



Daftar MoU Bilateral Tahun 2024

No	Negara/Mitra	Judul MoU	Tanggal Penandatanganan dan Masa Berlaku	Tanggal Berakhir	Ruang Lingkup Kerja Sama dalam MoU
1	Australia / Therapeutic Goods Administration (TGA)	Exchange of Letters, Collaboration between the Indonesian Food and Drug Authority and the Australian Therapeutic Goods Administration for the Indo-Pacific Regulatory Strengthening Program	25 Juli 2024 / 2027	2027	<p>1. To collaborate with the aim of improving regulatory processes in BPOM for the purpose of ensuring timely access to quality-assured medical products that are safe for humans and efficacious for the detection, treatment and prevention of communicable and non-communicable diseases according to appropriate international standards and risk-benefit analyses.</p> <p>2. To collaborate in the development of options for implementation or enhancement of regulatory frameworks and systems for medical products including fit-for-purpose legal, policy, information technology and scientific evaluation infrastructure and mechanisms to meet national health needs.</p> <p>3. To securely exchange information about the regulatory processes and procedures for the evaluation of medical products to support regulatory decisions.</p> <p>4. To securely exchange information about specific medical products where the information is not considered commercial-in-confidence, or, when commercial-in-confidence, with the permission of the owner, when deemed necessary and in accordance with respective laws and regulations.</p> <p>5. To collaborate in the development of improved systems to anticipate, prevent, detect and control communicable disease threats, and to better prevent and control non-communicable diseases.</p>

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					<p>6. For the TGA to provide on-the job training and support regional workshops on relevant topics. These could include, but are not limited to, the following:</p> <ul style="list-style-type: none"> ● Technical assistance on the evaluation of dossiers for medical products (pre-market assessment of quality and manufacturing controls), including lifecycle management through variations; ● Technical assistance to support international activities including the WHO's regulatory strengthening activities; ● Technical assistance in developing systems and conducting safety, signal management using local database; ● Training on GMP for medicine for inspectors and desktop assessments of GMP compliance for manufacturers, covering the fields of radiopharmaceuticals, ATMPs, and blood products; ● Technical assistance for laboratory testing of medicines; ● Enhanced safety monitoring information systems, the management of medicine recalls, prevention, detection and control of substandard and/or falsified medical products; ● Risk-based decision making and ● Stakeholder information, education, and communication approaches. <p>7. To allow for regular in-country missions and bilateral visits to work on identified and accepted regulatory activities.</p> <p>8. To maintain open communication and transparency and participate in regional meetings that support collaboration with other agencies and building a sound knowledge base and working relationships.</p>

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					<p>9. To further the consideration of gender equity, disability and social inclusion including, but not limited to, the following activities:</p> <ul style="list-style-type: none"> ● Encouraging participation of staff of all genders, skill levels, cultural backgrounds, abilities, and rank to participate in project activities and meetings; ● Securely exchanging documentation, information and best practices on gender equity, disability, and social inclusion; ● Where possible and if required, translating English materials into Bahasa Indonesia to ensure maximum outreach and accessibility of training materials; ● Adapting presentation and visual materials to meet accessibility and inclusion communication standards and guidelines; ● Ensuring that all program meeting rooms are accessible to people with physical disabilities and ● Recording participation for every virtual and physical meeting and training of the program through a virtual registration form, when practical and appropriate. <p>10. To collaborate in a greater adoption of approaches and integration of climate change considerations.</p>

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2	Tanzania/Tanzania Medicines and Medical Devices Authority	Memorandum Of Understanding (MOU) between the Indonesian Food And Drug Authority The Republic of Indonesia and Tanzania Medicines & Medical Devices Authority (TMDA) The United Republic of Tanzania on Cooperation in the Field of Pharmaceutical Products and Regulatory Functions	3 September 2024 / 3 Tahun (+3 Tahun)	3 September 2030	<ol style="list-style-type: none"> 1. Exchange and sharing information, best practices, knowledge and skills regarding standards and regulations; 2. Facilitate information sharing to support TMDA in the implementation of regulatory reliance on the Indonesian FDA, in accordance with the terms mutually agreed upon by the Parties; 3. Undertaking capacity building programs (technical assistance), including workshop and training; 4. Facilitate the procedures for access to pharmaceutical products from both countries, in accordance with laws and regulations of each Party; 5. Development of notification system in case of contaminated, substandard and falsified medical products, or other related situations in each Party's territory that could potentially effect the public health of both Parties; 6. Exchange of visits of high-level delegations and experts; 7. Participation in international events organized by either Party; and 8. Any other forms of cooperation mutually agreed upon by the Parties in writing.