

Joint Declaration of Intent

between

the Ministry of Health, Pharmaceutical Division, Israel

and

the Federal Department of Home Affairs of the Swiss Confederation

**CONCERNING COOPERATION IN THE REGULATION OF
MEDICINAL PRODUCTS**

1. INTRODUCTION

The Ministry of Health of Israel represented by its Pharmaceutical Division (Pharmaceutical Division) and **the Federal Department of Home Affairs of Switzerland represented by Swissmedic, Swiss Agency for Therapeutic Products** (Swissmedic), wish to establish a framework for cooperation between the Pharmaceutical Division and Swissmedic (hereinafter referred as the “Participants”) in the area of the regulation of medicinal products as defined in paragraph 4 “Definitions”.

2. OBJECTIVES

The objectives of this Joint Declaration of Intent (JDI) 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 under the 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.

3. UNDERSTANDINGS

This JDI 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 JDI is intended to cover 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 each Participant, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal pre-decisional information.

4. DEFINITIONS

In this JDI “medicinal products” refers to:

- a. medicinal products as defined in Article 4 (a) of the Swiss Federal Act on Medicinal Products and Medical Devices 2000 as amended from time to time (Therapeutic Products Act, TPA), as follows: "products of chemical or biological origin, which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products."

and

- b. medicinal products as defined in the Israeli Pharmacy Ordinance (New Version) 1981 and amended from time to time, as follows: “medicinal products” - includes products for use in veterinary medicine and products with nutritional properties intended for intravenous administration, but excluding medical equipment.

5. AREAS 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 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 medicinal products; and
- b. Undertake collaborative activities, including, where practical, the exchange of personnel.

6. CONFIDENTIALITY

Each Participant may release either public or non-public information to the other Participant subject to each Participants’ own laws, regulations and policies.

Any information the Participants receive under the terms 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 consider 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. The Participants should advise one another of the non-public status of the information at the time that the information is shared.

Both Participants state that they have the authority to protect the non-public information provided to each other in confidence from public disclosure.

7. FINANCIAL ASPECTS

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

8. STATUS

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

8.2 In addition to this JDI, the Participants should endeavour to promote the conclusion of a framework agreement on Cooperation in the Fields of Health and Medicine.

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

8.4 Amendments may be made to the JDI with the mutual written consent of the Participants. The Participants may withdraw at any time from the JDI. Information about the intention to withdraw should be given to the other Participant one month in advance. Point 6 “Confidentiality” will continue to apply to any information shared prior to the withdrawal.

9. AGENCY CONTACT

The liaison officers for the administration of this JDI are:

- a. for the Pharmaceutical Division, the person holding the position of Director; and
- b. for Swissmedic, the person holding the position of Head of Networking.

Signed in Jerusalem

on this _____ day of _____ 2014, which corresponds to the _____ day of _____, 5774 of the Hebrew Calendar.

For the Ministry of Health, Israel

....., Prof. Ronni Gamzu, Director General, Ministry of Health, Israel

For the Federal Department of Home Affairs of the Swiss Confederation

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