



**MISSION PERMANENTE DU BRESIL AUPRES DE L'OFFICE DES NATIONS UNIES
ET DES AUTRES ORGANISATIONS INTERNATIONALES A GENEVE**

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The Permanent Mission of Brazil to the United Nations Office and other International Organizations in Geneva presents its compliments to the Office of the United Nations High Commissioner for Human Rights and has the honor to refer to the joint communication OL BRA 10/21, dated 14 October 2021, from the Chair-Rapporteur of the Working Group on the issue of human rights and transnational corporations and others business enterprises, and others.

The Permanent Mission of Brazil in Geneva would like to forward the attached observations of the Government of Brazil regarding the aforementioned letter.

The Permanent Mission of Brazil in Geneva avails itself of this opportunity to renew to the Office of the United Nations High Commissioner for Human Rights the assurances of its highest consideration.



Geneva, 19th October, 2021

*To the Office of the United Nations High Commissioner for Human Rights (OHCHR)
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ANNEX

OBSERVATIONS FROM THE GOVERNMENT OF BRAZIL REGARDING LETTER OL BRA 10/2021 (10/14/2021)

Regarding the aforementioned joint communication sent by the Working Group on the issue of human rights and transnational corporations and others business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights, the following information has been received from the Ministry of External Relations:

- *The views of the Brazilian Government on the proposed temporary waiver of certain COVID-19 TRIPS protection*

In the TRIPS Council, Brazil has supported an evidence-based discussion that results in effective benefits to combat the pandemic. Since the beginning of the negotiation phase at the WTO, we have been promoting solutions that contribute in practice to the increase in the production and the dissemination of vaccines and medicines, as well as to the increase in the national production of these goods. Brazil has acted constructively and has sought to contribute to achieving effective results (in terms of concrete access to vaccines and medicines) and timely (in view of the pandemic's sanitary urgency).

In this regard, please find below the joint Press Release published by the Ministries of Economy, Health and External Relations, on September 4th, 2021:

[QUOTE]

Brazil co-sponsors initiative at the WTO to expand the production and distribution of vaccines

Brazil will co-sponsor, together with Australia, Canada, Chile, Colombia, Ecuador, New Zealand, Norway and Turkey, an initiative that advocates the immediate engagement of the World Trade Organization (WTO) in negotiations for the expansion of production and distribution of vaccines and of drugs that can contribute to overcoming the Covid-19 pandemic. The initiative entitled "Expanding WTO Action in Global Efforts for the Production and Distribution of Vaccines and Other Medical Products Against Covid-19" converges with the historical Brazilian positions on the matter and with the search for responsible, transparent and effective solutions that Brazil has been promoting in international forums in response to the pandemic.

The initiative encourages the new Director General of the WTO, Ngozi Okonjo-Iweala, to mediate contacts between developers and manufacturers of vaccines and other medical equipment, with a view to: i) ensuring the identification and use of installed capacity for the production of these medicines; ii) facilitate the execution of licensing agreements for the transfer of technology, expertise and know-how; and iii) identifying and consensually resolving any commercial barriers to the production and distribution of these products, including those related to intellectual property.

The proposal not only responds to the need to generate consensus that has always guided Brazilian position at the WTO, but also coincides with the idea, outlined by the new WTO DG, and shared by Brazil, of a "third way" that promotes effective engagement and immediate action of all members of the Organization in the fight against the COVID-19 pandemic.

Brazil understands that the TRIPS Agreement comprises an adequate set of incentives for innovation and flexibilities enshrined in the Doha Declaration on TRIPS and Public Health, including in light of the principle of public interest, to face health crises. Brazil will continue to participate in all discussions at the WTO on initiatives to combat the pandemic, including those related to the intellectual property system.

Finally, it is important to note that all WTO member countries - Brazil included - are authorized by the TRIPS Agreement to enact the compulsory licensing of patents as a way to meet public order imperatives, a modality even provided in national legislation. Brazilian legislation is fully in line with the TRIPS Agreement and contains all the provisions to encourage innovation, technology transfer and various types of licensing agreements.

[UNQUOTE]

- The relevant national policies, laws, and practices, including the use of compulsory license orders under the TRIPS Agreement by the Brazilian Government

a. Intellectual property:

As for administrative processes of intellectual property, the Ministry of Health ("Ministério da Saúde" - MS) used the terms of Article 13 of INPI/PR Resolution 239/2019, which allows the MS to request priority in the examination of patent applications referring to pharmaceutical products and processes. The National Intellectual Property Institut ("Instituto Nacional de Propriedade Intelectual" – INPI) was asked to prioritize examination of the following technologies:

- Medicines: Remdesivir, Tocilizumab, Sarilumab and Favipiravir; Rocuronium; Pancuronium; Desflurane; Ethosuximide; Remifentanyl; Norepinephrine; Isoflurane, Ketamine and Propofol;
- Vaccines: Coronavac Sinovac Biotech Ltd/ Dynavax Technologies Corp/ Serum Institute of India Ltd; BBIBP-CorV Beijing Institute of Biological Products/Sinopharm; Covaxin (BBV152 A,B,C); Based on Viral Vectors: ChAdOx1-S (AZD-1222, Covishield); Sputnik V (Gam-COVID-Vac) and Ad26.COV2.S1 (JNJ-78436735); RNA-based: Tozinameran (BNT162b2) – Comirnaty®, mRNA 1273 Moderna Therapeutics and CVnCov (CureVac);
- Monoclonal Antibodies: REGN-COV-2 (Casirivimab + Imdevimab) and Banlaniivimab in monotherapy and in combination with etesevimab with temporary authorization for emergency use approved by the Sanitary Authority, ANVISA.

- b. Incorporation of new technologies into the Single Public Health System (“Sistema Único de Saúde” – SUS)

Publication of Ordinance GM/MS No. 1.1291, of June 2, 2021, which provides for the simplified administrative process of incorporation or alteration of health technologies by the SUS in case of relevant public interest, pursuant to Article 29 of Decree No. 7.646/2011.

- c. Import of essential products to combat COVID

Resolution RDC n. 483/2021, of March 19, 2021, of the National Health Surveillance Agency (“Agência Nacional de Vigilância Sanitária” – ANVISA), provides, in an extraordinary and temporary manner, the requirements for the import of new medical devices and drugs identified as priority for use in health services, due to the international public health emergency related to SARS-CoV-2. Based on the aforementioned resolution, which simplified the list of requirements and the administrative procedure for authorization of exceptional importation of the aforementioned drugs, it is informed that so far, the following actions regarding the import processes have been instructed and carried out by the MS:

- International drug procurement process for Orotracheal Intubation (OTI) procedure via the Pan American Health Organization (PAHO);
- Instruction of the process for receiving donations of OTI drugs offered by the company Vale S.A. and imported from China;
- Instruction of the process for receiving international donation of OTI drugs offered by the Spanish Agency for International Cooperation (Spain);
- Instruction of the process for receiving international donation of OTI drugs offered by Portugal;
- Instruction of the process for receiving international donation of OTI drugs offered by Ireland; and
- Instruction of the process of receiving international donation of OTI drugs offered by the Chinese company Jiangsu Guotai International Group Co. (GTIG)

The Ministry of Economy within the scope of the Foreign Trade Chamber (Camex), through Gecex Resolution nº 17/2020 (updated by Gecex Resolutions nº 22, 28, 31, 32, 33, 34, 44.51, 67, 75, 90, 103, 118 and 133 of 2020; and 144, 146, 162, 182, 188 and 211 of 2021), reduced to zero the rate of import tax on medicines and products. The list of products was defined based on requests by the Ministry of Health, which used as a reference the list of the Pan American Health Organization/World Health Organization (PAHO/WHO); the Ministry of Health guidelines for hospital management of patients with COVID-19; National Council of Municipal Secretariats of Health (CONASEMS) list to guide the acquisition by Municipalities; Resolutions of the Board of the National Health Surveillance Agency (RDCs); and eventual adjustments requested by the Brazilian private sector.

- d. Regulatory and Sanitary Measures

Anvisa has already adopted several regulatory measures to simplify administrative procedures in the area of medicines, with a view of making more flexible requirements for the approval of clinical trials and registration of medicines and vaccines for the treatment of COVID-

19, in order to contribute to the population's access to therapeutic options to fight the pandemic, without relinquishing its role of ensuring the safety, quality and efficacy of products made available on the national market.

The analysis deadlines of the import processes can be publicly monitored through the panel available at

<https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoesanaliticas/importacao/tempo-de-analise> . It is possible to verify that, since the declaration of the Public Health Emergency of National Importance (ESPIN) as a result of the Human Infection by the new Coronavirus (2019-nCoV), through Ordinance No. 188, of February 3, 2020, more than 80 % of all import licenses subject to Anvisa's consent had their first manifestation within 72 hours and over 95% within 5 days.

In Resolution RDC No. 475, March 10, 2021, which determines the procedures and requirements for submitting a request for temporary authorization for emergency use, on an experimental basis, of drugs and vaccines for Covid-19 to face the health emergency public of national importance resulting from the outbreak of the new coronavirus (SARS-CoV-2), Anvisa established pre-submission meetings for the purpose of dealing with the temporary authorization for emergency (AUE).

Anvisa implemented the COVID-19 in vitro Diagnostic Product Analytical Monitoring Program, created through a partnership with the National Institute for Quality Control in Health (INCQS/Fiocruz). The measure is part of the post-market monitoring activities of the tests approved for commercialization in Brazil, given the pandemic caused by the new Coronavirus (Sars-CoV-2).

Anvisa has published several Board Resolutions (RDCs) to facilitate and accelerate the process of importing vaccines, medical devices and drugs identified as priorities for use in health services, due to the international public health emergency related to SARS-CoV- two. Other regulatory and health information can be accessed through the website <https://www.gov.br/anvisa/pt-br/assuntos/paf/coronavirus/regulamentos-e-medidas>

Further information about specific legislation to fight COVID-19 published by the Presidency of the Republic from the beginning of the pandemic to the most recent publications can be accessed at http://www.planalto.gov.br/ccivil_03/Portaria/quadro_portaria.htm

In addition, the MS, through its General Coordination of the Health Industrial Complex, carried out a Preliminary Assessment of unit operations and productive operational capacities installed in animal and human health laboratories, with potential to carry out upstream, downstream, Fill & Finish stages of vaccines against SARS-COV-2:

- Visit to laboratories in Brazil that produce vaccines for veterinary use in order to get to know their productive and technological capacities;
- Visit to a private pharmaceutical laboratory in order to get to know the company's facilities, as well as its production and technical capacities. The company had sent a Presentation Letter to the Ministry of Health informing the capacity to produce the API and to carry out the bottling of doses of vaccines against SARS-COV-2, which motivated the visit.

Regarding the compulsory licensing of any technology or product, it is reported that, since the beginning of the pandemic, the need to enact the compulsory licensing of any technology or product has not been identified. A law that seeks to change the operation of compulsory licensing in cases of public health emergencies was approved by the National Congress in August and should enter into force soon.

- ***The ways in which the Brazilian Government supports efforts for international economic and scientific cooperation and international solidarity***

The Brazilian system of science, technology and innovation (CTI) has supported the development of technological solutions to respond to the challenges posed by the COVID-19 pandemic. The public effort relies on investments in order of R\$1.2 billion, which have resulted in several actions to combat COVID-19: industrial reconversion initiatives; research and development of drugs, tests and personal protection equipment; virus sequencing research; digital application development; vaccine research, among others. These initiatives involve partnerships between public and private entities, as well as academia.

a. International cooperation in STI

With regard to international cooperation in science, technology and innovation between Brazil and other countries in the fight against COVID-19, different approaches have been made since the outbreak of the pandemic.

In 2020, a call to support international cooperation research projects to fight COVID-19 was launched among BRICS countries. A total of 111 proposals were submitted, of which 12 were selected for support, with an investment of R\$7.2 million from Brazil (resources from Ministry of Science, Technology and Innovation – MCTI, and MS). Brazil is the only BRICS country to participate in all approved projects, which involve 5 research areas: new diagnosis technologies; vaccines and medications; virus genetic sequencing; artificial intelligence applied to drugs, vaccines, treatments; and studies to assess the overlap of SARS-CoV-2 and other morbidities such as tuberculosis.

Within the scope of the Horizonte2020 research and innovation financing program, activities were carried out in 6 research projects with the European Union related to COVID-19, aimed at diagnostics, therapies and vaccines. Two projects were also selected with the participation of Brazilians for the emergency call of COVID-19 promoted by the European Commission.

The Respiratory Virus and Measles Laboratory at the Oswaldo Cruz Institute (IOC/Fiocruz) was named one of the two World Health Organization (WHO) Reference Laboratory for Covid-19 on the American continent. The unit will support laboratories in the region, especially in low- and middle-income countries; perform genetic sequencing of samples for global reference; track the evolution of the virus and identify mutations that may be relevant for diagnostic testing, vaccine development, and treatments; develop and implement state-of-the-art testing methods.

In intergovernmental science, technology and innovation commissions held with other countries and in multilateral forums, Brazil seeks to discuss the topic of cooperation in the area of combating COVID-19, such as the 61st and 62nd Specialized Meeting on Science and Technology of the Mercosur, the meetings of the Latin American Biotechnology Center (CABBIO), 29th joint commission in CTI Brazil-Germany, 5th meeting of the Working Group on Innovative High Technology Brazil-Sweden, as well as meetings at the OECD and OAS.

Brazil also participates in meetings promoted by the United States' Office of Scientific and Technological Policy (OSTP/USA), to share scientific data on COVID-19, such as the development of vaccines, treatments and research ongoing. The initiative brings together 14 countries (Germany, Australia, Canada, South Korea, Spain, India, Ireland, Italy, Japan, New Zealand, Portugal, Singapore, Switzerland and the United Kingdom), in addition to the European Union. So far, 16 meetings have been held with the participation of representatives from the MCTI and the Brazilian embassy in Washington.

b. International Cooperation in the Development of Vaccines

On 6/27/2020, the Ministry of Health signed a technology transfer agreement with the United Kingdom for the production of the IFA and vaccines of the pharmaceutical company AstraZeneca developed by the University of Oxford, by Fiocruz. On 9/30/2020, the Butantan Institute and the company "Sinovac Life Science" from China signed a contract that includes the transfer of technology for the Coronavac vaccine, which should be fully produced at the Butantan Institute.

In addition to the vaccines developed abroad, there are about 15 vaccine proposals resulting from research carried out by national laboratories. One is ready to start the clinical phase, awaiting the availability of supplies for the manufacture of test batches, which has been hampered by the scarcity of international supply. It is Versamune-CoV-2FC-MCTI, developed by USP Ribeirão Preto in partnership with the Brazilian company Farmacore Biotechnology and the North American PDS Biotechnology Corporation. R\$ 4 million have already been invested in the development of the vaccine, including animal studies in the pre-clinical phase. R\$30 million will be released for the beginning of studies with volunteers, in phases 1 and 2. In the third and final phase, investments of around R\$300 million are expected.

Two other strategies supported by the MCTI complete the pre-clinical phase: a nasal spray vaccine, from the USP Medical School; and an ambivalent vaccine against flu and covid-19, the Spintec MCTI-UFMG, developed by the Vaccine Technology Center (CT Vacinas), of the Federal University of Minas Gerais (UFMG). With the conclusion of the pre-clinical phase, the vaccines will go through phases 1 and 2, with planned investments in the order of R\$20 to R\$30 million; and for phase 3, with an estimated cost between R\$250 and R\$320 million.

A fourth promising vaccine, the one produced in the United States by the company HDT, was licensed for development in Brazil by Cimatec (Bahia). It is an RNA vaccine whose clinical tests must be carried out in India and Brazil. It already has ANVISA protocol.

Brazilian research institutes also contributed to the clinical trials of 4 vaccines with foreign technology: Pfizer-Biontech, Astrazeneca/Oxford, Sinovac and Janssen-Cilag (Johnson&Johnson).

At the multilateral level, the Ministry of External Relations, together with other Brazilian institutions, participates in the WHO Working Group on Vaccine Manufacturing with a view to creating a "hub" for the transfer of technologies related to vaccines against COVID-19, with an initial focus on technology of messenger RNA. Brazil was chosen to host one of these centers, which will support regional efforts to produce and distribute vaccine.

Also in partnership with the WHO, Brazil participated in the WHO World Forum on Local Production, in virtual format, from June 21 to 25, with minister Marcos Pontes as "keynote speaker" at the opening of the event. The Forum should be held regularly as a new mechanism to promote local production and facilitate technology transfer.

c. Disclosure of Brazilian Technological Solutions in the fight against COVID-19 abroad
In the understanding that the dissemination of information contributes to the fight against the disease, Itamaraty has disclosed the actions developed by scientists, research centers, companies and public entities aimed at the advancement of scientific knowledge and technological development to fight the pandemic, organized by the Department of Technological Promotion. Throughout 2020, our embassies, consulates and missions to international organizations received 10 telegraphic circulars with information on the subject, which were disseminated to government and private interlocutors at these posts.

d. Cooperation in S,T&I of MS and MCTI

The MS has a specific funding line for the topic, namely: "Vaccines, with the objective of supporting the development of pre-clinical, clinical or multicenter studies of international and/or national cooperation with the objective of promoting the development of vaccines against COVID-19". So far, approximately R\$ 11.5 million has been invested in the development of vaccines. The MCTI allocated around R\$ 800 million in the areas of R,D&I to fight COVID-19, more specifically for the following initiatives:

- Development and clinical trials of vaccines and new drugs;
- Large-scale sequencing of the country's circulating viruses;
- Clinical trials of drug replacement;
- Environmental monitoring of wastewater;
- Monitoring of SARS-COV2 and other viruses in wild animals;
- Development of diagnosys tools;
- Assessment of sequelae and consequences of COVID-19.

Fiocruz coordinated, in Brazil, the Solidarity clinical trial, of the World Health Organization (WHO). Launched by the WHO, the initiative aims to investigate the effectiveness of four treatments for Covid-19 and will be implemented in 18 hospitals in 12 states, with the support of the Department of Science and Technology (DECIT) of the Ministry of Health.

The Solidarity trials are a combination of efforts around the world to provide a rapid response on which drugs are effective in treating Covid-19 and which are ineffective and should not be used. Answering these questions requires thousands of patients to participate in drug trials. To reach the required number more quickly, WHO is combining the global effort of many countries.

e. Humanitarian cooperation:

Considering the urgency to acquire medical and hospital products essential to combating the coronavirus in all countries of the world, there was a shortage of several items in the national and international market, mainly Personal Protective Equipment (PPE), causing the Federal government to take protective attitudes with regard to national supply.

Even with the protective measures adopted, the MS carried out the actions:

- Assist in the release of retained cargoes of supplies for care and prevention to COVID-19 after a technical assessment of each of the responsible areas, to ensure that there would be no national shortage;
- Donations of PPE and equipment were made to Latin American countries to help other countries in the treatment of people affected by the disease. Such donations were always made after a technical evaluation by each of the responsible areas, to ensure that there would be no national shortage.

f. Export of essential products to combat COVID-19

Secex Ordinance No. 16 of 03/18/2020: established rules for the issuance of a special export license (LI), in order to monitor the export of health products to combat Covid-19 and ensure that there was no national shortage.

g. Brazil's multilateral cooperation in confronting COVID-19

At the multilateral level, Brazil has participated in initiatives that promote international solidarity in the search for universal solutions to the health crisis that affects all countries. We know that the acute phase of the pandemic will only be overcome when all countries have the necessary tools for its containment and response. In short, no one is safe until everyone is safe.

Brazil advocates equitable and affordable access to safe, effective and quality vaccines, diagnostic tests and treatments, and believes that the promotion of technology transfer mechanisms and tools to strengthen national health systems is essential.

Brazil is engaged in the ACT Accelerator (ACT-A) and the COVAX Facility, in addition to supporting the Solidarity Call to Action and the COVID-19 Technology Access Pool (C-TAP), important international initiatives to promote development and ensure access tools and supplies needed to fight the COVID-19 pandemic.

h. Initiatives to strengthen local production of vaccines, medicines and other health products

Brazil has worked closely with PAHO, neighboring countries, and from different regions to strengthen health systems and share best practices and lessons learned about the pandemic.

With the advance of vaccination in several countries, Brazil has urged COVAX to guarantee immediate access to vaccine doses to participating countries. The initiative's success depends on its agility and capacity to distribute vaccines, in order to guarantee equitable access for all countries.

Given the global shortage of vaccines, mainly due to limitations in manufacturing capacity and bottlenecks in the global supply chain, Brazil has been working to consolidate an international legal framework that encourages the local production and distribution of supplies, vaccines, medicines and other medical products. In this sense, the Brazilian government has been engaged in discussions in forums such as WHO, PAHO and PROSUL, with the objective of benefiting and strengthening our health industrial complex and contributing to more equitable access to vaccines and other supplies for countries in development.

The Brazilian government is committed to facilitating processes that favor the transfer of technology to Brazil and other developing countries, which we believe to be of strategic interest to promote global health and overcome health emergencies. There is a special interest of the Brazilian government in incorporating messenger RNA (mRNA) vaccine technology.

Brazil welcomed the decision by WHO and PAHO to support Brazil, together with Argentina, in our efforts to host regional centers for the production of vaccines with mRNA technology.

The choice to make Brazil one of the centers for the transfer of vaccine technology is a result and a demonstration of the Brazilian capacity. The country has a robust health industrial park, including public and private laboratories, with full capacity to supply immunization agents to countries in the region, as well as to international mechanisms such as COVAX.

- ***Laws and policies of the Brazilian Government on full transparency in its contracts with pharmaceutical companies purchasing vaccines, including all elements of vaccine development, procurement, and provision***

The Medicines Market Regulation Chamber (CMED-ANVISA) through CTE-CMED Resolution No. 8 of July 2, 2021 defined that for new medicines and vaccines against Covid-19, the Executive Secretariat of CMED will establish a provisional price for commercialization in the Covid-19 pandemic period.

The Executive Secretariat of CMED has defined procedures for drug pricing, as described below:

- Medicines with health registration approved by Anvisa: follow the procedure established in CMED Resolution No. 02/2004. In these cases, there is no change in relation to pricing procedures in place before the Covid-19 pandemic.
- Medicines without sanitary registration approved by Anvisa, not being a new molecule in Brazil: follow the procedures established in Resolution CTE-CMED No. 09/2021. Provisional prices are granted based on the average of the national market for medicines with the same molecule, concentration and pharmaceutical form.

Medicines without sanitary registration approved by Anvisa, in the case of a new molecule in Brazil or vaccines for Covid-19: follow the procedures established in Resolution CTE-CMED nº 08/2021.

CMED does not assess prices, so pricing takes place through direct negotiation between companies and the Government.

The Executive Secretariat of CMED clarifies that its performance is strictly based on the rules established in the higher levels of CMED, which are unanimously defined by the four Ministries that comprise it. Decisions related to increasing access to new technologies are discussed at the higher levels of this Chamber.

Public purchases in Brazil are regulated by Law N° 8666/93. On the website Portal de Compras (<https://www.gov.br/compras/pt-br>) public notices, bids and auctions for the acquisition of products, including those for health, are published. On the website Portal da Transparencia (<https://www.portaltransparencia.gov.br/contratos>) it is possible to monitor purchases made by the Ministry of Health. to the combat of COVID-19 (<https://datastudio.google.com/u/0/reporting/1ddb773f-0254-4c9c-9b5c-b70602688bb3/page/2nwRB>).

The MS, through the Department of Health Economics, promotes the rational use of public resources in health, using economic information that helps public managers in decision-making. The Health Price Database is a system with the purpose of registering and making available online information on public and private purchases of medicines and health products. This tool monitors the behavior of prices in the healthcare products market, contributing to the improvement of negotiations with suppliers.