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SWITZERLAND

Missing policy coherence: trade interests overriding right to health?

Executive summary

Switzerland applies a human rights approach to health in its development cooperation. As a State party to the International Covenant on Economic, Social and Cultural Rights (ICESCR, Covenant), it has committed to contributing towards realizing the right to health in developing countries. As a member of the World Trade Organisation (WTO), Switzerland is complying with the WTO General Council Decision of 30 August 2003, which allows exports of generic drugs under compulsory licensing to countries in need, but has not yet applied the mechanism. As a promoter of the World Health Organization's (WHO) Global Strategy adopted in 2008 and of the Millennium Development Goals, Switzerland also committed to promote health innovations and access to affordable essential drugs in developing countries.

However, Switzerland is supporting trade rules that put at risk its obligations with respect to the right to health in other countries. The intellectual property (IP) rules on medicines in its free trade agreements (FTAs) negotiated as a member of the European Free Trade Association (EFTA), mostly go beyond minimal WTO standards and include extended patent terms and exclusive rights over experimental data. Such rules delay the introduction of cheaper generic drugs and hamper access to medicines for the most disadvantaged people in trade partner States. For example, including TRIPS-plus provisions in the EFTA-India FTA currently under negotiation would provide Swiss transnational corporations yet another instrument to exercise pressure on the domestic IP regime and its safeguards for public health. Switzerland has also asked the Thai government to restrict the latter's use of compulsory licenses. Such policies go against Switzerland's development cooperation efforts and do not comply with its international human rights obligations.

Also of concern are Switzerland's IP enforcement strategies in multilateral fora, such as its participation in the negotiations for a controversial anti-counterfeiting trade agreement (ACTA). Moreover, Switzerland has to take into account the right to health when providing IP technical assistance to developing countries. It is also crucial that the State party provides complete and transparent information regarding trade policy that might affect the right to health to its Parliament and civil society groups. Finally, as a member of the World Health Organization (WHO), the State party should implement the WHO Global Strategy more expeditiously.

Right to health: Switzerland's international obligations and commitments

Dimensions of the right to health

As a State party to the International Covenant on Economic, Social and Cultural Rights (Covenant), Switzerland is obliged "to take steps individually or through international assistance and cooperation, especially economic and technical…" towards fully realizing the rights recognized in the Covenant. The international dimension of this obligation means that States must protect, respect and fulfil economic, social and cultural rights not only nationally, but also in other countries.[1] In the case of the right to health, which includes access to affordable medicines,[2] the Covenant requires States to (i) respect the enjoyment of the right to health, (ii) prevent third parties from violating the right to health and (iii) facilitate access to essential health facilities, goods and services in other countries. States parties should also ensure that the right to health is given due attention in international agreements and when acting as members of international organizations.[3] Another important dimension of the right

to health is the "the right to seek, receive and impart information and ideas concerning health issues."[4] This means that States parties have the obligation to ensure access to information and participation in health related decision-making.

Multilateral framework and access to medicines

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed by all members of the WTO, sets minimum standards on intellectual property rights (IPRs). The Agreement includes flexibilities to facilitate access to medicines. Eligible countries, in particular least developed economies, may grant compulsory licenses to produce cheaper generic versions of patented medicines or allow parallel imports of patented medicines that are sold at lower prices in other countries. These flexibilities were reaffirmed by the Doha Declaration, which promotes the protection of public health and especially access to medicines for all.[5] The Declaration also recognized that under TRIPS, compulsory licenses are not useful for countries without pharmaceutical manufacturing capacities.

To remedy this situation, the WTO General Council decided on 30 August 2003[6] to introduce a temporary waiver to the TRIPS Agreement, allowing WTO member States to export medicines made under a compulsory license to countries that cannot produce pharmaceuticals themselves. This flexibility was incorporated as a permanent amendment to the TRIPS Agreement on 6 December 2005.[7] Switzerland adopted this amendment in 2006 and revised its patent law to allow exports under a compulsory license. The revised law came into force on 1 September 2008.[8] Since then, generic drugs produced under a compulsory license in Switzerland can be put at the disposal of countries facing public health problems. So far, the State party has not applied the mechanism.[9]

Switzerland also was one of the promoters of the *Global strategy and plan of action on public health, innovation and intellectual property* (WHO Global Strategy)[10] and committed to implement it nationally and internationally as fast as possible.[11] The Strategy "aims to promote new thinking on innovation and access to medicines..."[12] and, among other measures, invites States to "encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement....".[13] Furthermore, Switzerland committed to contribute to the achievement of the UN Millennium Development Goals, including providing access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies (Goal 8, target 17).

Missing policy coherence: development vs. trade

Switzerland's free trade policy

Switzerland's overall goal in providing development cooperation in health aims "to reduce inequities by strengthening pro poor health systems and making the offer more responsive to the needs".[14] This goal is based on a human rights approach to health and means that the competent authority, the Swiss Agency for Development and Cooperation (SDC) is advocating "for the priority of public health matters in debates on intellectual property and in trade considerations."[15] However, as a member of the European Free Trade Association (EFTA),[16] Switzerland is promoting trade rules that put at risk its obligation to respect, protect and fulfil the enjoyment of the right to health in other countries.

In its *Report on Foreign Economic Policy 2008*, Switzerland explicitly states that certain aspects of intellectual property within EFTA FTAs go beyond the minimal standards of TRIPS, due to the country's economic interests.[17] Pharmaceuticals are an important sector of the Swiss economy: in 2008, Swiss exports of medicines amounted to 55 billion Swiss francs, or 77% of all exports of chemical and pharmaceutical products and almost a third of the total Swiss exports.[18] Globally, Switzerland is among the 10 biggest exporters of pharmaceuticals, with a share of over 4% of world exports in that sector.[19] The so-called "TRIPS-plus" provisions on medicines within EFTA FTAs mainly refer to the extension of the patent term and to exclusive rights over experimental data. In practice, such provisions delay the introduction of cheaper generic medicines and therefore hamper access to medicines for the most vulnerable population groups.

Switzerland justifies the **extended patent terms** beyond the 20 years stipulated by TRIPS by the delays that may occur during the marketing approval of a new pharmaceutical product. It argues that the patent holder should receive a compensation for these delays to be able to recover research and development (R&D) costs.[20] However, IP experts dispute the necessity for such extensions.[21] **Exclusive rights over experimental data** within EFTA FTAs generally provide for a minimum of five years during which experimental data of pharmaceutical products cannot be used without the consent of the data originator.[22] The experimental data is required to prove the safety and efficacy of new medicines to obtain marketing approval. This means that a generic producer has to either seek the consent of the test data originator, namely by providing a financial compensation, or to repeat the tests, which are very expensive and time-consuming. Thus, generic producers are likely to introduce their product only at the end of the exclusivity period.[23] Data exclusivity might also prevent the registration of medicines produced under a compulsory license. Finally, as data exclusivity is not linked to the patent status of a pharmaceutical product, it could even impede the introduction of generics when there is no patent on a drug.[24]

The Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, in his report to the Human Rights Council in March 2009, points out in detail the impacts of TRIPS-plus in FTAs on the right to health and access to medicines. He recommends that "developed countries should not encourage developing countries and LDCs [least developed countries] to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health."[25]

Pressure on domestic patent law in India

In India, the Swiss company Novartis has challenged domestic patent policy by filing law suits before the courts. In the case of the company's patent application for Glivec, a drug against blood cancer, the Indian Intellectual Property Appelate Board (IPAB) decided in June 2009 not to grant the patent, arguing that it lacked innovation and that the price was too high.[26] The decision was partly based on Section 3(d) of the Indian patent law, which prohibits "evergreening" practices. The latter refer to pharmaceutical companies seeking to prolong patent terms by making small changes to existing drugs. Such mechanisms delay the introduction of cheaper generic versions. Although this is the third refusal by Indian courts to grant a patent to Glivec, Novartis decided to appeal against the IPAB decision and its interpretation of Section 3(d).[27] Indian civil society groups strongly oppose such practices.[28]

Currently, EFTA is negotiating a FTA with India, one of the biggest producers and exporters of generics worldwide. If TRIPS-plus rules are included in the FTA, the policy space of the Indian government to maintain public health safeguards within national legislation would be reduced. Such rules would also provide Swiss transnational pharmaceutical companies (see Novartis example below) with yet another tool to exercise pressure on the Indian patent regime. Pursuing such a policy when negotiating FTAs, which contradicts the Swiss engagement in the field of development cooperation, does not take into account the right to health. Switzerland should refrain from promoting IP provisions going beyond WTO's minimal standards when negotiation FTAs with developing countries. In March 2009, EFTA-member Norway, in discord with the Swiss IP policy, withdrew from including IP rules in the negotiations with India, setting therewith an important precedent to support access to affordable medicines and to respect the right to health internationally.[29]

Struggle on compulsory licenses in Thailand

Thailand has authorized compulsory licenses[30] on patented HIV/AIDS and cancer drugs on several occasions, making use of the WTO TRIPS flexibilities as reaffirmed by the Doha Declaration. These licenses respond to the country's public health needs and enable the government to provide affordable generic drugs for a broader population affected by these diseases. In January 2008, Thailand authorized compulsory licenses on four medicines against cancer, involving the Swiss patent holders Novartis and Roche. Both opposed Thailand's decision[31] and were supported by the Swiss government, which asked the Thai authorities to review their policy on compulsory licenses, advocating for a restrictive use of compulsory licenses and arguing that these threaten investment in R&D in Thailand.[32]

Considering that the Doha Declaration (article 5(b)) affirms that States have the right to determine the grounds upon which compulsory licenses are granted and the Covenant's obligation to respect the right to health in other countries, Switzerland should not promote a restrictive use of compulsory licenses and other TRIPS flexibilities with regard to public health priorities of developing countries.

IP enforcement

Global IP enforcement strategies supported by Switzerland in bi- and multilateral fora are another area of concern. Currently, the government is participating in the negotiations for an anti-counterfeiting trade agreement (ACTA), which "aims to establish international standards for enforcing intellectual property rights in order to fight more efficiently the growing problem of counterfeiting and piracy."[33] Although it is necessary to tackle piracy and counterfeiting, such a treaty could have adverse impacts on the legitimate production, transportation and sale of generic medicines. Civil society groups in many countries have criticised the secrecy around the treaty negotiations. Switzerland should promote transparency[34] in accordance with the requirements under the right to health, which include access to information concerning health issues.[35] Moreover, the State party should encourage the participation of more developing countries in the negotiations to ensure that the outcome does not hamper access to affordable medicines.[36]

Technical assistance programmes

Switzerland provides technical assistance in IPRs to developing countries bilaterally as well as a member of EFTA and international organizations such as the WTO and the World Intellectual Property Organization (WIPO). Over the past years, concerns have been raised at WIPO that such technical assistance programmes are not fully adapted to developing countries' IP and public health needs.[37] Based on the final report of the Commission on Intellectual Property Rights, Innovation and Public Health,[38] the WHO Global Strategy addresses this concern. It emphasizes that States should "promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries."[39] In conjunction with Article 2 (1) of the Covenant, Switzerland must ensure that the technical assistance – whether provided bi- or multilaterally to developing countries – promotes the use of TRIPS flexibilities as reaffirmed by the Doha Declaration and the General Council Decision of 2003, to guarantee the right to health for all, especially the most vulnerable groups.

Working towards more coherence in foreign health policy?

Interdepartmental cooperation and coherence

The Federal Departments of Foreign Affairs (FDFA) and Home Affairs (FDHA) agreed in 2006 to promote better interdepartmental coordination and coherence in foreign health policy. The Swiss Agency for Cooperation and Development (SDC) and the Office of Public Health lead the implementation of the strategic goals of the policy, with the collaboration of the State Secretariat for Economic Affaires (SECO) and other departments. The interdepartmental agreement mentions the divergent interests regarding IP and access to medicines and refers to the growing responsibility taken by the private sector to collaborate in tackling the issue.[40] Due to their mandates, SECO and SDC pursue diverging goals in the field of access to medicines. Nevertheless, considering its obligations under the Covenant, Switzerland should work towards adopting a rights-based approach to health throughout all departments involved in national and foreign health policy, including SECO.

Participation and transparency

The Federal Council, Switzerland's executive branch, regularly consults the parliamentary Committees of Foreign Affairs and Economic Affairs and Taxations of both chambers with regard to negotiating mandates for FTAs.[41] The Committees also review concluded FTAs before they are submitted for ratification to the two chambers. Also, a special parliamentarian delegation is assigned to represent the Federal Assembly in EFTA. However, the National Council's Committee of Foreign

Affairs has repeatedly criticized the Federal Council for not involving the Committee members sufficiently when taking important decisions on foreign policy-making.[42]

SECO maintains a dialogue with civil society groups through the "Liaison group WTO-NGO". This mechanism provides regular information to public and private interest groups on the government's bi- and multilateral trade activities. Participants have the opportunity to present concerns and recommendations. Swiss NGOs working on trade- and health-related issues also submit petitions to the Parliament. However, civil society organizations think that the official trade policy making is not transparent enough and that their concerns are not given due account.[43]

The information regarding IP rules within ETFA FTAs submitted by the Federal Council to the Parliament states that TRIPS-plus regulations on medicines represent a precision,[44] an improvement or progress of the IP protection level when compared with the multilateral regime.[45] However, the public health implications of using such strict IP rules are not mentioned. To comply with the right to health, including access to information on health issues,[46] the information submitted to Parliament should spell out public health implications of bilateral trade rules that go beyond multilateral standards, especially when developing countries are involved.

Questions and recommendations

Which steps has the State party taken to respect the enjoyment of the right to health in developing countries with regard to international trade?

The State party should take into account its obligation to respect the enjoyment of the right to health in developing countries in all aspects of its trade policy. In particular, Switzerland should 1) refrain from promoting TRIPS-plus provisions when negotiating FTAs with developing countries and 2) respect the right of developing countries to use the TRIPS flexibilities and to define their public health priorities.

Which steps has the State party taken to ensure that the IP technical assistance it provides to developing countries is oriented towards the latter's innovation and public health needs?

The State party should ensure that the technical assistance on IP matters it provides to developing countries individually or as a member of EFTA, the WTO and the WIPO is conform with the obligations of States parties under the Covenant, in particular the right to health.

What are the measures taken by the State party to ensure access to information and consultation of the Parliament and civil society groups regarding trade policy-making and access to medicines?

The State party should ensure that the information provided to civil society groups and the Parliament spells out public health implications of its trade-related IP policy.

Which measures has the State party planned to take regarding the implementation of the WHO *Global strategy and plan of action on public health, innovation and intellectual property* at national and international level?

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3D → Trade – Human Rights – Equitable Economy is a Swiss non-profit organization based in Geneva. Our work seeks to ensure that trade and related policies are developed and applied in ways consistent with human rights and the promotion of an equitable economy. Human rights mechanisms such as the Committee on Economic, Social and Cultural Rights can play a crucial role to achieve this objective by reminding States that international trade and related rules have to comply with human rights obligations.

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[1] ICESCR, article 2(1), as interpreted by CESCR *General Comment No. 3*, 1990, http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument
[2] CESCR, *General Comment No. 14*, article 12(b) on affordability of health facilities, goods and services, 2000, http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument
[3] ICESCR, article 12, as interpreted by CESCR *General Comment No. 14*, *op. cit.*
[4] CESCR, *General Comment No. 14*, article 12(b) on information accessibility, *op. cit.*
[5] *Doha Declaration on the TRIPS Agreement and public health*, 14 November 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[6] *Decision of the General Council of 30 August 2003 regarding the TRIPS Agreement and public health*, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
[7] However, to become a formal amendment, it still has to be signed by two thirds of the WTO members.
[8] Autorités fédérales de la Confédération Suisse, Loi fédérale sur les brevets d'invention (Loi sur les brevets, LBI), articles 40d et 40e, http://www.admin.ch/ch/f/rs/232_14/
[9] According to the WTO notification system, only Rwanda has solicited its application to import generic drugs from Canada, October 2009, *TRIPS and public health: dedicated webpage for notifications*, http://www.wto.org/english/tratop_E/TRIPS_e/public_health_e.htm
[10] Adopted on 24 Mai 2008 by the World Health Assembly
[11] However, Switzerland also indicated that the implementation would depend on balancing the divergent opinions regarding access to medicines within the Federal administration. Federal Department of Foreign Affairs, *Rapport sur la politique extérieure 2009*, http://www.eda.admin.ch/etc/medialib/downloads/edazen/doc/publi/aussen.Par.0002.File.tmp/AB09_fr.pdf, p. 111-112
[12] WHO, WHA61.21, 24 Mai 2008, http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, p. 6
[13] *Ibid*., p. 15
[14] Federal Department of Foreign Affairs, Swiss Agency for Development and Cooperation, *SDC health policy 2003-2010*, http://www.deza.admin.ch/en/Home/Themes/Health, p. 10-11
[15] *Ibid.*
[16] EFTA was set up in 1960 as an intergovernmental organization to promote trade liberalization and economic integration. Its present members are Switzerland, Norway, Island and Liechtenstein. Since 1995, EFTA has extended its network of FTAs outside the European Union, concluding FTAs with Canada, Chile, Croatia, Colombia, Egypt, the Gulf Cooperation Council (GCC), Israel, Jordan, Republic of Korea, Lebanon, Macedonia, Mexico, Morocco, the Palestinian Authority, Peru, Singapore, the Southern African Customs Union (SACU), Turkey and Tunisia.
[17] State Secretariat for Economic Affairs, *Rapport sur la politique économique extérieure 2008*, http://www.seco.admin.ch/themen/00513/00514/index.html?lang=fr, p. 81
[18] Interpharma, *Balance commerciale des produits pharmaceutiques en 2008*, October 2009, http://www.interpharma.ch/fr/faites-et-statistiques/le-marche-du-medicament-en-suisse/6607.asp?ShowBackButton=1
[19] SGCI Chemie Pharma Schweiz, *Leading export nations (2007)*, October 2009, http://www.sgci.ch/plugin/template/sgci/*/9830
[20] See EFTA-Chile FTA, Annex XII, article 3(b); EFTA-Colombia FTA, article 6.9 (5). The agreements are available at http://www.efta.int/content/free-trade/fta-countries. For a summary of TRIPS-plus provisions on medicines within EFTA FTAs concluded between 1995-2004 see Berne Declaration, *Deprive Doha of all Substance*, August 2004, http://www.evb.ch/cm_data/depriveDoha.pdf
[21] Carlos Correa, 'Implications of bilateral free trade agreements on access to medicines', *Bulletin of the World Health Organization*, Vol. 84, No 5 (2006): 399-404
[22] See EFTA-Chile FTA, Annex XII, article 4; EFTA-Colombia FTA, article 6.11; EFTA-Lebanon FTA, Annex V, article 4 (6 years of exclusivity); EFTA-Tunisia FTA, Annex V, article 4, available at http://www.efta.int/content/free-trade/fta-countries. The EFTA FTAs with Colombia and Chile only include exclusivity rights over test data for pharmaceuticals which use "new chemical entities". The EFTA-Colombia FTA mentions further that "in an exceptional case" the 5 year term could be reduced if public health interests would need to take precedence over data exclusivity. These precisions might to some extent reduce the adverse effects on access to medicines. Nevertheless, the fact of including exclusive rights over experimental data always implies complications for introducing cheaper drugs and should therefore be avoided.
[23] WHO Regional Office for South-East Asia, *Briefing Note. Access to Medicines,* March 2006, http://www.searo.who.int/LinkFiles/Prevention_and_Control_BF_MAR06.pdf
[24] *Ibid.*
[25] UN Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, *Anand Grover*, A/HRC/11/12, 31 March 2009

[26] PB Jayakumar, 'Novartis loses battle for cancer drug patent', *Business Standard*, Mumbay, 5 July 2009, http://www.business-standard.com/india/news/novartis-loses-battle-for-cancer-drug-patent/362951/
[27] Berne Declaration, *Novartis Clivec patent case in India*, 31 August 2009, http://www.essentialdrugs.org/edrug/archive/200908/msg00044.php l
[28] See 'India. Intellectual Property and Access to Medicines: Developments and Civil Society Initiatives in India', in Renata Reis, Veriano Terto Jr. and Maria Cristina Pimenta (organizers), *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, Rio de Janeiro: ABIA, 2009
[29] Intercultural Resources, FTA-Watch India, *Ongoing negotiations: EFTA-India FTA*, Digest No. 5, 2, April 2009, http://fta.icrindia.org/ongoing-negotiations/efta-india-fta2.html
[30] A compulsory license refers to the process whereby a country is allowed to grant licenses to companies or individuals without the patent owner's consent, in order to manufacture, use, sell or import a generic version of a patented product.
[31] Finally, the compulsory license on Novartis' anti-cancer drug Clivec was not implemented. After negotiations with the Thai government, the company agreed to provide it for free to more patients. For detailed information on the issue see Berne Declaration, *La Suisse attaque les licenses obligatoires en Thaïlande,* 25 April 2008, http://www.evb.ch/p14166.html
[32] *Ibid.*
[33] The US and Japan brought up the initiative in 2006 and Switzerland has been involved since the definition of the treaty's contents in 2007.
[34] Presently, the only publicly available document is *ACTA - Summary of key elements under discussion*, April 2009, https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/j1070401e.pdf
[35] CESCR, *General Comment No. 14*, article 12(b) on information accessibility, *op. cit.*
[36] The countries currently negotiating are Australia, Canada, the European Union and its 27 member States, Japan, Jordan, Mexico, Morocco, New Zealand, Korea, Singapore, Switzerland, the United Arab Emirates and the United States, October 2009.
[37] UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, chapter 8, September 2002
[38] *Public Health, Innovation and Intellectual Property Rights*, World Health Organization, 2006, available at http://www.who.int/intellectualproperty/report/en/
[39] WHO, WHA61.21, *op. cit.*, p. 15
[40] FDFA and FDHA, *Politique extérieure suisse en matière de santé. Convention d'objectifs pour la politique extérieure en matière de santé*, 2006, available at http://www.bag.admin.ch/themen/internationales/index.html?lang=fr, p. 13
[41] In the Swiss parliament, the National Council's Committee of Foreign Affairs and the Council of States' Economic Affairs and Taxations Committee are primarily responsible for negotiating mandates for FTAs.
[42] National Council, *La Commission de politique extérieure du Conseil national pendant la 47e législature (2003 – 2007),* December 2007, p. 9
[43] See Berne Declaration and Alliance Sud, *Liaisons dangereuses: les accords bilatéraux de libre-échange Nord-Sud*, 2008
[44] See Feuille fédérale (FF) for the approval of the EFTA-FTAs with Lebanon, FF *2005* 1139, Tunisia, FF *2006* 1751, Egypt, FF *2008* 843, available at http://www.admin.ch/ch/f/ff/index.html
[45] EFTA-Chile FTA, FF *2003* 6517, EFTA-Colombia FTA, FF *2009* 2001, http://www.admin.ch/ch/f/ff/index.html
[46] CESCR, *General Comment No. 14*, article 12(b) on information accessibility, *op. cit.*