MEMORANDUM OF UNDERSTANDING

Between

the Federal Department of Home Affairs of the Swiss Confederation represented by Swissmedic, Swiss Agency for Therapeutic Products
(hereinafter referred to as "**Swissmedic**"**)**

and

the Medicines Control Council, Republic of South Africa
(hereinafter referred to as "**the MCC**"**)**

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), and Medicines Control Council (MCC) (hereinafter referred to as the “Participants”) wish to establish a framework for cooperation in the area of the regulation of therapeutic products. Therapeutic products include pharmaceutical products for human and animal use including Active Pharmaceutical Ingredients (APIs) and medical devices.

2. 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) medicine, scheduled substance, medical device or IVD as defined in section 1 of the Medicines and Related substances Act, 1965 (Act No.101 of 1965) as amended.

3. OBJECTIVES / PURPOSE

3.1. 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 sharing of documentation relating to the regulation of Therapeutic Products, to improve the efficiency and quality of regulatory functions throughout the lifecycle of Therapeutic Products;

(c) to encourage the development of collaborative activities between the Participants, promote and maintain good review practices; 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.

(e) The purpose of exchanging information and documentation is to enhance each Participant's regulatory processes and decision–making practices.

3.2 This MoU represents the understanding reached by the Participants, in particular the following:

(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.

(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.

4. AREA OF COOPERATION / SCOPE

The Participants declare their intention to:

4.1 establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Participant, including:

(a) Policies, procedures, guidance documents, and other technical documents for which the Participants have responsibility;

(b) Information related to the categorization of Therapeutic products e.g. priority review status, orphan drug designation;

(c) Information contained in, and about clinical trial or investigational applications for Therapeutic products, including adverse event reports or evaluation reports from the different discipline reviews e.g. clinical, chemistry and manufacturing;

(d) Information about ongoing clinical trials for Therapeutic products including information related to clinical trial site inspections aimed at determining compliance with good clinical practice;

(e) Information contained in or about Therapeutic Products marketing applications, including evaluation reports from the different discipline reviews e.g. chemistry and manufacturing, clinical, biologics, and results from any on-site evaluations;

(f) Information that supports the conformity of Therapeutic Products marketing applications with applicable regulatory requirements, including results from pre-approval consistency testing, post- approval lot release testing and information on testing methodologies or algorithms for biological pharmaceuticals or product sample test results for chemical pharmaceuticals;

(g) Information related to compliance and completed enforcement activities e.g. product or establishment investigations;

(h) Information regarding the suppliers of Therapeutic Products that are the subject of specific shortage situations in either jurisdiction;

(i) Inspection reports or other information that supports the compliance of facilities that manufacture, wholesale, test or import Therapeutic products with applicable regulatory requirements;

(j) Information on facilities licensed, registered or authorised in each Participant country that then market Therapeutic Products in the other Participant's country;

(k) Information related to import refusals for reasons related to safety, quality or integrity of a shipment;

(l) Post market surveillance information having potential impact on public health including Vigilance information and information about impending regulatory actions e.g. proposed market withdrawal and product recalls;

(m) Information on safety and quality defects reported for, and product recalls effected for, Therapeutic Products manufactured and /or supplied in South Africa or Switzerland;

(n) Information on practices and procedures, relating to the development of policy, regulation, legislation, including strategies designed to ensure that regulatory systems are transparent and open. Information regarding decision making on risk benefit management, risk communication or public involvement strategies, and consideration for ethical or other socio-economic issues in the development of new regulatory frameworks;

(o) Information technology management systems, database systems, and other related computer applications that support the evaluation, testing and investigation of Therapeutic Products applications, or the inspection of facilities in which Therapeutic Products are manufactured;

(p) Any other information technology or systems that may be mutually agreed upon from time to time.

4.2 Collaborative activities may include exchange of personnel, training and development of professional competence in the evaluation, assessment or regulations of specific Therapeutic Products, collaborative research relating to safety, efficacy and quality of Therapeutic Products, and the planning of joint workshops, conferences, or meetings.

5. ACKNOWLEDGEMENT

The Participants acknowledge that the information and documentation described in clause 4 above, may only be exchanged at the request of the other Participant.

6. CONFIDENTIALITY

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

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

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

6.4 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.

6.5 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. Each Participant should advise the other of the non-public status of the information at the time that the information is shared.

6.6 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 ARRANGEMENTS

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

8. STATUS

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

8.2 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.

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

9. 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 MCC, the person holding the position of Registrar

Signed in … on …

For Swissmedic, Swiss Agency for Therapeutic Products

Jürg H. Schnetzer, Director, Swissmedic

For Medicines Control Council

Mandisa Hela, Registrar, MCC