



Misión Permanente de Colombia ante las Naciones Unidas

No 1160-E

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Ms. Ruth Dreifuss
Mr. Festus Gontebanye Mogae
Co-chairs
Unite Nations High-Level Panel on Access to Medicines

We would like to express our high appreciation for the important work initiated by the High Level Panel on Access to Medicines, in order to assess proposals and recommend solutions to address this global challenge, taking into account international human rights law, public health needs, trade rules, and the rights of inventors, among other elements.

The intention of this letter is to present an executive report of the process headed by the Ministry of Health and Social Protection of Colombia for the declaration of public interest of Imatinib, in order to consider this case as an input for the work of the high-level panel. Please also find attached Resolution 2475 (June 14, 2016) which declares the existence of public interest to the drug Imatinib and requests the National Commission for Prices for Drugs and Medical Devices to submit Glivec to the regime of direct price control.

My wish is to provide you an illustration, clearly and succinctly, about the process advanced by the Ministry, as well as the status of the matter.

I will be ready to clarify any concerns regarding this particular case.

Sincerely yours,

Cordialmente

Maria Emma Mejia
Ambassador, Permanent Representative of Colombia
to the United Nations

Process for the declaration of public interest of imatinib in Colombia

Executive Report

- This process formally began on November 24 2014, when the civil society in Colombia, represented by CIMUN, Foundation IFARMA, and Mission Health formally requested to the Ministry of Health and Social Protection a public interest declaration to grant access to the drug imatinib in Colombia.
- The Ministry studied the request, verified the legal requirements and initiated an administrative action through Resolution No. 354 of 2015.
- As part of the process, the Ministry communicated the initiation of the administrative action to Novartis AG, as holder of the patent, about, as well as to other holders of sanitary registers of drugs with the active substance imatinib. Likewise, the Ministry received comments from the interested parties concerning the civil society request.
- It is important to highlight that, in compliance with the principles of transparency and publicity, the Ministry posted on its website all the information related to the administrative procedure of a public interest declaration (<https://www.minsalud.gov.co/salud/MT/Paginas/medicamentos-propiedad-intelectual.aspx>)
- Meanwhile, after the deadline for comments, the Technical Committee for the Statement of Public Interest Reasons established in the Unique Commerce Sector Decree, and composed of Ministry's technical staff, began its activities.
- The Committee met for the first time on April 30, 2015, to discuss the relevant evidence, and in consequence, the Technical Secretary of the Committee ordered a series of proofs and accepted those requested by the parties in order to determine the relevance and feasibility of the request made by organizations of Colombian civil society.
- Once the recollected and constructed evidence was valued, as well as all comments received during the administrative action, the Committee met on October 23, 2015, and February 17, 2016, to decide on the recommendation that would address the request for the declaration of existence of reasons of public interest.
- The Committee issued a recommendation to the Minister of Health and Social Protection, consisting on promoting price negotiations of Glivec® with Novartis AG and stating the public interest reasons to the drug imatinib in order to issue a compulsory license. This recommendation is based on the need to reestablish competition, progressively lost at the time of the concession of the patent.

- The recommendation report issued by the Committee was published on the website of the Ministry, together with other documentation associated with the administrative procedure.
- As part of the regulation procedure, the Ministry received comments on the report from interested parties.
- Once the term for comments was completed, the Technical Secretary of the Committee submitted to the Minister the recommendation report along with comments received throughout the administrative procedure, including those presented against the request.
- Taking into account the Committee recommendation, the Minister initiated a negotiation process of the price of Glivec with Novartis AG through a formal letter where making an initial offer of 140 Colombian pesos per mg of Glivec, as maximum retail price.
- Novartis AG responded to the invitation to negotiate, indicating that negotiations on the price of Glivec with the Ministry were unfeasible. In spite of the fact that there were several meetings between the Ministry and Novartis, it was not possible to achieve an agreement.
- In this vein, and once all of the information that was part of the procedure was analyzed, the Minister issued the Resolution 2475 (June 14, 2015) which declares the existence of public interest to the drug imatinib. Through this resolution, the Ministry requests, alternatively, to the National Commission for prices for Drugs and Medical Devices to submit Glivec to the regime of direct price control using a general methodology that simulates competence.
- Only until the resolution of declaratory becomes definitive, that is to say, after the writs of reversal on it are resolved, the National Commission for Drugs and Medical Devices prices may continue the action to explore a general methodology to reduce the price of Glivec that reflects the benefits of competition.

Finally, it is worth to mention the the Minister of Health and social Protection, received a support letter from the World Health Organization stating that *"The WHO Expert Committee on the Selection and Use of Essential Medicines decided in 2015 to add imatinib to the WHO Model List of Essential Medicines. The committee noted in the report "that the prices are likely to be major barriers to access to these medicines". It discussed prices controls and "alternative policy approaches, such as voluntary or compulsory licenses, or government use" as possible means to ensure affordability of patented essential medicines"*.

<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/wha69p-e3020-carta-oms.pdf>