MEMORANDUM OF UNDERSTANDING

between

Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic)

and

the Medicines and Healthcare products Regulatory Agency (MHRA)

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), and the Medicines and Healthcare products Regulatory Agency (MHRA) (hereinafter referred to as the "Participants") wish to establish a framework for cooperation in the area of the regulation of therapeutic products.

2. OBJECTIVES

2.1 The objectives of this Memorandum of Understanding (MoU) are:

a. to promote an understanding between the Participants of each other's regulatory framework, requirements and processes;

b. to facilitate the exchange of information and documentation relating to the regulation of therapeutic products;

c. to encourage the development of collaborative activities between the Participants; and

d. to enhance the ability of the Participants in the provision of their services relating to or in connection with public health, to meet the needs of their respective population.

2.2 This MoU represents the understanding reached by the Participants, in particular

a. that each Participant has jurisdiction over specific therapeutic products and may define those products differently. This MoU is intended to cover all types of therapeutic products regulated by the Participants and permit meaningful collaboration between the Participants; and

b. that some information may be classified as non-public / confidential information exempt from public disclosure under the laws and regulations of each Participant, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal pre-decisional information.

3. DEFINITIONS

In this MoU "therapeutic products" means:

a. medicinal products and medical devices as defined in Article 4 (a) and (b) of the Swiss Federal Act on Medicinal Products and Medical Devices 2000 as amended from time to time (Therapeutic Products Act, TPA); and

b. medicinal products as defined in Article 1 (as amended) of Directive 2001/83/EC and medical devices as defined in Article 1(2)(a) of the Medical Devices Directive 93/42/EC.

4. AREA OF COOPERATION

The Participants declare their intention to:

a. establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Participant, including policies, practices, standards, laboratory testing, pre-market assessment, post-market vigilance, market compliance, regulation of manufacturers, regulation of clinical trials and requirements for the regulation of therapeutic products; and

b. undertake collaborative activities, including, where practical, the exchange of personnel.

5. CONFIDENTIALITY

a. Each Participant may release either public or non public information to the other Participant based on each Participants' own laws and policies.

b. The release of information is subject to each Participants' own procedures described in the respective laws and policy guidelines.

c. Any information the Participants receive under the terms of this MoU is protected from disclosure according to the applicable national laws of each Participant.

d. The Participants understand that some information they receive from each other may include confidential information protected from public disclosure under each Participants' laws and regulations.

e. The Participants understand that this non-public information is shared in confidence, and that each Participant considers it critical that the other Participant maintains the confidentiality of the information insofar as it is able to do so. Public disclosure of this information by one of the Participants could seriously jeopardize any further scientific and regulatory interactions between the Participants. Each Participant should advise the other of the non-public status of the information at the time that the information is shared.

f. The Participants recognise that there may be occasions when the Participant with whom confidential information is shared may as a result of receiving that information need to take measures to protect public health which may necessitate sharing some or all of such confidential information with certain other agencies. In those circumstances the Participants are expected to only decide to share the information in consultation with the other Participant.

g. Both Participants recognise that if requests for information in their possession (including otherwise non-public information received from the other Participant) are demanded by judicial, parliamentary order or other order issued under statute, the Participant may surrender the information to the court, legislature, or person concerned. If such an order is received for otherwise non-public information received from the other Participant, the Participant under order to produce the information is

expected to inform the requestor immediately and to work with the requestor to protect the non-public information from public disclosure insofar as this is possible.

6. FINANCIAL ARRANGEMENTS

Each Participant is responsible for the administration and expenditure of its own resources associated with activities conducted under the MoU.

7. STATUS

a. The MoU is not intended to create any legally binding obligation between the Participants.

b. Nothing in this MoU imposes an obligation on either Participant to release information, either public or non public information to the other Participant. It is a matter for either Participant to determine if they release information based on its own applicable laws and policies.

c. The MoU comes into effect on the day on which it is signed by the last Participant.

8. AGENCY CONTACT

The liaison officers for the administration of this MoU are:

a. for Swissmedic, the person holding the position of Head of Networking, and

b. for MHRA, the person holding the position of Head of EU and International Policy.

Signed in duplicate in Interlaken, Switzerland on 10th of October 2016.

For Swissmedic, Swiss Agency for Therapeutic Products	For the Medicines and Healthcare products Regulatory Agency
……	…….
Jürg H. Schnetzer, Director, Swissmedic	Dr Ian Hudson, Chief Executive, MHRA