



*Permanent Mission of Brazil to the United Nations Office and other International Organizations
in Geneva
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Geneva, Switzerland*

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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 refers to the urgent appeal UA BRA 10/2020 from the Special Rapporteur on the elimination of discrimination against persons affected by leprosy and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

In this connection, please find in the Annex attached to this note the correspondent information provided by the Ministry of Health of Brazil.

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, November 20, 2020.

To the
OHCHR
Special Procedures Branch
Geneva



ANNEX

I - Please provide any additional information and any comments you may have about the above-mentioned claims.

About the shortage of multidrug therapy (MDT), in June 2019, the Ministry of Health sent to the World Health Organization (WHO) a form with the quantities expected to supply the country in 2020. The WHO has scheduled three shipments of medication by air.

In December 2019, the Pan American Health Organization (PAHO/WHO) informed Brazil that there would be delays in MDT imports due to complications in its production. On that occasion, the WHO suggested rationing treatment stocks, a difficult procedure due to the demand being calculated based on the cases registered in the 'Sistema de Informação de Agravos de Notificação' (Sinan). The Ministry of Health also informed that the implementation of the single treatment in SUS was scheduled for September 2020, requiring additional amounts of multibacillary treatment (MB).

It was then agreed that, between June and July 2020, the demand would be reassessed and, if there were still a need to order additional quantities, the Ministry of Health would place the order. However, in the first months of 2020, the WHO reported that MDT production was not yet normalized and shipments to Brazil would have to be recalculated.

It should be mentioned that the problems resulting from the lack of MDT in SUS affected only the provision of adult multibacillary treatment (MBA). Finally, on 8/30/2020, a shipment of MDT MBA was delivered to Brazil and, on 9/3/2020, forwarded to the states.

It is also worth noting that the Ministry of Health is waiting for documentation from the WHO to begin the process of importing a consignment of MDT MBA and 100 mg clofazimine, which were requested with extreme urgency in August 2020. However, the WHO informed that it would delay sending the shipment, since risks in the drug's quality were identified by Novartis. Furthermore, it should be borne in mind that the Ministry of Health started, in 2019, the process of acquiring 50mg and 100mg clofazimine through PAHO/WHO. Deliveries are scheduled for December 2020.

As for supply in the state of Pernambuco, on 04/30/2020, the Ministry of Health was informed by the State Program of Hansen's Disease that, for 2020, it had adopted average monthly consumption quantities and that the amounts of medicines sent would be insufficient for supplying the demand in the public service. Given the disparity between the amounts requested in 2019 and 2020, the Ministry of Health invited the State Secretary of Health of Pernambuco to a meeting where the state Sinan database's inconsistencies were presented.

In August 2020, the Ministry of Health again asked the pharmaceutical assistance (PA) of Pernambuco for the quantities in stock to clarify the real need for additional medication shipments. The state AF requested a meeting to align the medication schedule. It was

decided that AF will periodically update and report consumption to the Ministry. The distribution to the units should be carried out based on the in treatment patients' data and the state distribution logistics to serve the municipality rationally. It should be noted that the drugs were sent to Pernambuco on 10/04/2020, with delivery scheduled for 10/9/2020.

Finally, state managers widely know that the donation of medicines by WHO is carried out according to the cases registered in Sinan, according to the current guideline of the Ministry of Health and the tabulation of epidemiological data in the system. Therefore, there is no sending of quantities of drugs without proper proof.

II - Please provide detailed data on leprosy and COVID-19, including the number of people affected among those tested positive for COVID-19, by sex, age and region. Please provide information about those residing in former colonies where the risk of COVID-19 infections can be more significant.

The official system's leprosy notification form does not include data on Covid-19. Nevertheless, the national leprosy program is conducting a probabilistic study in order to obtain it.

III - Please provide detailed information about the measures taken to guarantee access to multidrug therapy (MDT) and basic sanitation for women affected by leprosy in Brazil. Please indicate any emergency actions to respond to the shortage of MDT in the context of COVID-19. Please provide details about MDT's current stock situation in the country and the number of blisters requested by Brazil in 2019 and 2020.

Because of the situation mentioned in item I, referring to the access to multidrug therapy (MDT), the Ministry of Health adopted the following measures:

The Ministry communicated to the WHO that any delay in starting the import process would lead to national shortages;

On 03/19/2020, the Ministry sent a letter to the states describing what care should be given to people affected by leprosy in the context of the Covid-19 pandemic. This communication emphasized the impossibility of providing MDT for one additional month, despite SUS programs' recommendation, given the lack of stock;

On 07/14/2020, the Ministry informed states about the postponement to January 2021 of the expansion in the use of clofazimine for patients with paucibacillary leprosy, considering the delay in the MDT import;

The Ministry asked the WHO, through different communication channels, for information on MDT production. The organization responded in August 2020, stating that the shortage occurred due to the temporary suspension of the production of the active pharmaceutical ingredient of dapsone. Besides that, due to the COVID-19 pandemic, there were difficulties in transportation of medicines to Brazil, considering the low

availability of flights from India and the high air freight costs. It is emphasized that the states were immediately informed of the reasons for the scarcity of MDT;

The Ministry systematically updated, through electronic mail, state leprosy and pharmaceutical assistance programs on the MDT import and stock scenario in Brazil;

The Ministry informed states that there was no possibility of including the clofazimine to MDT PB to make up for the lack of adult MDT MB blister, as there is not enough stock for these patients, as they represent 80% of the total;

The Ministry considered recommending the use of a substitute therapeutic regimen for adult MB patients (clofazimine, minocycline and ofloxacin), but the available stocks would also not be sufficient to meet demand. The emergency acquisition of these medicines would not meet SUS in time, taking into account given the process legal deadlines;

In search for alternatives, the Department of Logistics of the Ministry of Health (DLOG / SE / MS) is discussing with the WHO ways to facilitate the import of medication by sea;

It is adopting measures that make national production feasible. However, the pharmaceutical industry demonstrates no interest in producing medicines for neglected diseases;

It requested information from Novartis, pharmaceutical company that produces the medicine, and pointed out the urgency to receive new shipments by plane. The company stated that the production process was normalized. Likewise, the Ministry of Health made itself available to pay shipping fees. However, in the meantime, the WHO had already found available flights;

In September and October 2020, it reiterated to the WHO the immediate need of adult MDT MB shipment, considering the Brazilian agencies' processing deadlines;

Finally, for the years 2019 and 2020, WHO had programmed to donate the following amounts of medicines to Brazil:

Yearly Quantity of Polychemotherapy donated by WHO (blisters)

2019

Adult Multibacillary - 216,000
Children's Multibacillary - 12,096
Adult paucibacillary - 12,960
Children's paucibacillary - 2,592

2020

Adult Multibacillary - 301,218
Children's Multibacillary - 8,640
Adult paucibacillary - 52,704
Children's paucibacillary - 6,912

IV - Please provide detailed information about the measures taken or that are being taken by authorities to produce essential medicines for leprosy. If this is not the case, please explain the reason, as well as indicate how Brazil guarantee access to essential health care for people affected by leprosy in all moments.

There is an ongoing process in the Ministry of Health to foster the national production of MDT. The negotiations are being coordinated by the Secretariat of Health Surveillance (SVS/MS) and the Secretariat of Science and Technology and Strategic Inputs for Health (SCTIE/MS). Both bodies are conducting a public hearing for national laboratories and a public call for governmental laboratories. The SVS notice will be published in the Official Gazette of the Union in November 2020.

V - Please provide information about the action taken to guarantee the rights to health benefits and social security for people affected by leprosy, especially in the context of COVID-19.

In March 2020, an information note was circulated and, in June 2020, a circular letter was sent to State Coordinators of the Leprosy and Pharmaceutical Assistance Program on the treatment for people affected by leprosy in the context of the Covid-19 pandemic in the Unified Health System (SUS).

Concerning social security benefits, there is no specific measure created for people affected by leprosy and Covid-19. Nevertheless, the Brazilian government approved, in April 2020, the Emergency Aid, a financial benefit intended for informal workers, individual micro-entrepreneurs (MEI), self-employed and unemployed persons, as a protection measure during the Covid-19 crisis. Any citizen has the right to benefit since the following rules are fulfilled:

a) Being over 18 years of age, except in the case of adolescent mothers; b) Not having active formal employment; c) Not receiving benefits paid by the Social Security National Institute (INSS), as retirement, pension or others; d) Not being a beneficiary of unemployment insurance, 'defeso' insurance or an income transfer federal program, except for Bolsa Família; e) Being in a family with monthly income up to half the minimum wage (R \$ 522.50) per person or monthly total income up to three minimum wages (R \$ 3,135.00); f) In 2018, not having received taxable income over R \$ 28,559.70 (twenty-eight thousand, five hundred and fifty-nine reais and seventy cents); and g) Being an individual micro-entrepreneur, an individual taxpayer under the Social Security General Regime or an informal worker, even if unemployed.

VI - Please provide information about the measures taken to comply with Advice about leprosy and COVID-19 from WHO and other relevant organizations and the critical principles elaborated in the Charter Open by the Special Rapporteur on eliminating discrimination against people affected by leprosy and their families.

The Ministry of Health, the SUS coordinator body and a health policies inducer, adopted measures in line with the WHO's recommendations for leprosy and Covid-19. Thus, the Ministry of Health developed and disseminated information material on preventive measures to Covid-19 for people affected by leprosy. Furthermore, it issued recommendations for the adequacy of health services in the pandemic context, to ensure the continuity of the treatment concomitantly to the respect for the social isolation norms, and to decreased visits to health services. All information is available at

<http://www.aids.gov.br/pt-br/noticias/ministerio-da-saude-guides-continuity-of-treatment-for-leprosy> .

Additionally, the Ministry of Health has been holding virtual meetings with the state and municipal leprosy programs' coordinators to plan and monitor actions; organized virtual seminars on leprosy treatment with the participation of specialists and health professionals, in addition to preparing materials with information aimed at people affected by the disease and their relatives. These materials will be released on the National Day for the Fight against Leprosy in January 2021.
