Paul-Ehrlich-Institut

Bundesinstitut für Impfstoffe
und biomedizinische Arzneimittel

swissmedic

MEMORANDUM OF UNDERSTANDING

Between

The Federal Institute of Vaccines and Biomedicines, Germany (Paul-Ehrlich-Institut, PEI)

And

the Federal Department of Home Affairs acting in the name of the Federal Council of the Swiss Confederation

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The Federal Institute of Vaccines and Biomedicines (PEI) of Germany and **The Federal Department of Home Affairs, Switzerland acting for and on behalf of Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic),** wish to establish a framework for cooperation between the PEI and Swissmedic (hereinafter referred as the "Participants") in the area of the regulation of biological medicinal products as defined in paragraph 3 "Definitions".

2. OBJECTIVES

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 the products in scope of this Memorandum of Understanding;

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.

This MOU represents the understanding reached by the Participants, in particular

(i) that each Participant has jurisdiction over specific therapeutic products and may define those products differently. This MOU is intended to cover biological medicinal products regulated by the Participants and permit meaningful collaboration between the Participants; and

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

3. DEFINITIONS

In this MOU "biological medicinal products" means:
Vaccines for human use, medicinal products containing antibodies, allergens for therapy and diagnostics, blood and blood products and, more recently, tissue and medicinal products for gene therapy, somatic cell therapy, tissue engineering and xenogenic cell therapy

4. AREA OF COOPERATION

The Participants having reached the above understanding declare their intention to:

a. establish avenues of communication to facilitate the exchange of information about the regulation of biological medicinal 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 biological medicinal products; and

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

5. CONFIDENTIALITY

Each Participant may release information, either public or non public information, to the other Participant based on each Participants' own laws and policies.
The release of information is subject to each Participants' own procedures described in the respective laws and policy guidelines.

Any information the Participants receive under the terms of this MOU is protected from disclosure to any third party subject to the applicable national laws of each country.

The Participants understand that some information they receive from each other may include confidential information protected from public disclosure under the German/Swiss laws and regulations.

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. Public disclosure of this information by one of the Participants could seriously jeopardize any further scientific and regulatory interactions between the Participants. Swissmedic should advise the PEI of the non-public status of the information at the time that the information is shared and vice-versa.
Both Agencies state that they have the authority to protect the non-public information provided to each other in confidence from public disclosure.

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

7.1 Nothing in this MOU will impose an obligation on either Participant to release information, either public or non public information to the other Participant. It will be a matter for either Participant to determine if they will release information based on its own applicable laws and policies.

7.2 The MOU will enter into effect on the day on which it is signed by the last Participant.

7.3 The Participants may evaluate this MOU at any time and propose amendments to it. Any proposed amendments will be subject to consultations between the Participants. Amendments may be made to the MOU with the mutual written consent of the Participants.

7.4 The Participants may withdraw at any time from the MOU . Information about the intention to withdraw should be given to the other Participant at least one month in advance. Point 5 "Confidentiality" will continue to apply to any information shared prior to the withdrawal.

8. AGENCY CONTACT

The liaison officers for the administration of this MOU are:

a. for the PEI, the person holding the position of Coordinator International Relations*;* and

b. for Swissmedic, the person holding the position of Head of Networking

Signed in Langen, Germany

on this day of 2012

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by Klaus Cichutek, President Federal Institute of Vaccines and Biomedicines (PEI), Germany

Signed in Berne, Switzerland

on this day of 2012

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by Jürg H. Schnetzer, Director, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland