

MEMORANDUM OF UNDERSTANDING
BETWEEN
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION,
THE MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT
OF INDIA
AND
NATIONAL ADMINISTRATION OF DRUGS, FOOD & MEDICAL
DEVICES OF THE MINISTRY OF HEALTH AND SOCIAL
DEVELOPMENT OF THE ARGENTINE REPUBLIC
ON COOPERATION IN THE FIELD OF MEDICAL PRODUCTS
REGULATION

The Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, the Republic of India and

The National Administration of Drugs, Food & Medical Devices (ANMAT) of the Ministry of Health and Social Development of the Argentine Republic (hereinafter jointly referred to as the "Parties" and individually referred to as a "Party");

Taking into account the importance of medical products in saving lives, health recovery, treatment, prevention and diagnosis of diseases;

Recognizing the need to provide the population with safe, effective and quality medical products;

Aspiring to effective cooperation in the sphere of testing of medical products and their quality control, in order to ensure the protection of public health of the countries of the parties;

Recognizing the interest of both Parties in equal and mutually beneficial cooperation on a long term and stable basis

Have reached the following understanding:

ARTICLE 1 SCOPE

The Parties shall promote and develop cooperation in the field of medical products regulation within the respective jurisdiction by cooperating in the manner set out in this memorandum of understanding on the basis of equality and mutual benefit. The Parties will conclude separate agreements, as required, to carry out specific activities;

ARTICLE 2 AREAS OF COOPERATION

The cooperation between the Parties shall take place in the following areas:

- a. Pharmacovigilance of Medical Products & Medical Devices;
- b. Participation in scientific and practical conference, symposiums, seminars and forum organized by the country of each Party;
- c. Regulation of Medical Products and Cosmetics, and exchange of information thereon;
- d. Capacity building in mutually agreed areas;
- e. Visits to each other's country to understand the regulatory processes of both countries;
- f. Coordination at the international fora; and
- g. Any other areas of common interest.

ARTICLE 3 CONFIDENTIALITY COMMITMENT

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 Party notes 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 4
CONTACT DETAILS FOR THE IMPLEMENTATION OF THIS MOU**

The Parties shall exchange contact information of their authorized representatives responsible for the organization of exchange of information, within 60 days after the signing of this Memorandum.

**ARTICLE 5
FINANCIAL RESOURCES**

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

**ARTICLE 6
SETTLEMENT OF DISPUTES**

The present Memorandum is not considered as an international treaty and does not create rights and obligations under by 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 negotiations between the Parties through the official channels.

**ARTICLE 7
AMENDMENTS**

The Memorandum of Understanding may be amended at any time by mutual written consent of the Parties by Exchange of Notes between the Parties through the official channels.

**ARTICLE 8
ENTRY INTO FORCE AND TERMINATION**

1. This Memorandum of Understanding shall be effective from the date of signature and shall remain in force for a period of five (5) years. There-after it shall be automatically renewed for a further period of five (5) years, unless terminated in accordance with paragraph hereunder.
2. The Memorandum of Understanding may be terminated by either Party giving six (6) months written notice in advance through the official channel to other Party of its intention to terminate this MoU.
3. 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.

Done at New Delhi on this 18th day of February, 2019 in two originals in English, Spanish and Hindi languages, all text being equally authentic. In case of any divergence in interpretations, the English text shall prevail.

Sanjay Ranjan

FOR
CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION,
MINISTRY OF HEALTH & FAMILY
WELFARE OF THE REPUBLIC
OF INDIA

[Signature]

FOR
NATIONAL ADMINISTRATION
OF DRUGS, FOOD & MEDICAL
DEVICES OF THE MINISTRY
OF HEALTH AND SOCIAL
DEVELOPMENT OF THE
ARGENTINE REPUBLIC

Name :
Designation:

Name :
Designation: