MEMORANDUM OF COOPERATION (MOC)
BETWEEN
THE BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA)
OF THE FEDERATIVE REPUBLIC OF BRAZIL
AND
THE MINISTRY OF HEALTH, LABOUR AND WELFARE (MHLW)
OF JAPAN
ON COOPERATION OF THE PHARMACOPOEIAS

The Brazilian Health Regulatory Agency (ANVISA) of the Federative Republic of Brazil and the Ministry of Health, Labour and Welfare (MHLW) of Japan, hereinafter referred to as “Parties”, and individually as “Party”:

Recalling excellent relationship of trust and mutual cooperation among the Parties in various fora of medicines regulatory authorities and the confidentiality arrangement signed in November of 2012 in Manaus;

Recognizing that Brazilian and Japanese Pharmacopoeias (hereinafter referred to as “Pharmacopoeias”) contribute to quality of pharmaceutical substances and products including medicinal plants and excipients manufactured or distributed in each jurisdiction,

Noting interest of the Pharmacopoeias to strengthen their relationship and to promote cooperative activities in pharmacopoeial field; and

Taking into account the outcomes achieved by the Parties during the First Brazil – Japan Seminar on Regulation of Pharmaceutical Products and Medical Devices held on 2nd August of 2014;

Shared their views to expedite cooperation of the Pharmacopoeias under the following framework:

1. Purpose

The purpose of this Memorandum of Cooperation (hereinafter referred to as the "MOC") is to strengthen relations and to promote cooperation on standard setting of pharmacopoeia.
This MOC is not intended to create any legally binding obligations under national or international laws.

2. Institutions and Contact Points

The Parties are the institutions responsible for management of this MOC. The Parties hereby designate the following contact points in order to communicate with each other and exchange information on the framework:

a. For the Brazilian Side:
   Office of International Affairs
   Brazilian Health Regulatory Agency – ANVISA
   and
   Coordination of Pharmacopeia
   Superintendent of Medicines and Biological Products – SUMED
   Brazilian Health Regulatory Agency – ANVISA

b. For the Japanese Side:
   Evaluation and Licensing Division,
   Pharmaceutical and Food Safety Bureau,
   Ministry of Health, Labour and Welfare - MHLW
   and
   Division of Pharmacopoeia and Standards for Drugs,
   Office of Standards and Guidelines Development,
   Pharmaceuticals and Medical Devices Agency – PMDA

3. Means of Cooperation

The Parties organize bilateral meetings, workshop and internship in each country to share experiences and information on development of monographs and methods of testing under the terms of this MOC.

4. Technical Working Group

The Parties organize the Technical Working Group, when necessary, with staff members of the institutes and relevant experts to implement this MOC.

5. Minutes

The minutes of the bilateral meetings and the Technical Working Group meetings will be drawn up in English after each meeting.

6. Financial Arrangements

Each of the Parties will bear its own costs in relation to implementation of this MOC.

7. Miscellaneous

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, unless one of the Parties issues a written notice to the other Party of its intention to terminate this MOC ninety (90) days before the current expiration date.

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

Signed in duplicate in Tokyo, on the 11th of September, 2015, in the Portuguese, Japanese and English languages, each text having equal value. In case of any divergence of interpretation, the English text will prevail.

For the Brazilian Health Regulatory Agency of the Federative Republic of Brazil	**For the Ministry of Health, Labour and Welfare of Japan**
Director-President Brazilian Health Regulatory Agency	Director General Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare