Rio de Janeiro, May 4th, 2023

To Her Excellency Mrs Nísia Trindade
Minister of Health

Subject: Compulsory licensing of patents and patent applications related to dolutegravir

Your Excellency, Minister of Health Nísia Trindade Lima,

The Working Group on Intellectual Property (GTPI), part of the Brazilian Network for the Integration of Peoples (Rebrip) and coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA), brings together various civil society organizations, social movements and specialists linked to the issue of intellectual property and the right to health in Brazil. GTPI has been acting for 20 years, based on a public interest perspective, to mitigate the negative impact of patents on the realization of the fundamental right to health in our country.

Through this letter, we would like to (i) express our extreme concern regarding the situation of dolutegravir in Brazil[1] and (ii) request that the Ministry of Health take all necessary measures to enable the compulsory licensing of patents and patent applications related to this medicine.

Dolutegravir is a crucial drug in the fight against the HIV/AIDS epidemic. Recommended by the World Health Organization (WHO) as a first and second line treatment for all populations, this drug has been distributed by the Unified Health System (SUS) since 2017 and is used daily by more than 460,000 people in Brazil[2], making it the most widely used medication within the scope of the HIV/AIDS policy in our country.

Far from being a trivial fact, the wide access to dolutegravir was achieved with a lot of struggle from Brazilian civil society and needs to be constantly protected. That is why, after having acted intensely for its incorporation into SUS, we continue to fight for better conditions of access to this medicine, from the perspective of the SUS sustainability, the defense of national sovereignty

[1] FONSECA, Felipe Carvalho Borges da et al. Patentes: o intrincado caso do dolutegravir. Outra Saúde, São Paulo, 21 jan. 2023. Available in: https://outraspalavras.net/outrasaude/patentes-o-intrincado-caso-do-dolutegravir/
[2] Data referring to June 2022, presented by the Ministry of Health on 08/02/2022, through the Law on Access to Information (LAI) (Process No. 25072.025876/2022-60).

and against the risk of shortages. In particular, GTPI has gone to great lengths to prevent the undeserved grant of a patent related to dolutegravir (PI0610030-9).

Initially, several technical subsidies were presented to the National Institute of Industrial Property (INPI), demonstrating how the patenting of this drug would violate the fundamental right to health and the Industrial Property Law (LPI) itself, since it did not meet the minimum requirements of patentability. However, at the end of 2020, after a drastic change in the position of the INPI and without material consent of the National Health Surveillance Agency (Anvisa), this patent related to dolutegravir was illegally granted.

Thus, in early 2021, GTPI initiated an administrative proceeding within the INPI itself, requesting the declaration of nullity of this patent. However, in January 2023, the federal autarchy dismissed the request and decided to maintain this undue privilege. At the same time, in early 2022, the GTPI started to act as *amicus curiae* in a nullity lawsuit filed against this same patent[3], presenting several technical subsidies that reinforce its nullity. This process, however, is still ongoing and there is no prospect of ending soon.

In the meantime, the undue patent related to dolutegravir remains in force and, until the present moment, continues to jeopardize the sustainability of public health policies in our country. The holders of this privilege, ViiV Healthcare Company (a joint venture between GSK and Pfizer created in 2009) and Japan's Shionogi & Co., Ltd., began to abuse the powers of this undue monopoly to prevent the manufacture and distribution of generic versions of this drug in Brazil.

Based on an illegal monopoly, these foreign companies are trying to prevent the Ministry of Health from acquiring part of their stock of dolutegravir from the Partnership for Productive Development (PDP) formed between the Pharmaceutical Laboratory of the State of Pernambuco, Governor Miguel Arraes (Lafepe) and the Brazilian company Blanver Farmoquímica e Farmacêutica S.A..

In addition to expressing its concern regarding the facts narrated above, the GTPI requests that the Ministry of Health take all the necessary measures to enable the compulsory licensing of patents and patent applications related to this medicine[4]. More specifically, without prejudice to other forms of compulsory licensing, we understand that this is an obvious case of **public interest** and should be dealt with in accordance with art. 71 of the Brazilian Industrial Property Law.

[3] Case No. 5005427-49.2022.4.02.5101, filed before the court of the 13th Federal Court of the Judiciary Section of Rio de Janeiro

[4] According to a survey conducted by GTPI in April 2023, compulsory licensing should cover, at least, patent PI0610030-9 and patent applications PI0923217-6, BR122021016565-3 and BR112013002461-5

From our point of view, in the present case, compulsory licensing would be justified for the following reasons:

- **Health sovereignty:** Compulsory licensing allows the Brazilian State to have the necessary legal certainty to acquire part of its stock of dolutegravir from a fully national public-private partnership, consolidating this specific initiative and strengthening the Health Economic-Industrial Complex as a whole. This is, without a doubt, an essential and impossible to ignore State policy after the recent traumas of the Covid-19 pandemic;
- **Public policy coordination:** Compulsory licensing would allow the Brazilian State to find the necessary balance between its own public policies, such as the promotion of the fundamental right to health, PDPs and patents of invention. It is not in the public interest for the patent monopoly to make the operation of a PDP completely unfeasible and jeopardize the policy of access to medicines;
- **Price reduction:** Compulsory licensing would allow the Brazilian State to acquire part of its stock of dolutegravir at a considerably reduced price and save public resources. According to data presented by Blanver, if the PDP met only half of the demand of the Ministry of Health, there would be savings of R$ 120,600,000.00 (one hundred and twenty million, six hundred thousand reais) per year[5]. This factor becomes even more decisive when one considers, more broadly, the sustainability of public health policies in the midst of fiscal austerity measures;
- **Decreased supply risk:** As pointed out by the National Health Council (CNS)[6], compulsory licensing would allow the Brazilian State to acquire dolutegravir from different suppliers, considerably reducing the risk of shortage of a product used daily by more than 460,000 people in the country.

[5] These data were presented by Blanver's lawyers on 10/19/2022, in the records of the Bill of Review No. 5008464-61.2022.4.02.0000, within the scope of the 2nd Specialized Panel of the Federal Regional Court of the 2nd Region (TRF-2) At the time, they considered that the annual demand of the Ministry of Health would be 180 million pills of dolutegravir and compared the price offered by the Lafepe/Blanver PDP for the year of 2023 (R$ 3.70 per pill) with the price offered by the patent holders for the year 2022 (BRL 5.04 per pill).

[6] NATIONAL HEALTH COUNCIL. Recommendation No. 029, of October 20, 2022. It recommends actions to counteract the threats of supplying the antiretroviral drug Dolutegravir in 2023, blocking the purchase of generics. Brasília, DF, 20 Oct. 2022. Available in: http://conselho.saude.gov.br/recomendacoes-cns/2681-recomendacao-n-029-de-20-de-outubro-de-2022.

Indeed, although the compulsory licensing of patents is commonly related to cases of abuse (art. 68 of the Brazilian Industrial Property Law) and national emergencies (art. 71 of the Brazilian Industrial Property Law), it is fundamental to keep in mind that these are not the only circumstances that justify the application of this institute. The public interest not only constitutes a solid justification for the granting of compulsory licenses in Brazil, as it has already been invoked in the important case of the drug efavirenz, in the second Lula administration, in 2007.[7]

Far from being an "extremist" or "radical" measure, as some rich countries, transnational companies and their lobbyists want to make it seem, compulsory patent licensing is an efficient public policy for access to health and is fully aligned with the national and international legal system. It is important to highlight that this is an instrument used worldwide and, during the Covid-19 pandemic alone, it was used several times by the United States.[8]

Thus, in the case of dolutegravir, this measure would not only allow the patent holder to continue normally supplying this drug to the Ministry of Health, but would also require it to be directly remunerated by the PDP, its only competitor. That is, compulsory licensing would function only as a legal and temporary limitation of the patent monopoly. Without major losses for the patent holders and with great benefits for society.

It is important to note that an undeserved patent may prevent the PDP from producing, using, selling, importing, exporting, or stocking dolutegravir, thus harming public investment for the implementation of the PDP, making competition unfeasible and creating a scenario in which the patent holder can increase the price of the medicine based on the monopoly.

In light of the foregoing, we would like to reiterate our request that the Ministry of Health do everything in its power to enable the compulsory licensing of all patents and patent applications related to dolutegravir. Undoubtedly, this would be a crucial step towards putting an end to the years of institutional subservience that marked the recent past of this Ministry and promoting the fundamental right to health in our country.

GTPI has been monitoring the issue of the interaction between intellectual property and the right to health for more than two decades and is available to provide further arguments and information necessary for the Ministry of Health. Attached, we forward the mapping of patent

[7] CHAVES, Gabriela Costa. **Perguntas e respostas sobre o licenciamento compulsório do medicamento efavirenz no Brasil**. Rio de Janeiro: Associação Brasileira Interdisciplinar de Aids, 2007. 24 p. Available in: https://deolhonaspatentes.org/item/boletim-efavirenz/.

[8] KNOWLEDGE ECOLOGY INTERNATIONAL. **Selected differences between Article 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions**. Knowledge Ecology International, 2022. 13 p. Available in: https://www.keionline.org/bn-2022-3.

applications on dolutegravir. Our goal is to contribute to informed decision-making on the subject in question, for the benefit of society as a whole.

Yours sincerely,

Working Group on Intellectual Property[9]
Brazilian Interdisciplinary AIDS Association
National Articulation of AIDS

[9] Formed by: Brazilian Interdisciplinary AIDS Association (ABIA), Associação de Gays e Amigos de Nova Iguaçu, Mesquita e Rio de Janeiro (AGANIM-RJ), Conectas Direitos Humanos, Federação Nacional dos Farmacêuticos (Fenafar), Fórum Maranhense das Respostas Comunitárias de Lutas ao Combate as IST, HIV, Aids e HV, Fórum ONG AIDS RS, Grupo de Apoio à Prevenção da Aids da Bahia (Gapa/BA), Grupo de Apoio à Prevenção da Aids no Rio Grande do Sul (Gapa/RS), Grupo de Incentivo à Vida (GIV), Grupo de Resistência Asa Branca (GRAB), Grupo pela Vidda Rio de Janeiro (GPV/RJ), Grupo pela Vidda São Paulo (GPV/SP), Grupo Solidariedade é Vida, Instituto Brasileiro de Defesa do Consumidor (Idec), Internacional de Serviços Públicos (ISP), Médicos Sem Fronteiras (MSF), Rede Nacional de Pessoas Vivendo com HIV/AIDS no Estado de São Paulo (RNP+SP), Rede Nacional de Pessoas Vivendo com HIV/AIDS no Maranhão (RNP+MA), Rede Nacional de Pessoas Vivendo com HIV/AIDS núcleo Pernambuco (RNP+PE), Universidades Aliadas por Medicamentos Essenciais (UAEM)