

**MEMORANDUM OF UNDERSTANDING
BETWEEN
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION,
THE MINISTRY OF HEALTH AND FAMILY WELFARE, THE REPUBLIC OF INDIA**

**AND
THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL,
THE REPUBLIC OF INDONESIA**

**ON
COOPERATION IN THE FIELD OF PHARMACEUTICAL PRODUCTS, PHARMACEUTICAL
SUBSTANCES, BIOLOGICAL PRODUCT AND COSMETICS REGULATORY FUNCTIONS**

Central Drugs Standard Control Organization (CDSCO), The Ministry of Health and Family Welfare, Government of the Republic of India and the National Agency for Drug and Food Control of The Republic of Indonesia (hereinafter jointly referred to as "Parties" and individually referred to as "Party");

ACKNOWLEDGING the close, friendly and cordial relations already existing between the two countries;

DESIRING to seek collaboration to enhance the cooperation in pharmaceutical regulatory functions;

AWARE that mutual exchange of knowledge and ideas can strengthen the friendly relations in the fields of health and pharmaceutical products regulatory function between the two countries;

HAVE REACHED the following understanding:

Article 1

Objective

The Parties shall promote and develop cooperation in the field of pharmaceutical products, biological products and cosmetics regulatory functions within the respective jurisdiction by cooperating in the manner set out in this Memorandum of Understanding ("MoU") on the basis of equality and mutual benefit.

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Article 2

Areas of Cooperation

The Parties shall undertake cooperation in the field of regulatory functions related to:

- (a) Pharmaceutical products, including Active Pharmaceutical Ingredients;
- (b) Biological products, including vaccines, biotechnology/biosimilar;
- (c) Cosmetics;
- (d) Cooperation in multilateral fora; and
- (e) Any other areas agreed by the Parties.

Article 3

Forms of Cooperations

The cooperation between the Parties shall take the following forms:

- (a) Exchange and Sharing of information, best practices, and knowledge in the field of pharmaceutical, biologics and cosmetic regulations;
- (b) Technical visit related to familiarization of regulatory processes of both Parties;
- (c) Participation in international events organized by either Party;
- (d) Mutual cooperation in common areas at multilateral fora;
- (e) Joint training programs at mutually agreed areas, for the Party's regulatory authority;
- (f) Exchange of information between the Parties regarding safety and quality of pharmaceutical products, biological products and cosmetics, as allowed by respective prevailing laws and regulations, including information on product recalls; emergency notification in case of contaminated, substandard or adulterated products or other situation that could potentially affect the public health;
- (g) Periodic joint consultation between senior leadership of the Parties;
- (h) Any other form of cooperation as mutually decided upon in writing by the Parties.

Article 4

Points of Contact For The Implementation

The Parties shall appoint points of contact as the authorized representative of the Parties, which are responsible for the communication of organizing the implementation of the MoU:

- For the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, The Republic of India:
Phone number: +91 11 23236965
Fax Number: +91 11 23236973
Email address: dci@nic.in
- For The National Agency of Drug and Food Control of The Republic of Indonesia:
The Bureau of Cooperation, Jalan Percetakan Negara No. 23 Jakarta 10560
Phone number: +62 21 4287 5379
Fax Number: +62 21 4287 5379
Email address: ksln@pom.go.id

Article 5

Financial Resources

- (1) Each Party shall bear its own expenses related to any activities conducted under this MoU.
- (2) When it deemed necessary and by mutual agreement, the Parties may invite funds from any third party such as UN, WHO, etc. to support the activities under this MoU.

Article 6

Settlement Of Disputes

- (1) This MoU does not create rights and obligations under international law.
- (2) Any dispute between the Parties arising out of the implementation, application or interpretation of this MoU shall be settled amicably through consultation or negotiations between the Parties through diplomatic channels.

Article 7

Confidential Agreement

- (1) Each Party understands that the information exchanged between them may include confidential information that is not in the public domain in the country of the Party providing the information. The Parties note that it is essential that confidential information emanating from one Party will be treated as such by the other Party.
- (2) Each Party will make every reasonable effort to prevent: (a) the public release of confidential information that has been shared for the purposes set out in this exchange of letters; and (b) any other release of this information for purposes not set out in this Memorandum.

Article 8

Amendments

The MoU may be amended by mutual consent of the Parties through an Exchange of Notes between the Parties through diplomatic channels.

Article 9

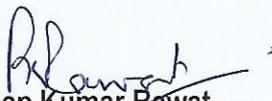
Entry Into Force and Termination

- (1) This MoU shall enter into force on the date its signing by the Parties.
- (2) The MoU shall remain in effect for a period of five (5) years, and may be renewed by mutual consent through an Exchange of Notes between the Parties through diplomatic channel.

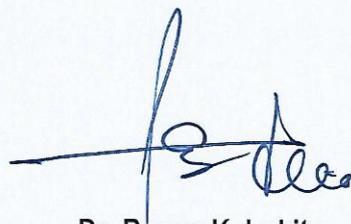
- (3) The MoU may be terminated by either party giving three (3) months written notice in advance through the official channel to other Party of its intention to terminate this MoU.
- (4) The termination of this MoU shall not affect the completion of any project undertaken according to this MoU prior to the termination thereof, or the full execution of any cooperative activity that has not been fully executed at the time of termination, unless otherwise agreed upon in writing by the Parties.

Signed in ^{Jakarta} on 29 May 2018 in two original copies each in English, Hindi and Bahasa Indonesia, all text being equally authentic. In any case of divergence of interpretation, the English text shall prevail.

On behalf of
Central Drugs Standard Control Organization,
Ministry of Health and Family Welfare,
Government of India,


Pradeep Kumar Rawat
Ambassador of India to Indonesia

On behalf of
The National Agency for Drug and Food Control,
The Republic of Indonesia,


Dr. Penny K. Lukito
Chairperson