

MEMORANDUM OF UNDERSTANDING
BETWEEN

THE BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA),
MINISTRY OF HEALTH, GOVERNMENT OF FEDERATIVE REPUBLIC
OF BRAZIL

AND

THE CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, DIRECTORATE GENERAL OF HEALTH
SERVICES (CDSCO/DGHS), MINISTRY OF HEALTH AND
FAMILY WELFARE, GOVERNMENT OF THE REPUBLIC OF
INDIA

ON COOPERATION IN THE FIELD OF PHARMACEUTICAL
PRODUCTS REGULATION

The Brazilian Health Regulatory Agency (ANVISA) and the Central Drugs Standard Control Organization, Directorate General Of Health Services (CDSCO/DGHS), Ministry of Health and Family Welfare of the Republic of India (hereinafter jointly referred to as the "Parties" and individually referred to as a "Party");

TAKING INTO ACCOUNT the Agreement between the Government of the Federative Republic of Brazil and the Government of the Republic of India on Co-operation in the fields of Science and Technology, signed on July 22nd 1985;

TAKING INTO ACCOUNT the Implementing Agreement in the field of Health and Medicine to the Agreement between the Government of the Federative Republic of Brazil and the Government of the Republic of India on Co-operation in the fields of Science and Technology, signed on May 5th 1998;

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

AWARE that mutual exchange of knowledge and ideas can strengthen the friendly relations in the fields of health and pharmaceutical products regulation between the Parties;

CONSIDERING that the co-operation in the field of pharmaceutical products regulation can facilitate trade between the two countries in this sector;

HAVE REACHED the following understanding:

ARTICLE 1 SCOPE

The Parties shall promote and develop cooperation in the field of pharmaceutical products regulation within the respective jurisdictions 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 keep specific activities;

ARTICLE 2 COMPETENT AUTHORITIES

The Competent Authorities responsible for the implementation of this Memorandum of Understanding shall be:

- a) in the case of the Republic of India, the Central Drugs Standard Control Organization, Directorate General of Health Services of the Ministry of Health and Family Welfare; and
- b) in the case of the Federative Republic of Brazil, the Brazilian Health Surveillance Agency of the Ministry of Health (ANVISA/MS) ;

ARTICLE 3 AREAS OF COOPERATION



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

- a) Overseas Inspections;
- b) Bioequivalence and Bioavailability studies regulation;
- c) Clinical Trials regulation;
- d) Medical Devices regulation;
- e) Active Pharmaceutical Ingredients (APIs) regulation;
- f) Pharmacovigilance;
- g) Regulation of biological products;
- h) Drugs regulation;
- i) Pharmacopoeia;
- j) Not of Standard Quality/Spurious drugs;
- k) Any other areas of common interest.

ARTICLE 4 FORMS OF CO-OPERATION

Co-operation between the Parties shall take the following forms:

- a) Sharing of regulatory experiences and their best practices;
- b) Exchange of information on regulatory requirements of both countries;
- c) Visits to each other's country to get to know working procedures and regulatory processes of both countries;
- d) Participation in international events organized by Brazil and India;
- e) Coordination during international fora; and
- f) Exchange of information on topics of mutual interest.

ARTICLE 5 CONFIDENTIALITY COMMITMENT

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

Each Participant 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 6 CONTACT DETAILS FOR THE IMPLEMENTATION OF THIS MoU

The Parties shall exchange contact details of the authorized representatives of the Parties, responsible for the organization of exchange of information, as well as for daily and urgent contact between the management of the Parties.



ARTICLE 7
FINANCIAL RESSOURCES

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 8
SETTLEMENT OF DISPUTES

The present Memorandum is not considered 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 Memorandum of Understanding shall be settled amicably through consultation or negotiations between the Parties through the diplomatic/official channels.

ARTICLE 9
AMENDMENTS

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


ARTICLE 10
ENTRY INTO FORCE AND TERMINATION

- 1) The Memorandum of Understanding shall enter into force on the day of its signature and shall remain in force for a period of five (5) years, thereafter, it shall be automatically renewed for further period of five (5) years at a time, unless terminated in accordance with sub- Article (3).
- 2) This Memorandum of Understanding may be terminated by either Party giving six (6) months written notice in advance through the official channel to the 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 _____ on this _____ day of _____ 2016 in two originals, each in the English, Hindi and Portuguese languages, all texts being equally authentic. In case, if divergence in interpretation, the English text shall prevail.

	
FOR THE BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA), MINISTRY OF HEALTH, GOVERNMENT OF FEDERATIVE REPUBLIC OF BRAZIL	FOR CENTRAL DRUGS STANDARD CONTROL ORGANIZATION OF THE GOVERNMENT OF THE REPUBLIC OF INDIA