World Health Organization

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In reply please refer to:

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Mr A. Gaviria Uribe
Ministro de Salud y Protección Social
Ministerio de Salud y Protección Social
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25 May 2016

Dear Minister,

I have the honour to thank you again for the fruitful bilateral meeting we had during the World Health Assembly in Geneva on 23 May 2016. At the occasion of this meeting, you mentioned the challenges Colombia is facing with respect to making essential medicines available at affordable prices. You have asked me for some specific advice with respect to the current procedure of issuing a compulsory licence for the cancer treatment imatinib.

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. In its Report[1] the Committee noted "that the prices are likely to be major barriers to access to these medicines." It discussed price controls and "[a]lternative policy approaches, such as voluntary or compulsory licenses, or government use" as possible means to ensure affordability of patented essential medicines. Compulsory licences are one tool that WTO Members can use where patents become a barrier to access to affordable treatment. The instrument has been used in the past years by a number of countries to make HIV treatment more affordable, but also with respect to some high-priced cancer treatments, notably by Thailand and India. The WTO Ministerial Conference in Doha in 2001 reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose [promote access to medicines for all]." The Declaration[2] recognizes that each WTO Member "has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Thus, each WTO Member is free to determine the grounds upon which a compulsory licence can be granted in its national laws. Unaffordable high prices of essential medicines, including for non-communicable diseases are a legitimate reason for issuing a compulsory licence.

cc: Señora Ministra de Relaciones Exteriores, Ministerio de Relaciones Exteriores, Subsecretaría de Organismos Internacionales, Santa Fe de Bogotá
Señor Secretario General, Ministerio de Salud, Santa Fe de Bogotá
Señor Director de Cooperación y Relaciones Internacional, Ministerio de Salud, Santa Fe de Bogotá
Permanent Mission of Colombia to the United Nations Office and Specialized Institutions at Geneva
E. Pisani, Director-General, IFPMA

[1] WHO. The Selection and Use of Essential Medicines - Report of the WHO Expert Committee, Geneva 2015.
[2] WTO declaration on the TRIPS Agreement and Public Health WT/MIN(01)/DEC/2

The WTO TRIPS Agreement lays down certain conditions for issuing a compulsory licence, including the requirement to make efforts to find an agreement with the patent holder. Possible solutions include price agreements and voluntary licences. I understand from you that you have proposed such negotiations to the patent holder of imatinib, to lower the price of this treatment in Colombia, but that unfortunately the company has not so far agreed to enter into discussions with you on this topic. As we have seen in the past. good faith negotiations can lead to mutually beneficial agreements; I hope that such negotiations can take place at the soonest.

Should you have any questions or should you wish further information, my team and I remain at your disposal to assist you in line with the mandate conferred to WHO by the Global strategy and plan of action on public health, innovation and intellectual property, to provide, upon request, in collaboration with other competent organizations, technical support to countries that intend to make use of the flexibilities contained in the WTO TRIPS Agreement as recognized by the Doha Declaration.

I wish you success in providing access to essential medicines to the people of Colombia.

Yours faithfully,

Dr Marie-Paule Kieny
Assistant Director-General
Health Systems and Innovation