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Lausanne/Switzerland, 10th of December 2015

Contact: Patrick Durisch

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Decision on the declaration of public interest regarding the cancer drug imatinib (Glivec) in Colombia

Dear Sir, Dear Minister,

We are very much concerned that no decision has been taken more than one year after Colombian public health organisations have submitted a motivated request for a declaration of public interest regarding the cancer medicine imatinib (marketed by Novartis as Glivec). This protracted process is contrary to the provisions foreseen in the legal texts governing this procedure in Colombia, which specify that the competent authority will have three months to make a decisionⁱ.

It is also worrying that the Ministry of Health and Social Protection has not released any official update regarding the status of the process nor the expected timing of the decision, despite the important delay and the initial intention of a transparent process. The dedicated website containing all the selected relevant documents (“pruebas decretadas”) that should serve as a basis for decision is not accessible anymore at the time of writing these lines.

Together with other international NGOs, we swiftly condemned last August the unacceptable pressure from the Swiss government relying on outright falsehoods to dissuade Colombia to declare imatinib of public interestⁱⁱ. In a recent response to an intervention made by a member of the Swiss Parliament, the Federal Council continues to rely on misleading facts, such as implying that several other medicines containing the active substance imatinib are still available on the Colombian market, alongside Glivecⁱⁱⁱ. Some years ago, Thailand resisted similar political pressure coming from Switzerland and the United States and eventually decided to issue government-use licenses to several medicines, including cancer ones – the impact in terms of public health gains (access to medicines) and government budget savings has been impressive^{iv, v}.

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Whilst the response of the Swiss government to our open letter^{vi} did not answer all our criticisms, the Swiss Minister of Economy, Mr. Johann Schneider-Ammann, at least confessed that “WTO member have all freedom to utilise the flexibilities of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the area of Public Health and of the Doha Declaration on TRIPS and Public Health”. This (late) recognition should comfort you in taking a sovereign decision based on the merits of the case and of Colombia’s public health priorities and resources, and not on undue corporate or political pressure.

As expressed elsewhere, “every day that passes without a declaration of the public interest is a gift to Novartis at the expense of the people of Colombia, forcing a health system in financial crisis to continue to bear unsustainable costs”^{vii}.

We hope for a prompt, independent and transparent decision on this important matter.

Yours respectfully,



Patrick Durisch
Health Programme Coordinator
Berne Declaration

References

ⁱ Article 4.5 of the Decree 4966 of 2009, amending the Decree 4302 of 2008

ⁱⁱ See Annex 1 or https://www.ladb.ch/fileadmin/files/documents/Gesundheit/DB_Lettre-ouverte_CF_Glivec-Colombie_150818.pdf

ⁱⁱⁱ Question 15.1081 of the Swiss MP Marina Carobbio Guscetti to the Federal Council “[Access to cheaper cancer medicine in Colombia: Pressure of the Seco](#)” (available in French, German or Italian only)

^{iv} Yamabhai I. et al. *Government use licenses in Thailand: an assessment of the health and economic impacts*. Globalization and Health 2011, 7:28

^v Mohara A. et al. *Impact of the introduction of Government use licenses on the drug expenditure on seven medicines in Thailand*. Value in Health 15 (2012) S95 – S99.

^{vi} See Annex 2 for the original letter (in French) and Annex 3 for an unofficial translation in English

^{vii} Love J. and Goldman A., *Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License*, Knowledge Ecology International – Inside View posted on [Intellectual Property Watch](#), 03 December 2015



Mister Johann Schneider-Ammann
Mister Didier Burkhalter
Mister Alain Berset
Federal Council
Bundeshaus
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Lausanne, 18 August 2015

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Declaration of public interest regarding the access to imatinib (Glivec®) in Colombia

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 licenseⁱⁱ. 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.

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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-authorized license to produce and market a cheaper generic version of a patented medicine on the condition that the authorized 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.

We remain at your disposal for further information.

Yours sincerely,



Patrick Durisch
Berne Declaration

The following organisations or personalities have signed-on to this letter:

- 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 (Europe)
- Health GAP (Global Access Project, USA)
- Knowledge Ecology International (USA)
- Knowledge Ecology International Europe (Switzerland)
- Observamed (Colombia)
- Prof. Franco Cavalli, oncologist, past president UICC (Switzerland)
- Public Citizen (USA)
- Salud por Derecho (Spain)
- STOPAIDS (UK)
- Treatment Action Campaign (South Africa)
- [...]

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

- 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>.
- <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closing-arguments.pdf> (last accessed on 9th August 2015).
- 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).
- https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last accessed on 9th August 2015).
- 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.
- Chien C., "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", *18 Berkeley Technology Law Journal* 853 (2003).
- 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_NuevaCartaMSyP_S_24mar15.pdf.
- Novartis Annual Report 2014.
- Ibid.
- <http://keionline.org/node/1697>.
- http://www.who.int/medicines/services/essmedicines_def/en/
- http://www.observamed.org/FMC_CMCB/Comunicaciones/FMC_DeclaratoriaInteresPublicoImatinib_NuevaCartaMSyP_S_24mar15.pdf.
- 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>.
- http://www.observamed.org/FMC_CMCB/Comunicaciones/FMC_DeclaratoriaInteresPublicoImatinib_NuevaCartaMSyP_S_24mar15.pdf.
- http://www.dane.gov.co/files/investigaciones/condiciones_vida/pobreza/bol_pobreza_mon_jul13_jun14.pdf



22 SEP. 2015

CH-3003 Berne, SG-DEFR, JSA

Courrier A

Déclaration de Berne
Monsieur Patrick Durisch
Av. Charles-Dickens 4
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Berne, le 18 septembre 2015

Déclaration d'intérêt public concernant l'accès à l'imatinib (Glivec®) en Colombie

Monsieur,

J'accuse réception de votre lettre du 18 août adressée également à Messieurs les Conseillers fédéraux Alain Berset et Didier Burkhalter et vous en remercie.

Vous vous référez à un courrier du 26 mai 2015 des autorités suisses dans le cadre d'une procédure de consultation publique du gouvernement de la Colombie pour déclarer le médicament Glivec® de Novartis d'intérêt public ce qui pourrait constituer une première étape en vue d'établir une licence obligatoire par le Bureau des brevets colombien.

Le gouvernement suisse est sensible aux besoins de santé publique de la population colombienne et aux situations difficiles liées notamment aux maladies graves dont le traitement nécessite des médicaments coûteux. La Suisse entretient de longue date un dialogue ouvert et constructif notamment avec la Colombie sur diverses questions d'intérêt commun, dont la santé.

La Suisse reconnaît pleinement que les membres de l'OMC ont toute liberté d'utiliser les flexibilités de l'accord de l'OMC sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) dans le domaine de la santé publique ainsi que de la Déclaration de Doha relative à l'accord sur les ADPIC et la santé publique. En 2006, la Suisse a été le deuxième parmi les 160 membres de l'OMC à autoriser la possibilité d'octroyer une licence obligatoire pour l'exportation de médicaments dans des pays en besoin.

En Colombie, comme dans la plupart des pays, les prix des médicaments sont fixés, évalués et modifiés par le gouvernement, notamment le ministère de la Santé. Ce dernier a lancé une consultation publique à laquelle la Suisse a participé pour préciser ses positions de principe. Les licences obligatoires ne sont pas une voie simple du fait qu'il faut trouver une entreprise apte à produire le médica-



ment, dans la quantité et à la qualité nécessaires, pour un prix déterminé. Selon la forme galénique du médicament, la production peut s'avérer très complexe. Des solutions plus rapides, plus efficaces et des mesures moins lourdes que les licences obligatoires devraient être préalablement examinées. Dans ce contexte, la Suisse favorise des négociations entre les autorités compétentes et le producteur originel concernant les prix ou le droit de licence. L'octroi d'une licence obligatoire ne devrait donc intervenir que si les autres options ne devaient pas aboutir au résultat recherché.

La Suisse poursuit au niveau mondial une politique qui protège la propriété intellectuelle. Dans le domaine pharmaceutique, les brevets sont très importants, voire essentiels, pour stimuler la recherche et le développement de nouveaux médicaments et les rendre disponibles sur les marchés. Il est donc dans l'intérêt de la Colombie de disposer d'un cadre juridique sûr et d'une protection des brevets.

La Colombie est un pays prioritaire pour la coopération économique suisse avec un programme annuel d'environ 15 millions de francs. L'action de la Suisse s'étend également à l'aide humanitaire avec des services de base pour les victimes du conflit, des actions pour promouvoir la sécurité humaine et des partenariats stratégiques. Ceci est complété par une politique de la paix et des droits de l'homme active. S'agissant de nos relations économiques avec la Colombie, elles sont excellentes avec un cadre important d'accords couvrant notamment le libre-échange, la promotion et la protection réciproque des investissements et les questions de double imposition. Le commerce bilatéral s'élève à plus d'un milliard de francs (2014) et les investissements des entreprises suisses atteignent 1.3 milliard de francs avec plus de 16'000 employés dans le pays.

La Suisse continuera à poursuivre à l'avenir son étroite coopération avec la Colombie en soutenant ses efforts dans nos domaines d'action afin d'améliorer constamment ses conditions-cadres et le niveau de vie de sa population.

Je vous prie d'agréer, Monsieur, mes salutations distinguées.

Johann N. Schneider-Ammann
Conseiller fédéral

Unofficial copy & translation of the original letter in French

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Berne Declaration
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Berne, 18th of September 2015

Declaration of public interest regarding the access to imatinib (Glivec®) in Colombia

Sir,

I acknowledge receipt of your letter dated 18 August that was also addressed to the Federal Councillors Mr. Alain Berset and Mr. Didier Burkhalter and thank you for that.

You refer to a letter of 26 May 2015 from the Swiss authorities during a public consultation procedure of the government of Colombia to declare of public interest the medicine Glivec® of Novartis, which could constitute a first step toward the issuance of a compulsory license by the Colombian patent office.

The Swiss government is sensitive about the public health needs of the Colombian population and about the difficult situations linked especially with the serious illnesses whose treatments require costly medicines. Switzerland has been conducting for a long time an open and constructive dialogue among others with Colombia on various questions of common interest, including health.

Switzerland fully recognises that WTO members have all freedom to utilise the flexibilities of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the area of Public Health and of the Doha Declaration on TRIPS and Public Health. In 2006, Switzerland was the second among the 160 WTO members to authorise the possibility to grant a compulsory license for the exportation of medicines to countries in need.

In Colombia, as in most countries, the prices of medicines are set, evaluated and modified by the government, in particular by the Ministry of Health. The latter one launched a public consultation to which Switzerland has participated in order to clarify its positions on questions of principle. Compulsory licenses are not an easy path as there is a need to find a company able to produce the medicine, in the needed quantity and quality, at a determined price. Depending on the dosage form of the medicine, production can prove to be very complex. Rapid solutions that are more efficient and measures that are less heavy than compulsory licensing should be examined first.

In this context, Switzerland favours negotiations between the competent authorities and the original producer regarding pricing or the right to license. The granting of a compulsory license should thus only occur if other options have not led to the expected result.

Switzerland follows at the international level a policy that protects intellectual property. In the field of pharmaceutical research, patents are very important, indeed essential, to stimulate research and development of new medicines and to make them available in the markets. It is thus in the interest of Colombia to have a secure legal framework and a protection of patents.

Colombia is a priority country for the Swiss economic cooperation with an annual programme of roughly 15 million [Swiss] francs. Switzerland is also active in the field of humanitarian aid with basic services for the victims of conflicts, actions to promote human security and strategic partnerships. This is complemented by an active peace and human rights policy. As far as our economic relations with Colombia are concerned, these are excellent with an important set of agreements that cover inter alia free trade, the reciprocal promotion and protection of investments, as well as matters of double taxation. The bilateral trade amounts to more than 1 billion [Swiss] francs (2014) and investments of Swiss enterprises reach 1.3 billion [Swiss] francs with more than 16,000 employees in the country.

Switzerland will pursue in the future its close cooperation with Colombia by supporting, in our policy areas, its efforts to constantly improve its framework conditions and the standard of living of its population.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Schneider-Ammann', written in a cursive style.

Johann N. Schneider-Ammann
Federal Councillor