Agreement for collaboration on Information Exchange Between The Agência Nacional de Vigilância Sanitária of Republica Federativa do Brasil And The Agence Nationale de sécurité du médicament et des produits de santé de la République Française

The Agência Nacional de Vigilância Sanitária of Republica Federativa do Brasil (hereinafter referred as to the "ANVISA") and the Agence Nationale de sécurité du médicament et des produits de santé de la République Française (hereinafter referred as to the "ANSM")
(hereinafter jointly referred to as the "Sides"),

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

INTENDING to establish a framework for the exchange of information between the Sides in the field of medicine, including raw materials for pharmaceutical use, biological products (blood, tissues and cells), medical devices and cosmetic products, in order to promote such exchanges;

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

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

Have reached the following understanding:

Paragraph 1: General Principle

1. This agreement for collaboration ("hereinafter referred to as the "agreement for collaboration") applies to information exchange to the extent jointly decided by the Sides. Within the framework of this agreement for collaboration, the collaboration covers all products regulated by both Sides and their relevant activities. The Sides acknowledge that each Side has jurisdiction over specific products, for which they may have different definitions.

2. This agreement for collaboration is not intended to create any legally binding obligations to share confidential information between the Sides. This agreement for collaboration does not restrict the Sides powers granted by the laws and regulations in their respective countries to fulfill their respective responsibilities.

3. This agreement for collaboration 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 Sides.

4. Are excluded of the scope of the agreement for collaboration and in any case will not be exchanged :

   - Informations relating to personal privacy of an individual or the secrecy of personal files such as medical files,

   - information relating to European centralised procedure files (e.g. files under assessment before opinion granted by the Committee for Medicinal Products for Human Use - CHMP),

   - confidential information shared by a third party within the framework of any confidentiality comitment.

5. Nothing in this agreement for collaboration will be interpreted as conferring upon the receiving Side any rights to the information transmitted by the disclosing Side, whether that information is confidential or not.

Paragraph 2: Information exchange

1. When information is exchanged under this agreement for collaboration, it is understood that the Sides, 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.

2. The commitment to protect the confidentiality of information exchanged under this agreement for collaboration will not prevent the Sides from using that information to carry out the tasks entrusted to them provided that such confidentiality is protected.

3. The Sides may use information exchanged under this agreement for collaboration to ground their health policy decisions.

4. Working-level consultation meetings will be held annually, to discuss specific details of information exchange through mutual consent of the Sides, except in a case that the Sides decide differently through mutual consent. It could be face to face meetings during international conference or by video or tele-conference.

Paragraph 3: Definition of confidential information

For the purpose of this agreement for collaboration, the term "confidential information" means information submitted and listed as confidential by the disclosing Side, trade secret information, commercial and financial information and in general, to information protected by Brazilian or French laws and regulations.

Paragraph 4: Respect for Information confidentiality

1. The Sides understand that the information exchanged under this agreement for collaboration may include information that is non-public in the country of the disclosing Side. The Sides will inform each other of the confidential nature of the information at the moment of exchange. Within the framework of this agreement for collaboration, each Side commits to protect the confidentiality of all confidential information received from the other Side and not to disclose that information to any third party.

2. The Sides confirm that they have the authority to protect the confidential information received during the execution of this agreement for collaboration.

3. Each Side 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 Side to the other.

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

5. The Sides 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 Side.

Paragraph 5: Persons or institutions to which confidential information may be transmitted

1. Provided that the provisions of Paragraphs 6 and 7 of this agreement for collaboration are complied with, information provided by one Side to the other may be transmitted to the staff and the advisory committee members of the receiving Side, or to experts or external institutions appointed by the receiving Side.

2. Disclosure of confidential information should be strictly limited to persons or institutions mentioned in subparagraph 1 who need to be aware of the confidential information directly for work purposes, to issue advice, to strengthen their expertise or to work on the issue that prompted the request for disclosure of confidential information.

3. Any other use of confidential information is not allowed.

Paragraph 6: Respect for information confidentiality by the Sides and their employees

1. The Sides will ensure that confidential information exchanged under this agreement for collaboration will not be disclosed, circulated or commented upon in any way by their employees.

2. The Sides will ensure that their employees exercise professional discretion and observe their duty of confidentiality.

Paragraph 7: Respect for confidentiality by experts, external organizations and their staff

The Sides will take all necessary measures to prevent the disclosure or use of confidential information by advisory committee members, experts or external organizations and their staff who have been appointed by the receiving Side for the purpose of achieving its mission and who have had access to confidential information transmitted within the framework of this agreement for collaboration.

Paragraph 8: Limits on confidentiality and restricted use

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

a) the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the disclosing Side (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 Side; or

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

d) the information was made available to the receiving Side 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 Side without having access to the information of the disclosing Side.

Paragraph 9: Duration of confidentiality commitment

1. The confidentiality commitment in relation to confidential information transmitted within the framework of this agreement for collaboration is not limited in time.

2. Notwithstanding the termination of this agreement for collaboration, the Sides will continue to protect confidential information against unauthorized disclosure or unauthorized use.

Paragraph 10: Discretion on non-confidential information

The Sides will protect all information received within the framework of this agreement for collaboration, which is not considered confidential information but is not in the public domain, from any unauthorized public disclosure. Such information will not be published in any form, including on the Internet.

Paragraph 11: Information enquiries

The Sides will send their information enquiries to the following representatives:

a) For the French Side, the person designated by ANSM in charge of the relationship with ANVISA,

b) For the Brazilian Side, the Head of the International Affairs Office.

Paragraph 12 : Areas of cooperation

The Participants having reached the above understanding will:

establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Side, including: policies, practices, standards, laboratory testing, pre-market assessment, post-market vigilance, market compliance, regulation of

manufacturers, regulation of clinical trials and requirements for the regulation of therapeutic products; and

undertake collaborative activities, including, when appropriate and after approval by each side for each request, the exchange of personnel.

Paragraph 13: Financial arrangements

Each Side will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under the agreement for collaboration.
In case of exchange of personnel, a specific written agreement regarding the expenditure linked to each mission will be signed by both sides.

Paragraph 14: Dispute Resolution

Any disputes arising from the interpretation and/or implementation of this agreement for collaboration will be resolved amicably through consultations between the Sides.

Paragraph 15: Amendment

Any amendment to this agreement for collaboration will be made by mutual written consent of the Sides.

Paragraph 16: Termination

1. This agreement for collaboration may be terminated at any time, by either Side, upon two (2) months' notice by recorded delivery with acknowledgment of receipt.

2. This agreement for collaboration 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 Sides. Any such termination will be immediately notified to the other Side.

Signed in duplicate, in the English language, which will be the valid text in case of any divergence of interpretation of this agreement.

In Brasília,
Date: 11.12.19

In Saint-Denis,
Date: 16 DEC. 2019

For Agência Nacional de Vigilância Sanitária of República Federativa do Brasil

Dr William Dib

For Agence Nationale de sécurité du médicament et des produits de santé de la République Française

Dr Dominique Martin