



Memorandum of Understanding (MoU)
Between
The Egyptian Drug Authority (EDA)
And
The Brazilian Health Regulatory Agency (ANVISA)

This Memorandum of Understanding (hereinafter referred to as "MoU")

was signed on the date of30-07-2025..... by and between:

1. The Egyptian Drug Authority (EDA) and its address is: 51 wezart el zeraa st. – Agouza – Giza, Egypt, legally represented by Dr. Ali ElGhamrawy in his capacity as Chairman of the Egyptian Drug Authority (**EDA or First Party**);
2. The Brazilian Health Regulatory Agency (ANVISA) and its address is: SIA Trecho 5, área Especial 57, Brasília, DF, CEP 71205-050, legally represented by Dr. Rômison Rodrigues Mota in his capacity as Acting Director President of ANVISA (**ANVISA or Second Party**).

(Hereinafter referred to individually as "Party" and collectively as "Parties")

Preamble

Whereas the Parties hereto **desire** to strengthen and further develop cooperation between the two countries in the field of medical products and devices;

Believing that such cooperation would serve common interests and contribute to the development of the pharmaceutical products in both countries;

As per previous meetings held between the parties on the 17th of January 2022 Virtually and on the 5th of June 2022 physically in Cairo;

Whereas the Parties confirmed their legal capacity to sign this MoU;

The Parties have reached the following understanding:

Article (1)

The Preamble is an integral part of this MoU.



Article (2) Objectives

The purposes of this MoU are to strengthen scientific, industrial, and technological capabilities of Both Parties, to broaden and expand relations between the scientific, industrial, and technological communities of both Countries, and to promote cooperation in areas of mutual benefit.

Article (3) Areas of Cooperation

All forms of cooperation set forth in this MOU should be implemented in accordance with the internal legislations of Both Parties. Cooperation may include the intention of both parties to:

- 1) Embark on several capacity building activities including virtual and face-toface training and workshops.
- 2) Share experiences regarding alerts, recalls, and reports of non-compliance.
- 3) Share knowledge and experiences related to pharmaceutical regulation, pricing, Medical Devices regulation, and clinical trials evaluation.
- 4) Engage in several activities and projects in order to share knowledge, expertise, and ideas.

Article (4) Data Exchange

Information and Data shall be exchanged between the parties to this MOU, in addition to any other data in the same area of cooperation that may be required, as long as it does not conflict with the data security and confidentiality policies of either party, through formal written communications.

Article (5) Confidentiality of Information

1. Confidentiality of "Data and Information" pertains to all commercial and technical information that have been disclosed by one of the parties to the other party, whether it is communicated in writing, orally or electronically.
2. All information exchanged under this MoU shall be considered as confidential and shall not to disclose to any third party without a formal written communication from the disclosing party, such information shall not be used for other purposes except for the purposes intended under this MOU.
3. The Parties confirm that they have the authority to protect the confidential information received under this MoU.

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هيئة الدواء المصرية



4. 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.

Article (6) Limits on Confidentiality

The principles of confidentiality 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.

Article (7) Contact Points

The liaison officials in relation to this MoU are:

- (a) EDA: the General Administration for Public Affairs and International Cooperation (foreign.affairs@edaegypt.gov.eg);
- (b) ANVISA: the International Affairs Office (rel@anvisa.gov.br) and the Coordination of International Cooperation (cooperacao@anvisa.gov.br).

Article (8) Facilitation of Cooperation

1. In furtherance of the terms of this MoU, and in accordance with the applicable laws, rules, regulations, and national policies in each country, both Parties should endeavor to work together to assist each other to facilitate the implementation of this MoU.
2. Each Party should facilitate, in accordance with its laws, rules, regulations, and national policies, the entry into and exit of personnel and equipment, as needed to carry out activities, projects, and programs within the framework of this MoU.



Article (9) Status

This MoU is not intended to create any legally binding obligations to share confidential information between the Parties and it does not restrict the Parties' powers granted by the laws and regulations in their respective countries to fulfill their respective responsibilities.

Article (10) Financial Obligations

1. The financial arrangements to cover expenses for the cooperative activities carried out within the framework of this MoU should be mutually accepted by both Parties on a case-by-case basis and subject to the availability of funds and resources, and in accordance with applicable laws and regulations within the Country of each Party.
2. This MoU does not constitute any obligation of funds by either Party.

Article (11) Amendments

1. Either Party may request in writing to amend this MoU.
2. Any amendment accepted by both Parties should be in writing and shall form an integral part of this MoU.
3. Such amendments shall enter into force on a date as determined by both Parties.
4. Any revision or modification should not prejudice the rights and obligations arising from or based on this MoU before or up to the date of such revision or modification.

Article (12) Consultation And Settlement of Disputes

1. Both Parties accept to consult periodically and at the request of either Party concerning the implementation of this MoU
2. Any dispute between both Parties arising out of the interpretation, or application of any of the articles of this MoU should be settled amicably through mutual consultation or negotiations between both Parties, without reference to any third party or international tribunal.

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Article (13) Entry Into Effect & Duration

1. This MoU shall enter into force for a period of 5 years, commencing from the date of signing, and may be renewed for five (5) more years, unless either Party formally notifies the other Party of its decision not to renew by giving a thirty (30) day written notice to the other Party.
2. Either Party may terminate this MoU by giving thirty (30) day written notice to the other Party. The Parties understand that, notwithstanding such termination, the dispositions on confidentiality and the restrictions on use contained in this MoU shall survive the termination.
3. Unless otherwise accepted by both Parties in writing, the termination of this MoU should not affect the implementation of any cooperative activity carried out under this MoU and not yet completed at the time of its termination.

IN WITNESS WHEREOF, the Parties, have signed this MoU in duplicate originals, in the Arabic, English and Portuguese languages.


ROMISON RODRIGUES MOTA
For the Brazilian Health Regulatory
Agency (ANVISA)

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DIRETOR
DIREA/ANVISA


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