MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
THE U.S. PHARMACOPEIA (USP)
AND
THE BRAZILIAN HEALTH SURVEILLANCE AGENCY (ANVISA)
ON
COOPERATION OF THE PHARMACOPOEIAS

The Brazilian Health Surveillance Agency (hereinafter referred to as "ANVISA") and the U.S. Pharmacopeia (hereinafter referred to as USP) (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;

RECALLING good 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 products, 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 U.S. Pharmacopeia and the Brazilian Pharmacopoeia (hereinafter referred to as "Parties") contribute to the quality of products 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 countries to fulfill their respective responsibilities.

3. This MOU will be carried out in accordance with the respective laws and regulations of the two countries 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 Ingredient (API);
B. Excipients;
C. Finished products;
D. Monographs, general chapters, methods, tests and assays;
E. Chemical medicines;
F. Herbal products;
G. Blood products;
H. Alternative medicine, including homeopathic, anthroposophic and anti-homotoxic medicines;
I. Biological medicines;
J. Radiopharmaceuticals;
K. Medical gases;
L. K Medical devices;
M. Food;
N. Dietary Supplements;
O. Compounding products;
P. Reference Standards; and
Q. 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 USP:

USP-Brazil Office (Barueri, SP)
and
Global External Affairs, USP-U.S. (Rockville, MD)

B. For ANVISA:

Office of International Affairs - AINTE
and
Coordination of Pharmacopeia - COFAR

9. The Parties agree to create an annual Work Plan outlining the organizations' activities undertaken together under the area of cooperation described in Section 2 of this MOU.

10. The Parties commit to organize, within a period of time that will not exceed 30 days after the execution of this MOU, a Technical Working Group that will be responsible for ensuring the annual Work Plan is appropriately managed, including planning, funding, execution, and evaluation. A lead individual will be identified by both Parties.

11. The Parties agree to evaluate all activities annually to ensure they are meeting the stated goals and objectives.

Section 4. Means of Cooperation

12. The Parties generally agree that, subject to the availability of funds and other resources, as determined by each Party in its sole discretion, and further subject to the timely negotiation and execution of written agreements mutually agreeable to both Parties, to:

A. Authorize the discussion of adoption 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 Pharmacopeias (USP-NF, FCC, DSC and Brazilian Pharmacopeia), on such terms as the Parties shall agree in the Work Plan. The access can be extended to the National Health Surveillance System, including the laboratories of the National Network of Laboratories of Health Surveillance;

C. Provide technical and scientific assistance and support that improves access to quality-assured medicines, protects patients from poor quality products, and supports workforce development to strengthen countries' quality assurance capabilities

D. Provide reasonable 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. 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. Share experiences and information on the development of reference standards;

K. 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

13. The minutes of the bilateral meetings and the Technical Working Group meetings will be drawn up in Portuguese or English languages. Each Party will be solely responsible for the translation.

14. All the information and data to be exchanged can be in Portuguese or English languages. Each Party will be solely responsible for the translation.

Section 6. Financial Arrangements

15. 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

16. 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

17. The Parties understand that the information exchanged under this MOU may include information that is non-public in the country of the disclosing Party.

18. The Parties will inform each other of the confidential nature of the information at the moment of exchange.

19. 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.

20. 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.

21. 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.

22. 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.

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

24. 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.

25. If public disclosure of confidential information is required under the laws and regulations of its country, 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.

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

27. 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. Miscellaneous

28. This MOU will be effective upon its signature, and will remain in effect for a period of three (3) years.

29. Any Party may suspend or terminate the effect of this MOU by officially notifying the other Party with at least ninety (90) days' notice in writing.

30. This MOU will terminate automatically and immediately in the event of new laws and regulations affecting its implementation or making it incompatible with the status of the respective Parties. Any such termination will be immediately notified to the other Party.

31. This MOU may be modified or extended by mutual consent at any time by both Parties.

Signed in duplicate in city São Paulo – SP, Brazil, on August 1st 2018, in the Portuguese and English languages, all texts having equal validity. [In case of any divergence of interpretation of this MOU, the English text will prevail.]

For the United States Pharmacopeia

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

For the Brazilian Health Surveillance Agency of the Federative Republic of Brazil

Fernando Mendes Garcia Neto
Interim President and Director