MEMORANDUM OF COOPERATION (MOC)
IN THE FIELD OF PHARMACOPOEIAS
BETWEEN
THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM) OF THE COUNCIL OF EUROPE
AND
THE MINISTRY OF HEALTH, LABOUR AND WELFARE (MHLW) OF JAPAN

The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe and the Ministry of Health, Labour and Welfare (MHLW) of Japan, hereinafter referred to as "Participants", and individually as "Participant", shared their views to expedite cooperation of the Pharmacopoeias under the following framework.

1. Principle

The purpose of this Memorandum of Cooperation (hereinafter referred to as this "MOC") is to strengthen relations and to promote cooperation in standard setting of pharmacopoeias.

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

2. Institutions and Contact Points

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

a. For the European Side:

The Director of the European Directorate for the Quality of Medicines & HealthCare - EDQM

b. For the Japanese Side:

Pharmaceutical Evaluation Division,
Pharmaceutical Safety and Environmental Health 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 Participants will organise a bilateral meeting, a workshop, and an internship once a year in principle in either country/region to share experiences and information on development of monographs and methods of testing under the terms of this MOC.

4. Technical Working Group

The Participants will organise, when necessary, an ad hoc Technical Working Group with staff members of the institutes and relevant experts, as part of the cooperation under this MOC.

5. Minutes

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

6. Financial Arrangements

Each of the Participants will bear its own costs in relation to the implementation of the cooperation under this MOC.

7. Miscellaneous

The cooperation under 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 Participants issues a written notice to the other Participant of its intention to terminate the cooperation under this MOC ninety (90) days before the current expiration date.
This MOC may be modified with the mutual written consent of the Participants.

Signed in Tokyo, on the 13th of September 2016, in duplicate in the Japanese and English languages, each text having equal value. In case of any divergence of interpretation, the English text will prevail.

For the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe	**For the Ministry of Health, Labour and Welfare of Japan**
Susanne Keitel Director European Directorate for the Quality of Medicines & HealthCare of the Council of Europe	Toshihiko Takeda Director General Pharmaceutical Safety and Environmental Health Bureau Ministry of Health, Labour and Welfare