

MEMORANDUM OF UNDERSTANDING

BETWEEN

**CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA**

AND

**AGENCIA NACIONAL DE REGULACIÓN, CONTROL Y VIGILANCIA
SANITRIA – ARCSA, DOCTOR LEOPOLDO IZQUIETA PÉREZ**

ON COOPERATION

IN THE FIELD OF MEDICAL PRODUCTS REGULATION

The Central Drugs Standard Control Organization(CDSCO), Ministry of Health and Family Welfare, Government of the Republic of India and Agencia Nacional de Regulación, Control y Vigilancia Sanitaria – ARCOSA, Doctor Leopoldo Izquieta Pérez (herein after jointly referred to as the "Parties" and individually referred to as a "Party");

INTENDING to establish the Medical Products Regulation Dialogue and Cooperation Framework in regards to pharmaceuticals including raw materials for pharmaceutical use, biological products, medical devices and cosmetic products (hereinafter referred to as the "Medical Products");

DESIRING to promote the exchange of information and cooperation in areas pertinent to medical products and the relevant administrative and regulatory matters within the jurisdiction of the Parties;

Have reached the following understanding:

ARTICLE 1

SCOPE

1. The purpose of this Memorandum of Understanding (hereinafter referred to as "MoU") is to facilitate a constructive dialogue on the laws and regulations pertinent to medical products as well as other relevant matters. The Parties, furthermore, will contribute to strengthening the relationship between India and Ecuador in the areas of medical products in line with their international responsibilities.
2. This MoU is not intended to create any legally binding obligations under national or international law.

ARTICLE 2

COMPETENT AUTHORITIES

The competent authorities responsible for the implementation of this Memorandum of Understanding shall be:

1. In the case of Republic of India, Central Drugs Standard Control Organization, Directorate General of Health Services of the Ministry of Health and Family Welfare; and
2. In the case of Republic of Ecuador, Agencia Nacional de Regulación, Control y Vigilancia Sanitaria – ARCSA, Doctor Leopoldo Izquieta Pérez; ;

ARTICLE 3

AREAS OF COOPERATION

The co-operation between the Parties shall take place in the following areas:

1. Promoting an understanding between the Parties of each other's regulatory framework, requirements and processes and facilitating future regulatory strengthening initiatives for both parties.
2. Exchange of information and cooperation on Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) and Good Pharmacovigilance Practices (GpvP).
3. Workplan, including technical meetings, to analyze Indian Pharmacopeia Recognition according to legal framework.
4. Exchange of safety information, including Pharmacovigilance, and adverse events where there is a particular safety concern related to the other party. This includes safety concerns relating to medicines and medical devices.

5. Participation in scientific and practical conferences, symposiums, seminars and forums organized by the Parties.
6. Capacity building in mutually agreed areas.
7. Coordination at the international fora.
8. Any other areas of common interest.

ARTICLE 4

CONFIDENTIALITY COMMITMENT

Each Party understands that information exchanged between them may include confidential information that is not available in public domain in the country of the Party providing the information. The Parties note that it is essential that confidential information emanated from one Party will be treated as such by the other Party.

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 Memorandum; and (b) any other release of this information for purposes not set out in this Memorandum.

ARTICLE 5

CONTACT POINTS

The Parties hereby designate the following contact points in order to communicate with each other and exchange information on the Medical Products:

1. For Indian Side:

International Cell, Central Drugs Standard Control Organization

2. For Ecuadorian Side:

International Relations, Agencia Nacional de Regulación, Control y Vigilancia Sanitaria.

ARTICLE 6

FINANCIAL RESOURCES

Each of the Parties shall bear its own expenses related to the activity within the present Memorandum unless it has been agreed to otherwise by the Parties.

ARTICLE 7

SETTLEMENT OF DISPUTES

The present Memorandum is not considered as an international treaty and does not create rights and obligations under international law.

Any dispute between the Parties arising out of the implementation, application or interpretation of this MoU shall be settled amicably through direct consultation or negotiation between the Parties through diplomatic/official channels.

ARTICLE 8

COMMENCEMENT, MODIFICATION AND TERMINATION

1. This MoU will commence on the date of its signature and will continue for a period of five (5) years. Thereafter the Parties may extend this MoU by exchange of letters for a further period of five (5) years, unless terminated in accordance with paragraph 3 hereunder.

3. The Memorandum of Understanding may be terminated by either Party giving six (6) months written notice in advance through the official channels to other Party of its intention to terminate this MoU.
4. The termination of this Memorandum of Understanding shall not affect the completion of any project undertaken by the Parties 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.

IN WITNESS WHEREOF the undersigned, being duly authorized thereto, by their respective Governments, have signed this Memorandum of Understanding.

Signed at **Quito, Ecuador** on this **7th day of November 2023** in three originals in Spanish, English and Hindi languages, all text being equally authentic. In case of any divergence in interpretations, the English text shall prevail.

**FOR CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, MINISTRY
OF HEALTH AND FAMILY WELFARE
OF THE GOVERNMENT OF THE
REPUBLIC OF INDIA.**



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Mr. Vanlalhuma
Ambassador Extraordinary and
Plenipotentiary of the Republic of
India

**FOR AGENCIA NACIONAL DE
REGULACIÓN, CONTROL Y
VIGILANCIA SANITARIA – ARCSA.
DOCTOR IZQUIETA PÉREZ OF THE
REPUBLIC OF ECUADOR.**



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Mr. Milton Eduardo Zambrano
Masache
Deputy Executive Director