

MEMORANDUM OF UNDERSTANDING

BETWEEN

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

AND

DIRECTORATE-GENERAL FOR MEDICINES,
FOODS AND SANITARY PRODUCTS,
ORGANIZATIONS OF MINISTRY OF PUBLIC HEALTH AND SOCIAL ASSISTANT OF
DOMINICAN REPUBLIC

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 Directorate-General for Medicines, Foods And Sanitary Products Organization of Ministry of Public Health and Social Assistant Government Of Dominican Republic(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 Dominican Republic 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

AREAS OF COOPERATION

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

1. Promoting an understanding between the Parties of the regulatory framework, requirements, processes and procedures of each one and facilitate future initiatives of regulatory strengthening of 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. Recognition of all standards of Pharmacopoeia.
4. Sharing of safety information, including Pharmacovigilance, and adverse events when there is a particular safety concern related to the other party. This includes safety concerns related to medical products.
5. Exchange of technical information for the Quality Control of Medicines.
6. Participation in scientific and practical conferences, symposiums, seminars and forums organized by the Parties.
7. Capacity building in mutually agreed areas.
8. Coordination in the international forums.
9. Any other area of common interest;

ARTICLE 3

CONFIDENTIALITY COMMITMENT

1. Each Party understands that information exchanged between them may include confidential information that is not available in the public domain in the country of the other 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.
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 MoU; and (b) any other release of this information for purposed not set out in this MoU.

ARTICLE 4

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 Indian Side:

International Cell, Central Drugs Standard Control Organization Directorate

General of Health Services, Ministry of Health and Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi -110002. Phone: 91-11-23216367 E-mail:
dci[at]nic[dot]in

2. For Dominican Side:

Directorate-General of Medicines, Foods and Sanitary Products of Ministry of
Public Health and Social Assistant, Government of the Dominican Republic. Av.
Hector Homero Hernandez, Ensache La Fe, Santo Domingo, D.N. Phone: 809-
541-3121 Website: msp.gob.do

ARTICLE 5

FINANCIAL RESOURCES

Each of the Parties shall bear its own expenses related to the activity within the
present MoU if it has not been agreed to otherwise by the Parties.

ARTICLE 6

SETTLEMENT OF DISPUTES

1. The present MoU is not considered as an international treaty and does not
create rights and obligations under by international law.
2. Any dispute between the Parties arising out of the implementation, application or
interpretation of this MoU shall be settled amicably through direct consultation or
negotiations between the Parties through the diplomatic / official channels.

ARTICLE 7

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 Parties may also renew this MoU by exchange of letters for a
further period of five (5) years, unless terminated in accordance with paragraph 3
hereunder.
2. The MoU may be amended at any time by mutual written consent of the Parties
by Exchange of Notes between the Parties through the diplomatic/ official channels.
3. The MoU may be terminated by either Party by giving six (6) months written
notice in advance through the official channel to the other Party of its intention to
terminate this MoU.

4. The termination of this MoU 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 MoU.

Signed at New Delhi on this 4th Day of October, 2023 in three originals in English, Hindi and Spanish languages, all three texts 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

DIRECTORATE-GENERAL FOR MEDICINES,
FOODS AND SANITARY PRODUCTS,
ORGANIZATIONS OF MINISTRY OF PUBLIC
HEALTH AND SOCIAL ASSISTANT OF
DOMINICAN REPUBLIC


Name: Ramu Abbagani 4/10/23

Designation: Ambassador
Embassy of India
Santo Domingo


Name: Ambassador José Julio Gómez,
Designation: Vice Minister of Bilateral Foreign
Affairs, Ministry of Foreign Affairs of the
Dominican Republic