Cooperation Arrangement between
the Government of Brazil, through the Brazilian Health Regulatory Agency ("ANVISA") and
the World Health Organization, through its Department of Essential Medicines and Health Products ("WHO")

The International Pharmacopoeia developed, maintained and published by the World Health Organization ("WHO")[1] comprises a collection of quality specifications for pharmaceutical substances (active ingredients and excipients) and dosage forms together with supporting general methods of analysis. Priority is given to medicines included in the WHO Model List of Essential Medicines and to medicines important for WHO health programmes which may not be included in other pharmacopoeias, e.g. new antimalarials. The International Pharmacopoeia is intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements.

The Brazilian Pharmacopoeia is a book of published and publicly available standards for pharmaceutical ingredients and finished medicinal products. It is prepared and published by ANVISA, Government of Brazil. It provides an authoritative statement of quality that a medicinal product is expected to meet during its period of use to the end of its shelf life.

In Brazil, the Pharmacopoeia is brought into force by Resolution of the Collegiate Board of Officers - RDC.

ANVISA and WHO, through its Department of Essential Medicines and Health Products, recognizing the importance of developing closer cooperation and exchange in the field of quality specifications for medicines, set out the following arrangements for the years 2019 to 2022, unless this Cooperation Arrangement is terminated earlier or renewed in accordance with its terms.

1. The main areas of cooperation the between ANVISA and WHO will be:

   a. General exchange of information on the quality specifications for medicines.

   b. Development of new monographs for pharmaceutical formulations of mutual interest.

[1] All activities ranging from development, maintenance to publication of *The International Pharmacopoeia*, including its Secretariat functions, have been implemented by WHO since its inception (Reference: WHA1.27, WHA3.10, WHA4.13, EB8:R40 and EB9.R95).

Cooperation may also take place between ANVISA and WHO outside the main areas of this Cooperation Arrangement where it is by mutual consent.

2. The aim of the cooperation is to expedite the process of elaboration and harmonization of monographs and to provide health specialists with specifications and analytical methods to assure safe and efficient medicines for pharmaceutical products identified jointly by ANVISA and WHO as described in this Cooperation Arrangement (the "Purpose").

3. Cooperation between the two organisations may take the following forms:

   a. A work plan and the sharing of draft monographs.

   b. Discussions on sharing information about pharmaceutical products of mutual interest intended for publication in the Brazilian Pharmacopoeia and International Pharmacopoeia (together referred to as the Pharmacopoeias)

   c. Where one of the Pharmacopoeias has an item on its work programme for which the other Pharmacopoeia already has a published monograph, the Pharmacopoeia wishing to prepare a specification may use the other Pharmacopoeia's published monograph as a starting point. Relevant supporting reports, recommendations of expert advisory groups and other associated data may be provided to enable validation.

   d. Where a new monograph for a dosage form is of mutual interest to ANVISA and WHO, development work may be shared between them. An initial draft specification is developed by one Pharmacopoeia and then evaluated for both Pharmacopoeias through their respective consultation procedures.

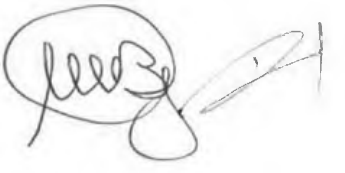
   e. Validation of Brazilian Pharmacopoeia methods at WHO Quality Assurance Laboratories.

   f. Discussions on the procurement of samples of materials of mutual interest.

   g. Publication of harmonised specifications in the Brazilian Pharmacopoeia and the International Pharmacopoeia.

   h. The two participants may acknowledge this joint effort within their publications and by other means, but not in connection with the promotion of any commercial products or service.

4. Each participant is the copyright owner of its respective Pharmacopoeia, also with the inclusion of materials from the other participant and/or materials jointly developed with the other participant under this Cooperation Arrangement.



5. Any cooperative activity as outlined above shall be subject to the availability of sufficient financial and human resources for that purpose, as well as each participant's programme of work, priority activities, internal rules, regulations, policies, administrative procedures and practices. Each participant shall be solely responsible for the manner in which it carries out, and (unless otherwise agreed) for funding, its part of the cooperative activities under this Cooperation Arrangement. WHO and ANVISA will be responsible for the travel and living expenses of their own respective staff on any visits that take place as a consequence of this Cooperation Arrangement.

6. In respect of any information marked as confidential it may receive directly or indirectly from the other participant, each participant shall take all reasonable measures to ensure that the confidential information shall not be used for any purpose other than the Purpose and shall not be disclosed to any person who does not have a need to know for the Purpose and is not bound by similar obligations of confidentiality and restrictions on use as contained in this Cooperation Arrangement. This clause 6 does not, however, apply to confidential information: i) which is in or enters the public domain other than by breach of this Cooperation Arrangement; (ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality; and (iii) which a participant can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the confidential information from the other participant.

7. This Cooperation Arrangement comes into effect on the last date of its signature by the participants and will continue in effect until 31 December 2022, unless terminated earlier by either participant pursuant to the following paragraph.

8. Either participant may terminate this Cooperation Arrangement at any time upon giving six months' written notice of termination to the other participant. Notwithstanding the foregoing, it is agreed that any termination of this Cooperation Arrangement by a participant shall be without prejudice to: (i) the orderly completion of any ongoing cooperative activity; and (ii) any other rights and obligations of the participants accrued prior to the date of termination.

9. Upon expiration of the initial term, this Cooperation Arrangement will automatically renew for one or more periods of three years each, subject always to the right of either participant to terminate this Cooperation Arrangement at any time with a six months' prior written notice in accordance with paragraph 8 above.

10. The content and operation of this Cooperation Arrangement will be reviewed by the participants after one year from its coming into effect and at such intervals after that as approved between ANVISA and WHO.

11. Nothing in or relating to this Cooperation Arrangement is intended to create binding international rights or obligations and nothing in this Cooperation

Arrangement shall be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement and/or as submitting WHO to any national court jurisdiction.

12. In the unlikely event that any difference shall arise in the interpretation or application of this Arrangement, the matter shall be submitted to the duly authorized representative of the legal body of the ANVISA/Ministry of Health of Brazil and to the Assistant Director General for Access to Medicines, Vaccines and Pharmaceuticals of WHO, who will finally settle the question personally and jointly or through their duly authorized representatives.

Signed on May 15, 2019 in English.

For the Government of Brazil
through Brazilian Health Regulatory Agency – ANVISA
William Dib
Director and President

For the World Health Organization
Mariângela Simão
Assistant Director General
Access to Medicines, Vaccines and Pharmaceuticals