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Bogota D.C.,

Ms. Marie Paule Kieny
Assistant Director General
Health Systems and Innovation
WHO
Ciudad

Dear Dr. Kieny,

We would like to express our high appreciation for the advice made in your letter regarding the process for the declaration of public interest of the essential medicine imatinib, which is very valuable for countries as Colombia, that are using for the first time the legal flexibilities established in TRIPS agreement and reaffirmed in DOHA declaration.

I would also like to share with WHO an executive report of the process headed by the Ministry of Health and Social Protection of Colombia. Please also find attached Resolution 2475 (June 14, 2016) which declares the existence of public interest over imatinib and requests the National Commission on Pricing of Drugs and Medical Devices to determine a new direct price control for Glivec.

Our 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.

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

Sincerely yours,

ALEJANDRO GAVIRIA URIBE
Minister of Health and Social Protection
Republic of Colombia

Process for the declaration of public interest of imatinib in Colombia

Executive Report

- This process formally began on November 24, 2014, when Colombian organizations 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 essential medicine 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 the patent holder, as well as to the holders of sanitary registers of drugs with the active ingredient imatinib. Likewise, the Ministry received comments from the interested parties concerning the 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 Declaration of Public Interest established by the Decree 1074, 2015, and composed by Ministry´s technical staff, began its activities.
- The Committee met for the first time on April 30, 2015, to discuss the relevant evidence. 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.
- The Committee analyzed the collected and constructed evidence, as well as all the comments received during the administrative action, in order issue a recommendation to address the request.
- On February 24, 2016, the Committee issued a recommendation to the Minister of Health and Social Protection, consisting on declaring the public interest reasons to the drug imatinib in order to issue a compulsory license, but promoting before a

price negotiation of Glivec. This recommendation addresses the need to reestablish the competition benefits, progressively lost at the time of the concession of the patent.

- The recommendation report issued by the Committee was published on the Ministry´s website, together with all the documentation associated with the administrative procedure.
- As part of the process, 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 all the comments received throughout the administrative procedure.
- Taking into account the Committee recommendation, the Minister initiated a price negotiation process with Novartis AG through a formal letter making an initial offer.
- 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 related to the procedure was analyzed, the Minister issued the Resolution 2475 (June 14, 2016) for the declaration of public interest over imatinib. Through this resolution, the Ministry requests, alternatively, to the National Commission on Pricing of Drugs and Medical Devices to submit Glivec to a general pricing 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 on Pricing of Drugs and Medical Devices may apply a general methodology to reduce the price of Glivec reflecting the benefits of competition.