Memorandum of Understanding
between
the Council of Europe (European Directorate for the Quality of Medicines and HealthCare – EDQM)
and
the Brazilian Health Regulatory Agency (ANVISA)
on
Cooperation of the Pharmacopeias

The Brazilian Health Regulatory Agency (hereinafter referred to as "ANVISA") and the Council of Europe (European Directorate for the Quality of Medicines & HealthCare (hereinafter referred to as EDQM)), hereinafter jointly referred to as the "Parties"),

CONSIDERING the necessity of strengthening their relationship and to promote cooperative activities in the pharmacopoeial field;

CONSIDERING the necessity of strengthening their cooperation on information exchange to successfully achieve their respective missions;

CONSIDERING that the Brazilian Pharmacopeia is an observer to the European Pharmacopeia Commission and considering the well established relationship of trust and mutual cooperation among the Parties;

INTENDING to establish a framework for the exchange of information between the Parties;

DESIRING to strengthen communication between the Parties in order to protect and enhance public health and the safety of the people in their respective countries by advancing their respective expertise;

DESIRING to facilitate and increase access to safe, effective and high quality medicines, and to contribute to quality improvement and safety in terms of control, with the help of leading experts from both countries in that field; and

RECOGNIZING that the European Pharmacopoeia and the Brazilian Pharmacopoeia (hereinafter referred to as "Pharmacopoeias") contribute to the quality of medicines and their components manufactured or distributed in each jurisdiction,

Have reached the following understanding and framework:

Section 1
General Principle

1. This Memorandum of Understanding ("hereinafter referred to as the "MOU") applies to the extent of the scope jointly decided by the Parties. The Parties acknowledge that each Party has jurisdiction over specific products, for which they may have different definitions.

2. This MOU is not intended to create any legally binding obligations under national or international laws between the Parties. This MOU does not restrict the Parties powers granted by the laws and regulations in their respective country/region to fulfill their respective responsibilities.

3. This MOU will be carried out in accordance with the respective laws and regulations of the respective country/region and subject to the availability of appropriated funds and personnel of the Parties.

4. Nothing in this MOU will be interpreted as conferring upon the receiving Party any rights to the information transmitted by the disclosing Party, whether that information is confidential or not.

Section 2
Purpose and area of cooperation

5. The purpose of this MOU is to strengthen relations and to promote cooperation on standard setting efforts of the Pharmacopoeias.

6. Within the framework of this MOU, the collaboration covers all products under scope of both Parties and their relevant activities, including, but not limited to:

   a. Active Pharmaceutical Ingredients (APIs);
   b. Excipients;
   c. Finished products;
   d. Monographs, general chapters, methods, tests and assays;
   e. Chemically-defined medicines;
   f. Herbal products;
   g. Blood products;
   h. Alternative medicines, including homeopathic, anthroposophic and anti-homotoxic medicines;
   i. Biological medicines;

j. Radiopharmaceuticals;

k. Medical gases;

l. Compounding products;

m. Reference Standards; and

n. Laboratory tests.

7. The Parties may, by mutual agreement, add to, or delete items from the list specified herein.

Section 3
Institutions and Contact Points

8. The Parties are the institutions responsible for management of this MOU. The Parties hereby designate the following contact points in order to communicate with each other and exchange information on the framework:

a. For EDQM:

EDQM Director

b. For ANVISA:

Office of International Affairs
and
Coordination of Pharmacopeia

9. The Parties agree to elaborate a Work Plan outlining the organizations' activities undertaken together under the area of cooperation described in Sections 2 and 4 of this MOU.

Section 4
Means of Cooperation

10. The Parties generally agree that, subject to the availability of funds and other resources, as determined by each Party in its sole discretion, to:

a. Authorize the adoption/adaptation of monographs, general chapters, methods, tests and assays described in one pharmacopoeia for the other;

b. Provide access to the newest edition of the compendia of both Pharmacopoeias, on such terms as the Parties shall agree;

c. Provide technical and scientific assistance and support;

d. Provide assistance and support in translation issues;

e. Organize scientific events, seminars, conferences, meetings, workshops and symposia;

f. Promote internship programs, technical visits and training, including on-site modules;

g. As permitted by the rules of each Party, admit the participation of representatives of the Parties, as observers or ad hoc advisors in the scientific and expert committees or working groups;

h. As permitted by the rules of each Party, share experiences and information on the development of monographs and methods;

i. Develop jointly projects for establishment, development and/or revision of monographs and methods;

j. As permitted by the rules of each Party, share experiences and information on the development of reference standards and run jointly projects for establishment, development and/or testing them;

k. Cooperate and share experiences in nomenclature issues, including generic, proprietary, non-proprietary, route, dosage form, drug and chemical names and code designations.

l. Cooperate in the context of global health and regulatory dialogues to develop and strengthen policy and regulatory approaches that highlight the importance of science-based public standards.

Section 5
Language

11. The minutes of the bilateral meetings and the Technical Working Group meetings will be drawn up in the English language by the end of each meeting. All the information and data to be exchanged will be in English.

Section 6
Financial Arrangements

12. Prior to the commencement of any activities under the MOU, the Parties shall prepare a written document that sets forth the responsibility, financial and technical, of each Party. Activities may begin only after such documentation has been approved by both Parties.

Section 7
Dispute

13. Any disputes arising from the interpretation and/or implementation of this MOU will be resolved amicably through consultations and good faith negotiation between the Parties.

Section 8
Confidentiality

14. The Parties understand that the information exchanged under this MOU may include information that is non-public in the country/region of the disclosing Party. The Parties will inform each other of the confidential nature of the information at the moment of exchange.

15. Both Parties understand that this non-public and confidential information is shared in confidence, and it is critical that the confidentiality of the information is maintained. Within the framework of this MOU, each Party commits to protect the confidentiality of all confidential and non-public information received from the other Party and not to disclose that information to any third party.

16. For the purpose of this MOU, the term "confidential information" means information submitted and listed as confidential by the disclosing Party, including commercial and financial confidential information, trade secret information, personal privacy information, law enforcement information or internal operational information and rules.

17. When information is exchanged under this MOU, it is understood that the Parties, as well as their respective staff, advisory committees' members and, when appropriate, external experts or organizations appointed by them, may have access to information that may be considered confidential.

18. The commitment to protect the confidentiality of information exchanged under this MOU will not prevent the Parties from using that information to carry out the tasks entrusted to them provided that such confidentiality is protected. The Parties may use information exchanged under this MOU to ground their health policy decisions.

19. The Parties confirm that they have the authority to protect the confidential information received during the execution of this MOU.

20. Each Party will take all necessary measures to inform the other of any effort made by an authority, judicial, legal or other, to obtain confidential information provided by one Party to the other.

21. If public disclosure of confidential information is required under the laws and regulations of its country/region or organisation, the receiving Party may decide whether such information will be disclosed or not through consultation with the disclosing Parties. If such information is disclosed, the receiving Party will take all appropriate legal measures to ensure that the information is disclosed in a manner that protects the information from subsequent unauthorized disclosure.

22. The Parties will take all necessary measures to inform each other of any changes to the laws, policies or procedures in their respective country/region that would affect the processing of confidential information received from the other Party.

23. The principles of confidentiality and restricted use mentioned above do not apply to information for which the receiving Party can clearly indicate and provide concrete evidence to the disclosing Party that:

a. the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the disclosing Party (as verified by written reports or other acceptable evidence); or

b. the information was already in the public domain or publicly known at the time of the disclosure by the disclosing Party; or

c. the information came into the public domain or was brought to public attention in the absence of any fault of the receiving Party; or

d. the information was made available to the receiving Party by a third party without breach of any legal confidentiality commitment; or

e. the information is the result of activities carried out independently by or on behalf of the receiving Party without having access to the information of the disclosing Party.

Section 9
Final Considerations

24. The Partners note that this Agreement:

a. does not affect the authority of the two organizations to carry out their regulatory responsibilities;
b. does not create any obligation to share information and that each Partner may decline to provide information to the other Partner.

25. Any disputes or disagreements with respect to the interpretation or implementation of the present Agreement will be resolved amicably by good faith negotiations between the Partners.

26. This Agreement is to commence on the date that Partners exchange signed copies of this letter, both in two original versions, in the English and Portuguese languages. In case of doubt between the Partners, the English version prevails.

Date: .....

Date: .....

For the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM)

Susanne Keitel, Ph. D.
Director

For the Brazilian Health Regulatory Agency (ANVISA)

Jarbas Barbosa da Silva Júnior, Ph.D.
Director and President