MEMORANDUM OF UNDERSTANDING

CONCERNING

CO-OPERATION ON THE REGULATORY OVERSIGHT OF VETERINARY MEDICINES

BETWEEN

SWISSMEDIC, THE SWISS AGENCY FOR THERAPEUTIC PRODUCTS

AND

THE VETERINARY MEDICINES DIRECTORATE

Swissmedic, the Swiss Agency for Therapeutic Products responsible for the authorisation and supervision of therapeutic products, and the Veterinary Medicines Directorate of the Department for the Environment, Food and Rural Affairs (VMD), hereinafter referred to as the Participants,

taking into account that they are responsible for the regulation of veterinary medicines in their respective countries;

recognising that they have similar approaches to regulation of veterinary medicines in the broad sense and at the practical level in relation to the type of data they required in relation to veterinary medicines;

recognising that there is mutual advantage to increasing the scope of and strengthening the framework for such cooperation;

have come to the following understanding:

1. PURPOSES AND OVERVIEW

1.1 The Participants intend to strengthen exchange of knowledge and expertise between themselves to enhance the efficiency and effectiveness of their respective roles.

1.2 This Memorandum of Understanding (MoU) is focused on cooperation in relation to the operational aspects of veterinary medicine regulation and will not cover broader government regulatory policy of either of the Participants.

1.3 Subject to the confidentiality provisions outlined in paragraph 3, the Participants may exchange information on regulatory assessments and risk management options in respect of veterinary medicines that they jointly cover.

1.4 The exchange of information and cooperative action between the Participants will relate to veterinary medicines regulatory matters of mutual interest.

2. OBJECTIVES

2.1 The objectives of this 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 veterinary medicinal products;

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

d. to enhance the ability of the Participants to share experience in scientific advice and regulatory science.

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 veterinary medicinal 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. ROLES AND RESPONSIBILITIES

3.1 The Participants envisage to meet at least quarterly to discuss matters of mutual interest.

3.1.1 Areas to explore will relate to veterinary medicines and may include opportunities to workshare, maximise resources and reduce administrative burdens.

3.1.2 Subject to paragraph 3 below, the Participants declare their intention to:

I. establish avenues of communication to facilitate the exchange of information about the regulation of veterinary medicinal products by each Participant, including policies, practices, standards, pre-market assessment, post-market surveillance, pharmacovigilance, scientific advice market compliance, regulation of manufacturers and requirements for the regulation of veterinary medicinal products; and

II. undertake collaborative activities

3.1.3 Information will be provided free of charge.

4. CONFIDENTIALITY

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

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

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

4.4 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.

4.5 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 jeopardise 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.

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

5. ADMINSTRATIVE ARRANGEMENTS

5.1 Changes by either Participant in legislation, operational policies, practices and procedures which relate to matters covered by the MoU, and which would impact on the operations of the MoU, will be notified to the other Participant and any consequential changes necessary to the MoU will be subject to consultation between the Participants.

5.2 The officers responsible for the administration of the MoU are:

5.2.1 The person holding the position of Deputy Chief Executive Officer, VMD and

5.2.2 The person holding the position of Director, Swissmedic.

5.3 The officers responsible for the day-to-day operations under this MoU are:

5.3.1 The person holding the position of Head of Regulatory Affairs, Veterinary Medicines Directorate, VMD; and

5.3.2 Persons holding the position of Head Division Veterinary Medicines, Swissmedic

5.4 Changes to contact officers will be notified within 10 working days and transitional arrangements put in place to deal with correspondence received in the interim. The Participants will assist each other when requested to identify sources of expertise to review applications or to review or provide other information.

6. REVIEW OF THIS MOU

6.1 Nothing in paragraph 6.1 precludes the Participants from jointly determining to amend this MoU at any time. A review of this MoU may take place on request from either Participant.

6.2 This MoU is comprised of this document and its amendments and schedules, as amended from time to time.

7. EFFECTIVE DATE AND TERMINATION OF THIS MOU

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

7.2 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 is a matter for either Participant to determine if they should release information based on its own applicable laws and policies.

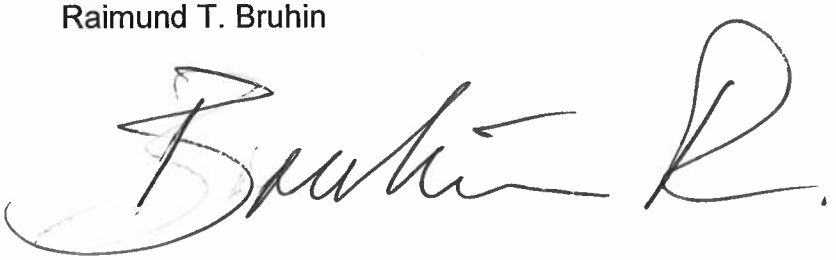
7.3 The MoU will come into effect on the day on which it is signed by both Participants or if signed on separate days, the day on which it is signed by the last Participant.

7.4. Either Participant may terminate this MoU by giving the other Participant a thirty (30) days written notice of its intent to terminate.

Signed in duplicate in Bern, Switzerland, this 26 of January 2023.

For Swissmedic, the Swiss agency of Therapeutic Products

Raimund T. Bruhin



For the Veterinary Medicines Directorate, United Kingdom

Gavin Hall