Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr Dirceu Barbano
Director Chairman
Brazilian Health Surveillance Agency

Dear Dr Barbano

ARRANGEMENT BETWEEN THE BRAZILIAN HEALTH SURVEILLANCE AGENCY AND THE AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION WITH RESPECT TO THE SHARING OF CONFIDENTIAL INFORMATION

1 The Brazilian Health Surveillance Agency (ANVISA) and the Australian Therapeutic Goods Administration (TGA) (collectively referred to as "the Participants"), as the respective authorities involved with and responsible for the regulation of therapeutic products in Brazil and Australia, have recognised the need to enhance their relationship with increased cooperation, by means of an exchange of letters (also referred to as "this Arrangement"), to facilitate the sharing of confidential information.

Background

2 The Participants share the common goal of protecting the health and safety of the populations of their respective countries by regulating the quality, safety, and efficacy or performance of therapeutic products manufactured or supplied in, imported into, or exported from, their respective countries, and have a history of co-operation and a high regard for each other's regulatory practices and systems.

3 This Arrangement recognises that each Participant has jurisdiction over specific products, defines those products differently, and amends definitions from time to time. Collaboration under this Arrangement is intended to cover all therapeutic products regulated by, and common to, the Participants under Australia's *Therapeutic Goods Act 1989* and Brazilian Law *9.782 of 26 January 1999*.

Purpose

4 The purpose of this Arrangement is to:

a) facilitate the exchange of information and documentation relating to the regulation of therapeutic products;

b) allow for the exchanged information and documentation to be used by the Participants to carry out their regulatory functions and duties;

c) strengthen communication between the Participants;

d) enhance the ability of Participants to protect and promote the health and safety of the population of their respective countries; and

e) provide improved regulatory performance and safety as a result of the sharing of the best regulatory expertise from both countries.

5 This Arrangement is not intended to compromise the regulatory authority of either Participant to carry out its responsibilities, nor to create any legally binding rights or obligations.

6 Each Participant will be in charge of the administration and expenditure of its own resources associated with the activities conducted under this Arrangement.

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Type of information that can be shared

7 The Participants understand that the type of information that they may share includes, but is not limited to:

a) guidance documents, policies, procedures and other technical documents, including draft and final documents;

b) information relating to applications for marketing authorisation and other regulatory approvals, and the pre- and post-market evaluation and assessment of therapeutic products;

c) without limiting the generality of paragraph b), in the case of applications for marketing authorisation relating to orphan medicines, this includes information (such as evaluation reports) dealing with, but not restricted to, the following data: quality data (being the chemical, pharmaceutical and biological data relevant to the application), non clinical data (being the pharmaco-toxicological data relevant to the application), clinical data and summary and overview reports (including those reviewing any risk management plan and labelling information, and setting out the rationale for the decision);

d) risk management plans;

e) post-authorisation vigilance data, particularly those of an urgent nature as well as safety concerns arising from periodic safety update reports and post-authorisation obligations, and other matters relating to the supply or monitoring of therapeutic products;

f) information about post-authorisation activities and activities of significant public health interest;

g) information related to the regulation and the assessment of the manufacturers of therapeutic products;

h) information relating to laboratory testing of therapeutic products, including testing methodologies or algorithms, and test results;

i) information relating to any cases, or possible cases, of counterfeit therapeutic products or tampering with or adulterating therapeutic products;

j) information relating to administrative arrangements including fees and charges; and

k) information technology systems supporting regulatory processes.

8 The Participants may limit the scope of the information shared under this Arrangement where dissemination or exchange of certain information would undermine any government policy, specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of Australia or Brazil, or the protection of the Participants' interests in the confidentiality of their proceedings.

Treatment of shared information

9 The Participants:

a) understand that information exchanged between them may include information that is not in the public domain in the country of the Participant providing the information;

b) will treat information received under this Arrangement as confidential and, except as provided elsewhere in the Arrangement, for their use only;

c) will share information in accordance with their respective national laws, policies and procedures;

d) will, subject to paragraphs 13 to 15, make every reasonable effort to prevent:

i. the public release of confidential information; and

ii. any other release of confidential information for purposes not set out in this Arrangement;

e) will protect the confidentiality of confidential information in accordance with their respective laws as well as the policies and procedures permitted by those laws. The

Participants consider it crucial to the sustainability of this Arrangement and future cooperation that confidential information shared between their respective agencies or branches be protected according to the respective laws from unauthorised use and disclosure; and

f) will make all reasonable efforts to inform the other Participant of any changes to their respective national laws, policies or procedures that may affect the treatment of confidential information provided under this Arrangement.

Third party information

10 Confidential information shared under this Arrangement by one Participant with the other Participant (the "receiving Participant") may be:

a) used by the receiving Participant for purposes set out in this Arrangement;

b) shared by the receiving Participant with third parties in accordance with paragraph 13; or

c) disclosed by the receiving Participant under paragraph 13, 14 or 15;

without the prior written consent of the business or entity to whom the information relates (although in the case of paragraph 14 disclosure may be subject to third party consultation and approval) provided that such disclosure or use is in accordance with this Arrangement or the receiving Participant's national laws, policies and procedures. However, a Participant sharing information with the receiving Participant may notify or seek the consent of any third party business or entity to whom the information relates before sharing information with the other Participant.

11 In the case of personal information (e.g., names, contact details or other information that could identify individuals referred to in the documents), the Participants will endeavour to delete any such personal information (e.g., the names of employees of a third party business/entity or patient details) prior to releasing such information.

12 The Participants may exchange the name and work contact details of employees or contractors of the Participants where appropriate, e.g. for the purpose of discussing shared information. In such cases, the Participant providing the personal information will endeavour to inform the affected individual:

a) that their personal information is being provided to the other Participant under the Arrangement;

b) of the purpose for which it is being provided (e.g., as a contact point for the purpose of discussing shared information); and

c) of any other matters that the Participants may request of each other, including as may be required under their respective national laws, policies and procedures.

Disclosure to employees, contractors etc

13 A Participant receiving confidential information under this Arrangement may disclose it to its employees, agents or contractors who:

a) require the information solely for work purposes in respect of this Arrangement;

b) will only use that information for purposes contemplated by this Arrangement; and

c) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits those persons to use the information only for the purposes of this Arrangement and requires them to protect the confidentiality of the information in accordance with the laws that are applicable to the Participant who receives the information.

Disclosure of confidential information

14 Subject to paragraph 15, if a Participant is contemplating:

a) public disclosure of confidential information received from the other Participant under this Arrangement;

b) disclosure to third parties, in response to a request to the TGA under the *Freedom of Information Act 1982* or in response to a request to ANVISA under the *Access to Information Law (Law No. 12.527/2011)*, of confidential information received from the other Participant under the Arrangement; or

c) any other disclosure to third parties not otherwise mentioned in this Arrangement;

that Participant will consult the Participant that provided the information before disclosure. The Participants may decide in writing upon the release of information (which may be subject to third party consultation and approval) if it is in accordance with their respective national laws, policies and procedures.

15

a) Each Participant will make all reasonable efforts to inform the other of any effort made pursuant to a judicial, legislative or other authority to obtain confidential information that has been received from the other Participant under the Arrangement.

b) If disclosure is required pursuant to such authority, the other Participant will endeavour to consult with the Participant that provided the information before disclosure and will make all reasonable efforts to ensure that the information is disclosed in a manner that protects the information from any subsequent disclosure that is not authorised by the judicial, legislative or other authority.

Administrative arrangements including contacts, timeframes and language

16 The Participants will make requests for information through their designated officers in charge of the administration of this Arrangement.

17 The Participants designate the following as their officers:

a) For ANVISA, the Head of the International Affairs Office; and

b) For the TGA, the Head, Office of Parliamentary and Strategic Support.

18 Each Participant will, in response to a request from the other Participant, endeavour to provide any relevant information it holds within 30 calendar days.

19 Each Participant will, in response to a request from the other Participant, wherever possible seek to provide information that is in English. In the case of a request for an evaluation report:

a) where a Participant holds a relevant evaluation report that is not in English, the Participant will endeavour to translate the full evaluation report into English; and

b) if requested by the other Participant, and it is possible to do so, provide a official/ government certificate that the report is a true and correct translation of the original.

Commencement, amendment and termination

20 This Arrangement, consisting of letters exchanged between the Participants, will enter into effect upon the date of the letter signed latest in time.

21 The Participants may amend this Arrangement at any time, in writing, upon their mutual consent.

22 The Participants will carry out a joint review of the currency and effectiveness of this Arrangement not more than three (3) years from the date of its entry into effect, or on such other date they may decide upon.

23

a) Either Participant may terminate this Arrangement by giving 30 days' notice to the other Participant;

b) The Participants may terminate this Arrangement at any time, upon their mutual consent;

c) Upon termination of this Arrangement, the Participants will continue to protect confidential information already provided under this Arrangement from unauthorised disclosure and use in accordance with the terms of this Arrangement.

24 We look forward to the entry into effect of this Arrangement allowing for the sharing of confidential information, and to continuing cooperation between ANVISA and TGA, in the best interests of public health.

Yours sincerely

Prof John Skerritt
National Manager
Therapeutic Goods Administration
3 December 2013