JOINT DECLARATION OF INTENT

Between

The Federal Ministry of Health of the Federal Republic of Germany, represented by The Federal Institute for Drugs and Medical Devices, (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)

And

the Federal Department of Home Affairs of the Swiss Confederation, represented by Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic)

CONCERNING COOPERATION IN THE REGULATION OF MEDICINAL PRODUCTS AND MEDICAL DEVICES

1. BACKGROUND

The Federal Institute for Drugs and Medical Devices (BfArM) and Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), (hereinafter referred to as the "Participants") wish to establish a framework for cooperation in the area of the regulation of medicinal products and medical devices as defined in section 3 "Definitions".

2. OBJECTIVES

The objectives of this Joint Declaration of Intent (JDI) are:

a. to promote an appreciation at 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 JDI;
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 JDI represents the understanding reached by the Participants, in particular

(i) that each Participant has jurisdiction over specific medicinal products and medical devices and may define those products differently. This JDI is intended to cover medicinal products and medical devices 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 JDI terms "medicinal products" and "medical devices" are understood

(i) as defined in the Directive 2001/83/EC and Directive 93/42/EEC. With regard to the legal scope of the BfArM sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogenic medicinal products, blood components manufactured using genetic engineering, and medicinal products which are intended for administration to animals are not subject of this JDI;

(ii) 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).

4. AREA OF COOPERATION

The Participants declare their intention to:

a. open up avenues of communication to facilitate the exchange of information about the regulation of medicinal products and medical devices by each Participant, including: policies, practices, standards, pre-market assessment, post-market vigilance, market compliance, regulation of manufacturers, regulation of clinical trials and requirements for the regulation of medicinal products and medical devices; and

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

5. CONFIDENTIALITY

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

The Participants concur that any information they receive in accordance with the provisions of this JDI is protected from disclosure according to the applicable national laws of each Participant.

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.

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 BfArM 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

Both Participants concur that each of them is responsible for the administration and expenditure of its own resources associated with activities conducted in accordance with the JDI.

7. STATUS

7.1 The JDI is not intended to create any legally binding obligation between the Participants.

7.2 Nothing in this JDI 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 want to release information based on its own applicable laws and policies.

7.3 The JDI will enter 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 JDI are:

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

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

Signed in Berne, Switzerland, on the 7th of January, 2014

gez. Schwerdtfeger……
by Walter Schwerdtfeger, President Federal Institute for Drugs and Medical Devices (BfArM), Germany

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