

# MINISTÉRIO DAS RELAÇÕES EXTERIORES

## Guia de Mensagem e Documentação - GMD

Caráter OSTENSIVO	Prioridade NORMAL	Destinatário <b>Ao ministro João Paulo Ortega Terra Chefe de Assuntos Internacionais</b>  <b>ANVISA, SIA trecho 5, área especial 57. Relações Internacionais (AINTE)</b>
Distribuição DCID		
Número <b>49</b>	Data 20/11/19	

Senhor chefe,

Encaminho, em aditamento à MO 151, de 20/11/19, o Memorando de Entendimento entre a Autoridade de Alimentos e Medicamentos da Arábia Saudita (SFDA) e a Agência Nacional de Vigilância Sanitária (ANVISA) sobre Cooperação no Campo de Produtos de Saúde e Cosméticos, assinado em Riad, no dia 30 de outubro de 2019.

Atenciosamente,  
Divisão de Cidadania DCID



**MEMORANDUM OF UNDERSTANDING  
BETWEEN**

**THE SAUDI FOOD AND DRUG AUTHORITY (SFDA)  
IN THE KINGDOM OF SAUDI ARABIA**

**AND**

**THE BRAZILIAN HEALTH REGULATORY AGENCY  
(ANVISA)**

**IN THE FEDERATIVE REPUBLIC OF BRAZIL**

**ON COOPERATION IN THE FIELD OF HEALTH PRODUCTS  
AND COSMETICS**

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## **Parties**

The parties to this Memorandum of Understanding (MOU) are:

- (a) The Saudi Food and Drug Authority (SFDA) in the Kingdom of Saudi Arabia, an independent body corporate established under the Saudi Council of Ministers resolution no (1) dated 07/01/1424 H, and
- (b) The Brazilian Health Regulatory Agency (“ANVISA”) in the Federative Republic of Brazil, an independent entity established by the Law 9.782/99 of the Federative Republic of Brazil, hereinafter collectively referred to as “Parties” and individually referred to as “the party”.

## **Purpose**

Recognizing the importance of ensuring quality, safety and efficacy of health products and cosmetics to protect and promote health of their respective people in addition to encourage, strengthen, promote, develop and facilitate the cooperation between both countries; and Desiring to set up a framework for a long-term cooperation between the Parties and to facilitate the exchange of information, experiences and visits, the Parties have reached the following understanding:

### **ARTICLE 1. Areas of Cooperation**

- 1) The Parties hereby confirm their intention to promote cooperation in the areas of health products and cosmetics.
- 2) For the purpose of this Memorandum, it is understood that health products include active pharmaceutical ingredients, medicines, vaccines, medical devices, diagnostics, assistive products, cell-and gene-based therapies.
- 3) The cooperation between the parties may include the following fields:
  - (a) good regulatory practices and alignment with international standards and regulations;
  - (b) pre-marketing assessment, including requirements and inspections of manufacturers;
  - (c) market compliance and post-marketing surveillance, including pharmacovigilance and

vigilance of other health products and cosmetics; or

(d) Any other fields of regulatory cooperation that may be jointly decided upon by the Parties.

#### **ARTICLE 2. Forms of Cooperation**

The mutual cooperation between the Parties may be undertaken through the following means:

- 1) Exchange of information, regulatory practices and scientific experience about the areas referred to in Article 1 above;
- 2) Exchange of training, according to work programs to be mutually agreed.
- 3) Exchange of information on developments in international fora related to the regulation of health products and cosmetics;
- 4) Any other forms of cooperation that may be jointly decided upon by the Parties.

#### **ARTICLE 3. Confidentiality**

- 1) The Parties agree that in case the information exchanged between them is to be treated as confidential this should be specified in the communication to the other.
- 2) Neither Party may disclose or distribute any confidential information received or generated under this Memorandum of Understanding to any third party or to the public, without prior written consent of the other Party.

#### **ARTICLE 4. Financial Arrangements**

Each Party is responsible for the administration and expenditure of its own resources associated with activities under this Memorandum of Understanding. The costs of any assistance provided by either Party at the request of the other Party will be borne by the requesting Party, unless otherwise jointly decided by the Parties.



#### **ARTICLE 5. Working Level Consultations**

The Parties may establish a working-level consultation or a technical panel of specialists to discuss priority areas of interests and cooperative activities under this Memorandum of Understanding.

#### **ARTICLE 6. Contact Points**

1) The Parties hereby designate the following contact points for the ongoing communication between the Parties to efficiently implement this Memorandum of Understanding:

- For SFDA: The Director of International Cooperation Department (email: [ICD@sfda.gov.sa](mailto:ICD@sfda.gov.sa) phone +966112038222) (ext. 2050);

- For ANVISA: The Head of the International Affairs Office (email: [rel@anvisa.gov.br](mailto:rel@anvisa.gov.br); phone +5561 34625404).

2) One Party should inform the other of any subsequent change of the above contact points name, title and contact information within a maximum period of thirty (30) days.

#### **ARTICLE 7. Settlement of Disputes**

Any differences, controversies or disputes arising from the interpretation and/or implementation of this Memorandum of Understanding are to be resolved amicably through consultations between the Parties, for which the English text of this MoU shall be treated as the authentic text.

#### **ARTICLE 8. Validity, Amendment and Termination**

1) This Memorandum of Understanding will come into effect on the date of its signature by the Parties and will remain effective for a period of five (5) years. Thereafter the Parties may extend this MoU by exchange of letters for a further period of five (5) years, unless

either Party notifies the other Party in writing of its intention to terminate this Memorandum of Understanding 90 days in advance.

- 2) The termination of this Memorandum of Understanding will not affect the duration or validity of any cooperative activities under this Memorandum of Understanding which are in progress at the time of the notification of the termination of this Memorandum of Understanding.
- 3) This Memorandum of Understanding may be amended by mutual written consent of the Parties.
- 4) All correspondence regarding this Memorandum of Understanding will be exchanged in English Language.

#### **ARTICLE 9. Intellectual Property Rights**

- 1) Definition: "Intellectual Property" includes but is not limited to all data, syllabi, lecture notes, lectures, presentation materials, case studies, templates, reports and other written, recorded, photographic or visual materials or other intellectual property
- 2) Ownership and Licenses as between the Parties, each Party shall retain ownership of its separately or previously developed Intellectual Property.
- 3) The Parties agree that no party shall use, copy or distribute any of the other party's materials without prior written permission.

#### **ARTICLE 10. General Provisions**

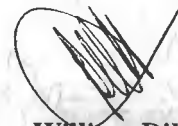
- 1) This Memorandum of Understanding will be carried out within the framework of the respective laws, regulations, institutional guidelines and any other applicable legal provisions of each Party.
- 2) This Memorandum of Understanding is not intended to create any legally binding obligations between the Parties under national or international laws.

Signed at \_\_\_\_\_ on this \_\_\_\_ day of \_\_\_\_\_, 2019 in two duplicate in English.



**Hisham bin Saad Aljadhey**

**CEO  
The Saudi Food and Drug Authority  
Kingdom of Saudi Arabia**



**William Dib**

**Director President  
The Brazilian Health Regulatory  
Agency  
Federative Republic of Brazil**

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