



Asociación de Laboratorios Farmacéuticos de  
Investigación y Desarrollo

## AFIDRO REJECTS MINSALUD'S DECISION REGARDING HIV MEDICATION

- *This decision ignores innovation's role in treating the disease, intellectual property regulations, due process, and the principle of medical autonomy.*

Bogotá, D.C., October 4, 2023. The Association of Pharmaceutical Research and Development Laboratories - Afidro expresses its disagreement and rejects Resolution 1579 of 2023 of the Ministry of Health and Social Protection, which declares the existence of reasons of public interest to submit a patent of the drug Dolutegravir to compulsory licensing. This Resolution ignores the intellectual property regulations, the due process, and the principle of medical autonomy contemplated in the Statutory Law on Health; as well as ignores the role that pharmaceutical innovation has played in the care of the disease and the quality of life of patients.

Intellectual property rights are not absolute, and there are circumstances in the regulations that allow for what is known as "flexibilities," which are exceptional measures to address a situation of imminent risk. An example of these flexibilities is compulsory licenses, which allows the State to limit the right of ownership for a specific time and purpose by authorizing the product's manufacture, imports, or commercialization to third parties without the owner's authorization. However, Colombia currently does not meet the requirements for using these flexibilities because the behavior of this disease in the country, nor its corresponding care, have not encountered substantial alterations or access barriers.

The percentage of people diagnosed with HIV who have access to drugs to treat their disease in Colombia is higher than the world average. According to a report by the High-Cost Account, at the year 2022, the coverage of therapy for this pathology had increased to 88% of those diagnosed in the country.

The industry remains committed to reaching 100% coverage of HIV therapy; however, we ratify that compulsory licensing is not the appropriate way to achieve this goal since patents have not become a barrier to access the drug. In addition, it is essential to highlight that several treatments are available in the country to treat these patients.

The above shows that the Ministry's decision needs to comply with the requirements of the national and international regulations for this type of measure. To continue with this process would be to ignore that intellectual property is the basis for developing new treatments and cures, as well as the principles of legal certainty and transparent rules.

The effects of this decision on medical autonomy are also of concern. This principle assumes that the physician defines the relevance of the treatments that best meet his patient's health needs according to his professional criteria. With this decision, it would produce a general clinical mandate to treat certain HIV patients (as defined in the Resolution) with Dolutegravir from now on. .



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It is important to note that, thanks to pharmaceutical innovation, HIV is no longer a death sentence for people who acquire the disease. According to the medical journal "The Lancet HIV," today, the life expectancy of a 20-year-old on treatment in Latin American countries is 70 years, compared to 78 years for the World population. Intellectual property rights are what supports the investment of time, money, and human resources to come up with innovative solutions that change the course of a disease.

Our affiliates reiterate their commitment to research and development to find innovative options to respond to the health challenges of the population, as well as to actions that strengthen timely access to treatments for Colombians.