# MEMORANDUM OF COOPERATION
# BETWEEN
# THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN
# AND
# THE CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
# OF
# THE MINISTRY OF HEALTH AND FAMILY WELFARE
# OF
# THE GOVERNMENT OF THE REPUBLIC OF INDIA
# ON
# MEDICAL PRODUCTS REGULATION DIALOGUE AND COOPERATION FRAMEWORK

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Central Drugs Standard Control Organization (CDSCO) of the Republic of India under the Ministry of Health and Family Welfare;

(hereinafter referred to collectively as the "Sides" and individually as "Side"),

INTENDING to establish the Medical Products Regulation Dialogue and Cooperation Framework in regards to pharmaceuticals including raw materials for pharmaceutical use, biological products, regenerative medicine products, medical devices, quasi-drugs and cosmetic products (hereinafter referred to as the "Framework"), (The term "quasi-drugs" refers to products (excluding equipment and instruments etc.) intended for uses related to health and hygiene, etc. and have mild action on human bodies. These products include, for example, drugs to prevent nausea, heat rush or loss of hair, to exterminate harmful insects and others such as fluid to wear contact lens. In India, these products are partially categorized as pharmaceuticals and others as cosmetic 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 Sides,

Have reached the following recognition:

## 1 – Purpose

1. The purpose of this Memorandum of Cooperation (hereinafter referred to as the "MOC") is to facilitate a constructive dialogue on the laws and regulations pertinent to medical products as well as other relevant matters. The Sides, furthermore, will contribute to strengthening the relationship between **Japan** and **India** in the areas of medical products in line with their international responsibilities.

2. This MOC is not intended to create any legally binding obligations under national or international law.

## 2 - Means of Cooperation

1. The Sides will hold an annual meeting to discuss major topics related to the laws and regulations pertinent to medical products in **Japan** and **India**, and to consider possible cooperation in areas of common interest aimed at sharing the best practices of the Sides with a view to harmonize regulations to the extent feasible.

2. The annual meetings will be held alternately in **Japan** and **India**, unless otherwise jointly decided by the Sides.

3. English will be used as the common language for the annual meeting.

## 3 - Working Group

Working Group(s) (hereinafter referred to as a "WG") may be established at the annual meeting based on mutual interests of the Sides. The WG(s) will be committed to developing and implementing activities based on its work plan. The WG(s) may consider holding of meetings, symposia and training workshops as determined by the Sides. The Sides may jointly decide to invite representatives from the relevant industries and academia to participate in the WG(s), depending on the agenda of the annual meeting.

## 4 - Contact Points

The Sides hereby designate the following contact points in order to communicate with each other and exchange information on the Framework:

a. **For the Japanese Side:**
   Evaluation and Licensing Division, Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare of Japan.
b. **For the Indian Side:**
   International cell division, Central Drugs Standard Control Organization
   .

## 5 – Minutes

The Minutes of the annual meetings will be drawn up in English after each meeting.

## 6 - Financial Arrangements

Each Side will bear its own costs in relation to the implementation of the cooperative activities under this MOC. The cost of translator(s) in annual meeting will be borne by the Side which hosts the meeting.

## 7 - Resolution of Differences

Any differences arising from the interpretation and/or implementation of this MOC will be resolved amicably through consultations between the Sides.

## 8 - Commencement, Modification and Termination

1. This MOC will commence on the date of its signature and will continue for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years. Either Side may terminate this MOC by giving a 90 days advance written notice to the other Side of its intention to terminate this MOC.

2. This MOC may be modified with the mutual written consent of the Sides.

In Witness Whereof, the duly authorized representatives of both Sides have signed this MOC.

Signed at Delhi on December 11, 2015 in two originals in the Japanese, Hindi and English languages, all texts being equally valid. In case of any divergence in interpretation, the English text will prevail.

For the
**Ministry of Health, Labour and Welfare of Japan**

**Director General**
**Pharmaceutical Safety and Environmental Health Bureau**
**Ministry of Health, Labour and Welfare**

**Signature:**

**Name : Hideaki Nakagaki**
**Date : December 11, 2015**

For the
**Central Drugs Standard Control Organization/ Ministry of Health and Family Welfare, Government of the Republic of India**

**Drugs Controller General (India)**
**Central Drugs Standard Control Organization**
**Ministry of Health and Family Welfare**

**Signature:**

**Name : G. N. Singh**
**Date : December 11, 2015**