

MEMORANDUM OF UNDERSTANDING

BETWEEN

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

AND

**THE PUBLIC HEALTH INSTITUTE OF CHILE
GOVERNMENT OF CHILE**

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 the Institute of Public Health of Chile, Government of Chile (hereinafter 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 "Framework");

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 Chile 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 Chile, the Institute of Public Health of Chile, Ministry of Health;

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. 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.
4. Participation in scientific and practical conferences, symposiums, seminars and forums organized by the Parties.
5. Capacity building in mutually agreed areas.
6. Coordination at the international fora.
7. Recognition of Indian pharmacopoeia.
8. Define the pharmacopoeia standards for recognition by the Parties, with a specific focus on evaluating the feasibility of including the Indian pharmacopoeia in this list.
9. 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 Framework:

1. For the Indian Side:

International Cell, Central Drugs Standard Control Organization

2. For the Chilean Side:

Institute of Public Health of Chile

**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.

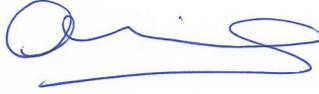
Any dispute between the Parties arising out of the implementation, application or interpretation of this MoU shall be settled amicably through direct consultation or negotiation between the Parties through diplomatic/ official channels.

**ARTICLE 8
COMMENCEMENT, MODIFICATION AND TERMINATION**

1. This MoU shall enter into force on the first day of the month, following the date of communication by the Parties regarding completion of their respective internal administrative procedure necessary for bringing this MoU into force. The MoU will continue for a period of five (5) years from the date of its entry into force. 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.
2. The Memorandum of Understanding may be amended at any time by mutual written consent of the Parties by Exchange of Notes between them through diplomatic/ official channels.
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, has signed this Memorandum of Understanding.

Signed at New Delhi on this 18th day of oct 2024 in two originals in the English, Hindi and Spanish 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	FOR PUBLIC HEALTH INSTITUTE OF CHILE, GOVERNMENT OF THE REPUBLIC OF CHILE

Name: RAJEEV SINGH RAGNUVANSHI

Name: Catterina Ferreres

Designation: Drugs Controller
CDSCO

Designation: Director