuticals and Medical Devices
	Jl HR Rasuna Said Kav 4-9, Jakarta 12950
	Telephone : +6221 5201590
	Fax : +6221 52921669
	Email : roy.himawan@kemkes.go.id
For MPP	Policy, Strategy and Market Access Director
	Rue de Varembe 7, fifth floor
	1202 Geneva
	Switzerland
	Tel : +41 (022) 533 5050
	Email : eburrone@medicinespatentpool.org

12. GENERAL

- 12.1 No alteration, variation or addition to this MOU shall be of any force or effect unless reduced to writing as an amendment to this MOU and signed by the Parties or their duly authorized signatories.
- 12.2 This document contains the entire agreement between the Parties regarding the Strategic Collaboration, and neither Party shall be bound by any undertaking, representation or warranty not recorded herein or added hereto without the consent of the Parties, except as agreed upon in any applicable future amendment.
- 12.3 The headings appearing in this MOU have been used for reference purposes only and shall not affect its interpretation.
- 12.4 Nothing in this MOU shall be deemed to constitute a partnership between the Parties (in the for-profit general understanding of the legal term) or to constitute either Party as the agent of the other.

12.5 Nothing contained in this MOU shall be construed as a waiver of the privileges and immunities enjoyed by either Party under national and/or international law, or as submitting either Party to any national court jurisdiction.

13. SETTLEMENT OF DISPUTES

Any dispute arising out on the interpretation or implementation of this MoU shall be settled amicably by consultations or negotiations between the Parties

14. COUNTERPARTS

This MOU may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

IN WITNESS WHEREOF the duly authorized signatories of MPP and MoH have signed this MOU in the English and Indonesian language. Both texts being equally authentic. In case of any divergence of interpretation of the MOU, the English text shall prevail.

for and on behalf of:

for the **MINISTRY of HEALTH of the REPUBLIC of INDONESIA**



Name : Lucia Rizka Andalusia

Title : Director General of Pharmaceutical and Medical Device

Dated : 27 May 2024

for the **MEDICINES PATENT POOL**



Name : Marie-Paule Kieny

Title : Chair of the Governance Board

Dated: 27 May 2024