Declaration of Public Interest Regarding Access to Imatinib (Glivec) in Colombia

[vc_row][vc_column][vc_column_text](Open letter to the Swiss Government)

To:
Mr. Johann Schneider-Ammann, Federal Councillor Head of the Federal Department of Economic Affairs, Education and Research
Mr. Didier Burkhalter, Federal Councillor Head of the Federal Department of Foreign Affairs
Mr. Alain Berset, Federal Councillor Head of the Federal Department of Home Affairs

Dear Federal Councillors,

The undersigned Colombian and international public health organisations express their utmost concern regarding the Swiss government's attempt to dissuade the government of Colombia to grant a compulsory license to allow affordable access to a high-priced patented Novartis cancer medicine.

In November 2014, Colombian public health organisations submitted a motivated request to the Minister of Health and Social Protection of Colombia to declare of public interest the access to imatinib (Glivec®) (i) . Imatinib is a medicine produced by Swiss pharmaceutical firm Novartis. It is used for the treatment of Chronic Myeloid Leukemia, a specific form of blood cancer, as well as for other types of cancers.

The Ministry of Health and Social Protection of Colombia is now considering the merits of the case and will soon decide whether or not to declare access to imatinib of public interest for Colombian citizens. Under Colombian law, a declaration of public interest can be a step toward a compulsory license. A compulsory license is an effective tool to ensure a substantial decrease in the price of a medicine.

However, in a letter of 26 May 2015, the government of Switzerland tried to dissuade Colombia from issuing a compulsory license (ii) . In this letter, the State Secretariat for Economic Affairs of Switzerland misinforms the Colombian government about the legal grounds on which a compulsory license can be granted. It also makes unfounded statements about the impact of such a license on pharmaceutical R&D and innovation. By sending this letter, the Swiss federal administration disregards the public health needs of the Colombian population.

The Truth: Countries have the full freedom to make use of TRIPS flexibilities, including compulsory licenses, as they see fit for public health purposes.

Compulsory licensing is a flexibility enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (iii) and reaffirmed by the Doha Declaration on TRIPS and Public Health (iv). Nothing in TRIPS restricts the use, the justifications, the circumstances or even the nature of the public health concern for which compulsory licences can be granted. The Doha Declaration clearly states that "each member [of the World Trade Organization] has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." It is therefore not a ''policy tool of last resort" as the Swiss government wrongly states in its letter. Compulsory licenses are an integral part of our internationally agreed patent system. High-income countries, including the United States (US), have also used compulsory licensing as a method to negotiate a lower price for medicines (v).

A compulsory license is not equal to expropriation and there is no evidence of a resulting decrease in investment in pharmaceutical R&D

A compulsory license is a government-authorised license to produce and market a cheaper generic version of a patented medicine on the condition that the authorised generic company pays a royalty to the patent holder. Therefore, a compulsory licence is not "tantamount to an expropriation of the patent owner", as stated in the letter of the Swiss government.

Moreover, the Swiss government states that compulsory licencing will reduce subsequent investments in research and development (R&D) and innovation. This cannot, however, be substantiated by empirical evidence. On the contrary, experience from countries who have issued many compulsory licenses over a long period of time (including Canada and the US) showed no measurable decline in innovation (vi). The impact on innovation is also likely to be marginal, given the insignificance of the Colombian market for imatinib (USD 23 million of sales in 2014 [vii]) in relation to the global market (USD 4.7 billion of sales in 2014 [viii]). In 2014, Novartis' sales of pharmaceutical products for Canada and the Latin America region account for only 10% of the worldwide sales (ix). Besides, some public health organisations openly question Novartis' claimed R&D investments in the development of Glivec® (x).

Public health benefit of a compulsory license on imatinib would be significant

Granting a compulsory license to allow for the generic production at affordable prices of imatinib is extremely important in terms of public health gains for Colombian citizens. Imatinib was recently placed on the Essential Medicines List of the World Health Organization, which represents a selection of products that should be available at all time and at a price the individual and the community can afford (xi). However, the median annual cost of Glivec® per patient charged by Novartis in Colombia is about US$ 20,000 (xii) whereas the Gross National Income per capita was US$ 12,600 in 2014 (xiii). The high prices charged by Novartis could be reduced by the introduction of generic products by 68-77 %. This would represent savings of around US$ 15,000,000 per year (xiv). This money can be used by the Colombian authorities to invest in improving health systems, building hospitals, water sanitation, nutrition and other critical investments in a country where

around 30% of people live under the poverty level (xv).

We ask the government of Switzerland to fully respect its commitments under the Doha Declaration on TRIPS and Public Health and to act consistently with its Foreign Health Policy approved by the Federal Council in March 2012. Switzerland should support the implementation of TRIPS, including all TRIPS flexibilities, by low and middle income countries. In particular, Switzerland should refrain from further exercising political pressure on Colombia and other low and middle income country governments that plan to implement compulsory licences or other TRIPS flexibilities for public health purposes.

SIGNATORIES:
Arbeitsgruppe Schweiz-Kolumbien (ask!, Switzerland)
Association d'aide médicale à l'Amérique Centrale (AMCA, Switzerland)
Berne Declaration (Switzerland)
BUKO Pharma-Kampagne (Germany)
Conferencia Episcopal Colombiana (Colombia)
Federación Médica Colombiana (Colombia)
Health Action International
Health GAP (Global Access Project, USA)
Knowledge Ecology International (USA)
Knowledge Ecology International Europe (Switzerland)
Observamed (Colombia)
People's Health Movement
Prof. Franco Cavalli, oncologist, past president UICC (Switzerland)
Public Citizen (USA)
Salud por Derecho (Spain)
STOPAIDS (UK)
Treatment Action Campaign (South Africa)
Young Professionals Chronic Disease Movement (USA)

CC:
Mr. Manuel Sager, Director, Swiss Development Agency
Mr. Pascal Strupler, Director, Swiss Federal Office of Public Health
Mr. Felix Addor, Deputy Director General, Swiss Federal Institute of Intellectual Property
Dr. Alejandro Gaviria Uribe, Minister of Health and Social Protection of Colombia
Dr. Javier Humberto Guzmán Cruz, Medicines and Health Technologies Director, Ministry of Health and Social Protection of Colombia
Dra. Carolina Gómez Muñoz, Ministry office adviser, Ministry of Health and Social Protection of Colombia

ENDNOTES:
i. Available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Solicitud-de-una declaracion-en-el-acceso-al-medicamento-IMATINIB.pdf.

ii.

https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closingarguments.pdf (last accessed on 9th August 2015).

iii. See for example the Frequently Asked Questions section Compulsory licensing of pharmaceuticals and TRIPS on the World Trade Organisation's official website (last accessed on 9th August 2015).

iv. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last accessed on 9th August 2015).

v. Reichman JH., "Compulsory licensing of patented pharmaceutical inventions: evaluating the options", The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics. 2009;37(2):247- 263. doi:10.1111/j.1748-720X.2009.00369.

vi. Chien C., "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", 18 Berkeley Technology Law Journal 853 (2003).

vii. Estimation based on the 2014 quarterly statistics reported by the pharmaceutical companies to the Colombian System of Information on the Price of Medicines (SISMED). For more details, see http://www.observamed.org/FMC_CMCB/Comunicaciones/FMC_DeclaratoriaInteresPublicoImatinib_NuevaCarta MSyPS_24mar15.pdf.

viii. Novartis Annual Report 2014.

ix. Ibid.

x. http://keionline.org/node/1697. xi
http://www.who.int/medicines/services/essmedicines_def/en/

xii.
http://www.observamed.org/FMC_CMCB/Comunicaciones/FMC_DeclaratoriaInteresPublicoImatinib_NuevaCart aMSyPS_24mar15.pdf.

xiii. GNI per capita based on purchasing power parity (PPP). The GNI per capita for Colombia based on the World Bank Atlas method is US$ 7,780 in 2014. See http://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD.

xiv.
http://www.observamed.org/FMC_CMCB/Comunicaciones/FMC_DeclaratoriaInteresPublicoImatinib_NuevaCart aMSyPS_24mar15.pdf.

xv.
http://www.dane.gov.co/files/investigaciones/condiciones_vida/pobreza/bol_pobreza_mon_jul13_jun14.pdf.[/vc_column_text][/vc_column][/vc_row]