MEMORANDUM OF UNDERSTANDING

AMONG

THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION, THE MINISTRY OF INDUSTRY AND TRADE OF THE RUSSIAN FEDERATION,

THE FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE (RUSSIAN FEDERATION),

THE NATIONAL HEALTH REGULATORY AGENCY(ANVISA)OF THE FEDERATIVE REPUBLIC OF BRAZIL,

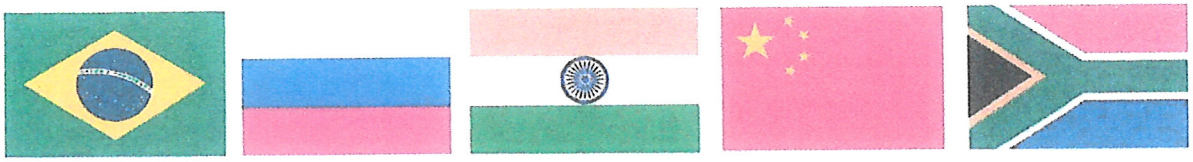
THE CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(CDSCO) OF THE REPUBLIC OF INDIA,

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA) OF THE PEOPLE'S REPUBLIC OF CHINA

AND

THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) OF THE REPUBLIC OF SOUTH AFRICA

ON COOPERATION IN THE FIELD OF REGULATION OF MEDICAL PRODUCTS FOR HUMAN USE



PREAMBLE

TAKING into account the Sanya Declaration of the III BRICS Summit of April 14,2011 underscoring the firm commitment of the Heads of State and Government to strengthen dialogue and cooperation in the fields of social protection, decent work, gender equality, youth and public health;

RECOGNIZING that, despite the diversity, the BRICS countries face a number of similar public health challenges, including inequitable access to health services and medicines for communicable and non-communicable diseases and growing health costs;

CONSIDERING the need to overcome barriers to access to affordable, efficacious, safe and quality medical products, vaccines and other health technologies;

BEARING in mind the need to have further and a wide-scope collaboration between the Ministry of Health of the Russian Federation, the Ministry of Industry and Trade of the Russian Federation, the Federal Service for Surveillance in Healthcare (Russian Federation), the National Health Regulatory Agency (ANVISA) of the Federative Republic of Brazil, the Central Drugs Standard Control Organization (CDSCO) of the Republic of India, the National Medical Products Administration (NMPA) of the People's Republic of China, the South African Health Products Regulatory Authority (SAHPRA) of the Republic of South Africa, (hereinafter jointly referred to as the "Parties" and individually referred to as "Party");

INTENDING to establish cooperation in the field of regulation of medical products for human use namely, active pharmaceutical ingredients, medicines, including traditional medicines, biological products, diagnostics and medical devices;

DESIRING to promote exchange of information and cooperation in areas pertinent to regulation of the aforementioned medical products and the relevant administrative and regulatory matters within the jurisdiction of the Parties;

CONSIDERING that the cooperation in the field of medical products regulation can facilitate access to safe, affordable, efficacious and quality medical products;

In line with the principles of equality, reciprocity and common benefit, the Parties share the intent to cooperate and have reached the following Memorandum of Understanding, herein after referred to as MoU.

PARAGRAPH 1

SCOPE

I. The Parties intend to promote and develop cooperation in the field of medical products regulation within the respective jurisdictions in the manner set out in this MoU on the basis of the principles of equality, reciprocity and common benefit.

II. The Parties may conclude separate agreements, if required, to govern specific areas of cooperation.

PARAGRAPH 2

AREAS OF CO-OPERATION

The cooperation between the Parties will take place in the following areas:

a) Medical products regulation;

b) Good Manufacturing Practices regulation and overseas inspections;

c) Bioequivalence and bioavailability studies regulation;

d) Clinical trial regulation;

e) Medical devices and diagnostics regulation;

f) Regulation of active pharmaceutical ingredients (APIs);

g) Regulation of biological products;

h) Pharmacopoeia;

i) Quality of medical products;

j) Pharmacovigilance and medical devices vigilance;

k) Any other areas of common interest.

PARAGRAPH 3

FORMS OF COOPERATION

Cooperation between the Parties may be carried out in the following forms among others:

a) Establishment of technical working groups, including formal, informal and electronic working groups;

b) Sharing of regulatory experience and best practices;

c) Exchange of regulatory information, including quality and safety alerts among the Parties and any other areas of common interest;

d) Visits among representatives of the Parties to get to know their working procedures and regulatory processes;

e) Participation in national and international events organized by the Parties;

f) Cooperation at international fora;

g) Exchange of experts for capacity building and;

h) Facilitation of regulatory landscape to promote R&D and adaptation through technology transfer of innovative medical products, including in the context of concerns such as anti-microbial resistance.

PARAGRAPH 4

MEANS OF COOPERATION

I. The Parties intend to engage on a continual basis through virtual and related modes of communication and will endeavor to meet at least once annually;

II. The annual meetings may be held in any of the five member countries of BRICS or in a third country, at the margins of international meetings, or by video conference as may be agreed to and with the participation of all five Parties;

III. English will be used as the working language for the annual meeting.

PARAGRAPH 5

CONTACT INFORMATION

I. Information exchanges related to the scope of this MoU will be sent through the following contact points of the Parties, which will be the official channel of communication for the Parties:

a) From the Russian Party: the Head of the Department of Pharmaceutical and Medical Industry Development of the Russian Ministry of Industry and Trade at glebushkina@minprom.gov.ru; the International Cooperation Department of the Federal Service for Surveillance in Healthcare at international@roszdravnadzor.ru; Deputy Director, Department of Medicines Circulation Regulation and Medical Devices, MoH of Russia KamaletdinovaAA@minzdrav.gov.ru,CHernyshevaEV@minzdrav.gov.ru; Deputy Director, Department of International Cooperation and Public Relations, MoH of Russia SoninOV@minzdrav.gov.ru;

b) From the Brazilian Party: The Head of the International Affairs office of ANVISA, rel@anvisa.gov.br;

c) From the Indian Party: The Drug Controller General of India of the Central Drugs Standard Control Organization at internationalcell@cdsco.nic.in; dci@nic.in;

d) From the Chinese Party: The Director General of Department of Science, Technology and International Cooperation at qinxl@nmpa.gov.cn; zhangying@nmpa.gov.cn;

e) From the South African Party: the Office of the Chief Executive Officer at boitumelo.semete@sahpra.org.za and the Office of the Chief Regulatory Officer at portia.nkambule@sahpra.org.za; Legal Regulatory Advisor at

bongani.ngcobo@sahpra.org.za .

II. The Parties will immediately inform each other, by e-mail, of any subsequent changes regarding their contact points for the purposes of this MoU.

PARAGRAPH 6

CONFIDENTIALITY AGREEMENT

I. If the information exchanged between the parties is considered as confidential, such exchange will be carried out in accordance with the legislation of the States of the Parties and international treaties to which the States of the Parties are Participants.

PARAGRAPH 7

FINANCIAL ARRANGEMENTS

I. Each Party will bear its own costs in relation to the implementation of the activities under this MoU.

PARAGRAPH 8

RESOLUTION OF DIFFERENCES

Any differences arising from the interpretation and/or implementation of this MoU will be resolved amicably through consultations between the Parties.

PARAGRAPH 9

COMMENCEMENT, MODIFICATION AND TERMINATION

I. The present MoU is not an international treaty and does not create any rights and obligations under international law.

II. Activities under this MoU may commence upon signature by all the parties and will continue for five (5) years. This MoU will be renewed automatically for further periods of 5 years if there are no objections from the parties.

III. This MoU may be modified with the written consent of all the Parties.

IV. Any amendments to this MoU will be presented and negotiated by the Parties, in the form of an addendum, and its entry into effect will follow the same requirements of this

MoU.

V. This MoU may be suspended or terminated by any Party, in whole or in part, by giving six months' written notice in advance through the official channels to all the other Parties of its intention to suspend or terminate this Memorandum. The suspension or termination of this MoU by one Party does not affect the remaining Parties.

VI. The termination of this MoU will not affect the completion of any project undertaken by the Parties prior to the termination of the MoU, or the full execution of any cooperative activity that has not been fully executed at the time of termination, unless otherwise agreed upon by the Parties.

VII. Any additional matters not covered by this MoU will be resolved by means of friendly mutual consultation on the basis of consensus among the Parties. This MoU will be subject to revision upon request of any of the Parties or in case of an extension of the scope of this MoU.

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the National Medical Products Administration (NMPA) of the People's Republic of China

Signatory's Name: LI Li
Signatory's Title: Commissioner
Signed in Beijing (place) on the 29 (date) of 12 (month) of 2023

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the Ministry of Health of the Russian Federation

Signatory's Name: Sergei Glagolev
Signatory's Title: Deputy Minister
Signed in Moscow (place) on the 6th (date) of 12 (month) of 2023.

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the Ministry of Industry and Trade of the Russian Federation

Signatory's Name: Vasily Osmakov
Signatory's Title: First Deputy Minister
Signed in Moscow (place) on the 12 (date) of 12 (month) of 2023.

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the Federal Service for Surveillance in Healthcare (Russian Federation)

Signatory's Name: Alla Samoylova
Signatory's Title: Head of Roszdravnadzor
Signed in Moscow (place) on the 8 (date) of 12 (month) of 2023.

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the National Health Regulatory Agency (ANVISA) of the Federative Republic of Brazil

Signatory's Name: Antonio Barra Torres
Signatory's Title: Director-President
Signed in BRASILIA (place) on the 1ST (date) of Feb. (month) of 2024.
BRAZIL

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

For the Central Drugs Standard Control Organization (CDSCO) of the Republic of India

Signatory's Name: RAJEEV SINGH RAGHUVANSHI
Signatory's Title: DRUGS CONTROLLER GENERAL (INDIA)
Signed in New Delhi (place) on the 18th (date) of 12th (month) of 2023.

the Memorandum of Understanding on Cooperation in the field of Regulation of Medical Products for Human Use
among drug regulatory authorities

In witness whereof, the undersigned have signed this MoU in seven copies in the English language.

15/11/2023

For the South African Health Products Regulatory Authority (SAHPRA) of the Republic of South Africa

Signatory's Name: Dr Boitumelo Semele - Nekhothele
Signatory's Title: Chief Executive Officer
Signed in SAHPRA (place) on the 15 (date) of 11 (month) of 2023.