







"NOW IS NOT THE TIME TO STOP RUNNING"

SWITZERLAND'S OBLIGATION TO
SUPPORT A GLOBAL PUBLIC GOOD
APPROACH TO COVID-19 DIAGNOSTICS,
VACCINES AND THERAPEUTICS

Shadow Report to the 83rd Session of the CEDAW

Shadow report to the 83rd Session of the Committee on the Elimination of Discrimination against Women

"Now is not the time to stop running":

Switzerland's obligation to support a global public good approach to COVID-19 diagnostics, vaccines and therapeutics

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on behalf of the Feminists for a People's Vaccine Campaign

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¹ "We can see the finish line. We're in a winning position. But now is the worst time to stop running", WHO Director General Dr Tedros makes urgent call for key actions to end the pandemic on 14 September 2022.

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1. Introduction

Almost four years since the onset of the COVID-19 pandemic, the multiple crises it generated and the continuing mutation of the virus makes it clear the pandemic is not over yet and needs to be effectively controlled. Central to this is equitable access to COVID-19 diagnostics, vaccines and therapeutics, and the removal of policy and institutional barriers, including intellectual property (IP) that block access and exacerbate the adverse gender impacts of the pandemic.

Influenced by the interests of its pharmaceutical companies, the government of Switzerland has constantly taken a hard line on international negotiations on IP, notably since it has been <u>earning</u> more profits per capita than any other country through the export of inventions protected by patents. The opposition to temporary IP waivers was again vehemently recapitulated at the 12th Ministerial Conference of the World Trade Organization (WTO) in June 2022. Switzerland along with the European Union (EU) and United Kingdom (UK) actively blocked a proposed waiver of IP related to diagnostics, vaccines, therapeutics and other medical products and technologies that was proposed in 2020 by India and South Africa and co-sponsored by 63 developing and least developed countries (LDC)². The Swiss Minister for Economics attending the Ministerial Conference was <u>reported saying</u> that any departure from basic principles of IP would not be acceptable to the Swiss pharmaceutical industry.

This Shadow Report, submitted on behalf of the Feminists for a People's Vaccine Campaign, focuses particularly on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), administered by the WTO, and the opposition by a minority of countries, including Switzerland, to a temporary waiver from implementation of a number of TRIPS articles for COVID-19 medical products and technologies. This opposition has severe and disproportionate impacts on the rights of women and girls, including the right to health in developing countries and LDCs, as discussed below. It undermines the substantive equality principle.

TRIPS was the result of lobbying by pharmaceutical, biotechnology and chemical industries which sought to ensure that governments entrenched the universalizing of IP protection. Today, there is widespread concern that the current IP system designed by corporations and developed country governments has <u>become</u> a serious impediment. TRIPS has exacerbated the problem of timely, equitable, and affordable

² See <u>Shadow Report</u> submitted to 83rd session of the Committee on the Elimination of Discrimination against Women for the review of Belgium by the Feminists for a People's Vaccine Campaign.

access to life-saving medicines³. As the EU's Report on Competition Enforcement in the Pharmaceutical Sector 2009-2017 shows, the situation is increasingly litigious with weak patents and abuse of patenting systems. This makes subsequent innovation difficult, and delays the entry of competitors. More stringent IP protections have not led to the much-touted increase in innovation in the pharmaceutical industry. As has been the situation in the response to COVID-19, even publicly funded innovations have been privatised, shrinking the knowledge commons, and enabling corporations to monopolise the supply and pricing of essential medical tools needed to fight the pandemic. As the Roosevelt Institute's Issue Brief states:

"Contrary to the industry's claims, unaffordable prescription drugs are not the price we must pay for the industry to find cures and innovate affordable medicines; rather, it is the price tag we pay for an industry that values profits over patients and public health. This profit-seeking is built in part by the rules that govern the industry and, more broadly, our economy that creates wealth for shareholders and executives at the expense of patients.... Life and health should not be for sale but equally available to all, and policymakers have tools to rewrite the rules of our economy to ensure that drug companies put public health before profits."

This report highlights the need for Switzerland's compliance with its obligations under Article 2 and 12 of the Convention on the Elimination of Discrimination against Women (CEDAW) to realise women's human rights both within and outside its territory. These obligations include Switzerland's duties to:

- (a) Refrain from making or contributing to the making of laws and policies which directly or indirectly result in the denial of women's equal enjoyment of their rights, extraterritorially as well as within its jurisdiction; these include refraining from supporting policies that prevent access to diagnostics, vaccines and therapeutics needed to respond to COVID-19;
- (b) Cooperate internationally and create an enabling environment conducive to the universal fulfillment of women's economic, social and cultural rights by supporting the temporary TRIPS waiver to facilitate universal and fair access to diagnostics, vaccines and therapeutics needed to fight the COVID-19 pandemic;
- (c) Recognise that the TRIPS framework has an adverse impact on prices and availability of medicines and that IP should not be a barrier to Switzerland's

³ As a response to public concerns on the negative impacts of pharmaceutical product monopolies the Doha Declaration on TRIPS and Public Health was adopted in 2001. Among other things, the Declaration reaffirmed that "TRIPS does not and should not prevent members from taking measures to protect public health, that TRIPS can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." The right of WTO members to use the TRIPS provisions, including TRIPS Flexibilities, for public health purposes was clearly reaffirmed.

international human rights obligations to share the benefits of scientific research widely and in furtherance of its human rights obligations.

Failure to comply with these core obligations has a **multiplier effect on all aspects of women's rights covered by the Convention**, including the rights to education, livelihoods and employment, and to live dignified lives free from violence.

In this regard, the CEDAW Committee 2020 joint call for action highlighting the urgent need of women and girls for international solidarity and cooperation remains highly relevant. As stated in section 1 of our Belgium shadow report, we reiterate that honouring this duty requires an equitable public good approach to COVID-19 to ensure protection of women's right to health and other human rights.

This duty is directly linked to a range of international human rights, including the right to enjoy the benefits of scientific progress, established by both Article 27 of the Universal Declaration of Human Rights (UDHR) and Article 15 of the International Covenant on Economic Social and Cultural Rights (ICESCR)⁴, and is the core obligation to ensure minimal levels of economic, social and cultural rights protected under ICESCR and CEDAW. In the case of the right to health, this includes essential primary health care, essential medicines as well as prevention, treatment and control of epidemics and other diseases by making relevant technologies available and implementing and/or enhancing relevant immunization programmes and other strategies⁵. Moreover, in the context of COVID-19, the CEDAW Committee has emphasized that States "must address women's increased health risk through preventive measures and by ensuring access to early detection and treatment of COVID-19."

As also stated in *section 2* of the above mentioned <u>shadow report</u>, the COVID-19 pandemic is far from over. One of the key causes of its prolongment is IP regimes which prevents equitable, non-discriminatory access to COVID-19 diagnostics, vaccines and therapeutics. Another is continued inequality in vaccination between regions. Approximately 1 billion people in developing countries remain unvaccinated and these countries face challenging access to important therapeutics and diagnostics⁶ which have invisible detrimental consequences to public health.

Moreover, as <u>WHO's technical lead on the pandemic recently stated</u>, the virus is still "intensely circulating" and the numbers reported are underestimated. Ensuring that these cases do not translate into "waves or deaths" relies on "effective tools such as

⁴ CESCR Committee, General Comment 25 on Science and Economic, Social and Cultural Rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights, E/C.12/GC/25, 30 April 2020, para 45.

⁵ See CESCR, General Comment 14, article 12.2(c), paras 16, 44.

⁶ By December 2021, of the more than 3 billion tests reported across the world, only 0.4% had been performed in developing countries.

vaccines and antivirals". Therefore, now is not the time to stop the fight for equitable access to COVID-19 diagnostics, vaccines and treatments. Indeed, while WHO noted that "the end is in sight" and "we are in a winning position", it correctly added that "now is the worst time to stop running". Without key actions, "there is still a risk of more variants, deaths, disruption, and uncertainty".

2. Disproportionate impact on women due to of lack of COVID-19 diagnostics, vaccines and treatments

We present below examples of how the pandemic and its prolongation due to the lack of vaccines have a disproportionate impact on women worldwide, resulting in violations of CEDAW Articles 10-12 and general recommendation 35.

While the full extent of the COVID-19 impact on women <u>has not been accurately measured</u>, several preliminary studies find that women are disproportionately impacted by COVID-19. In Asia Pacific even though men were more likely to die from COVID-19, women were receiving less information on how to prevent COVID-19, their emotional and mental health was disproportionately affected and, in some countries, women are facing more challenges in accessing medical care (<u>UN women</u>). Additionally, women as the majority of frontline health workers (<u>70% of the global healthcare workforce</u>) hold a mere 25% of the senior roles in the profession, have lower status and pay and are most at risk of infection.

Maternal and newborn health-care services have become less available, inaccessible or unaffordable for <u>millions</u> of women globally as a result of restrictions on movement. In a WHO <u>survey carried</u> across 105 countries, 68% experienced disruptions in family planning services due to the pandemic. Worldwide it is <u>estimated</u> that twelve million women lost access to contraception, leading to 1.4 million unintended pregnancies. In Africa, a <u>UN Women and UNFPA report</u> showed that maternal deaths have almost doubled in Kenya, and increased by 28% in Botswana and by 18% in Mozambique. The report also highlighted that abortion services, GBV communication and community engagement are often overlooked for inclusion in the national essential services package.

Emerging evidence suggests that women will suffer more from the economic crisis associated with the pandemic. While women make up 39% of global employment they accounted for 54% of overall job losses during the pandemic. According to the ILO and ECLAC, the impact of measures to limit spread of the virus will be higher in highly feminized sectors such as commerce, manufacturing industries, tourism and domestic service.

Women's workload has increased as they have to take on the care of the children who are not in school, provide health care for members of the family and deal with

increased hygiene requirements to prevent contagion. A <u>survey</u> carried out in 17 countries, indicated 48% of females found their "time doing household work has increased" against 38% of men.

Education is another area where COVID-19 has had a disproportionate impact on women since they are the majority of education workers worldwide. They had to respond to new forms of education without the possibility of training or the technological resources. A <u>UNESCO</u> study found girls were more at risk than boys to see a disruption in their learning due to additional responsibilities in their homes or lack of connectivity. With schools closed, it was mostly women who took over the care of children of school-age, <u>limiting their own chances to earn an income</u>.

COVID-19 also contributed to a <u>"shadow pandemic of violence against women"</u>. An Oxfam <u>report</u> shows an undeniable increase in gender-based violence during the COVID-19 pandemic through <u>analysis</u> of the number of calls made by survivors to domestic violence hotlines in ten countries during the first months of lockdown. There are other preliminary reports of this phenomenon in <u>Latin America</u> and <u>the Asia Pacific region</u>.

The Committee for the Elimination of Racial Discrimination (CERD) also <u>affirmed</u> that States must protect against the impact of the pandemic on individuals and groups subject to structural discrimination and disadvantage. **CERD called on all States including Switzerland to combat the pandemic**, guided by principles of international solidarity including <u>supporting the comprehensive TRIPS Waiver proposal</u>. It noted that discrimination "in significant part attributed to consequences of the historic racial injustices of slavery and colonialism that remain largely unaccounted for today". The unequal distribution of vaccines between and within countries "manifests as a global system privileging those former colonial powers to the detriment of formerly colonised states and descendants of enslaved groups," CERD noted.

3. Switzerland and the IP regime: lessons from the economic history of Switzerland

The government of Switzerland is aware of the detrimental effects of IP barriers to developing countries since it was primarily an importer of expensive patented technology when the Swiss pharmaceutical industry itself was emerging⁷. In 1990, the government of Switzerland specifically stated, in a message to parliament on development cooperation, that further extension of patent protection in the Third

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⁷ See Gerster, R. <u>Patents and Development: Lessons learnt from the Economic History of Switzerland</u>, Third World Network, 2001. This is a revised and updated publication of a paper first published in The Journal of World Intellectual Property, Vol. 1, No. 4 (July 1998).

World could be contrary to the interests of developing countries, since they are primarily importers of technology⁸.

Switzerland itself, despite its current opposition to temporary IP waivers, benefited heavily from the freedom to operate without patent barriers in the past and thereby enhanced Swiss technology and economic development. It was only from the mid-1970s to early 1990s that pharmaceutical product patenting became the norm throughout developed countries⁹. Switzerland finally provided for pharmaceutical products patents in the 1970s due to strong opposition from the chemical industry.

Patents are a form of monopoly that excludes third parties from commercial exploitation of a patented invention. It is anti-competition and many liberal advocates of free trade opposed the introduction of patents during political debates in the 19th century. When patent offices existed in the past, patents often covered mechanical inventions, not pharmaceutical products. The exclusion reflects the assessment that the costs of granting what are essentially private rights over such inventions would clearly outweigh the benefits¹⁰.

It is well known that the absence of the current patent system allowed Switzerland to develop industrially. The stance of Swiss manufacturers and industrialists in the late 19th century is illuminating. "100 years ago, Swiss industries were free to copy foreign inventions without restrictions. Switzerland had no patent laws and this situation was widely exploited" for Swiss industrial development.¹¹

Switzerland gained notoriety in Europe at that time, for "copying" inventions from elsewhere, and Swiss manufacturer A. Benziger was quoted in 1883 saying "Our industries owe their current state of development for what we have borrowed from foreign countries. If this constitutes theft, then all our manufacturers are thieves". ¹² Swiss chemical companies opposed patent protection and Switzerland was accused by France and Germany of pirating and copying. ¹³

Patent systems enjoyed in early industrial development were a far cry from the rigorous ones now imposed on developing countries due to TRIPS enforced in 1995¹⁴. They were lax containing many exclusions and IP, especially of other countries, was secondary to promoting domestic industry. Ironically, developing countries since TRIPS implementation are under pressure to behave to a standard that was not even remotely observed when the now advanced countries were at the similar, or even more advanced, stages of development. Developing countries today

⁸ *Ibid.* p. 23.

⁹ For Switzerland, in the late 1970s, see Shadlen, KC et al. <u>Patents. Trade, and Medicine: Past. Present and Future</u>, 2018. See also Dominique S. Ritter, <u>Switzerland's Patent Law History</u>, 14 Fordham Intell. Prop. Media & Ent. L.J. 463, 2004.
¹⁰ *Ibid.*

¹¹ Cited in Gerster (2001). See footnote 7.

¹² Protokoll des Schweizerischen Congresses betreffend die Frage der Einfuhrung des Erfindungs-Schutzes, abgehalten in Zurich im Rathhassaale den 24 und 25 September 1883, Zurich 1883 at page 88 cited in Gerster (2001) at page 7

 ¹³ Gerster (2001) at pages 6–7. See footnote 7.
 ¹⁴ Ha-Joon Chang, Intellectual Property Rights and Economic Development - Historical Lessons and Emerging Issues, 2001.

oppose patent laws for much the same reasons Switzerland did when it was building its manufacturing and industrial capacity at the beginning of the 20th century.

4. The role of Switzerland in trade negotiations including the WTO TRIPS Decision and its implications

Switzerland in trade negotiations

Switzerland, like the EU and US, demands TRIPs Plus provisions in negotiations with developing countries. This includes demands to adopt data/marketing exclusivity, patent term extension etc.¹⁵ The effect is prolonged market monopoly of holders of IP, with disastrous consequences for public health and the populations in developing countries. For the economic costs of such provisions on States refer <u>our shadow report on Belgium</u>.

Switzerland's interventions at the TRIPS Council

In its interventions before the TRIPS Council, Switzerland has often repeated that it is the presence of the IP regime which has led to quick vaccine innovation and response to the pandemic. In September 2021, minutes record Switzerland as stating:

"A number of delegations have recalled that the global COVID-19 pandemic has caused millions of deaths and devastating social and economic harm. We agree. While the world still faces immense challenges in fighting the pandemic, we should, however, also look at the progress that has been made. Had it not been for the innovators, the researchers and developers who rushed to find an effective antidote against the deadly virus, we would see millions more victims and would be still today helpless against this virus. Without the tested and trusted international IP regime and WTO TRIPS Agreement, these innovators, investors, researchers and developers would not have been prepared, ready on the starting blocks, to start the race for finding an effective vaccine against the new coronavirus."

This, however, could not be further from the truth, and is not supported by Switzerland's own experience. In relation to the COVID-19 vaccines, we reiterate:

• The National Institutes of Health in the US had been funding basic research for the last two decades upon which Operation Warp Speed and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiatives were leveraged in the race for a COVID-19 vaccine. The research in

¹⁵ See for eg. https://www.bilaterals.org/?indonesia-efta-cepa-trips-plus

the years prior to the pandemic <u>played</u> an important role in the speed and success of COVID-19 vaccine development.

- Billions of public funds were poured into the production of the vaccines themselves and in advanced purchase agreements. Moderna received almost <a href="mailto:almost-gailt
- By June 2021, the voluntary COVID-19 Vaccines Global Access (COVAX) donation scheme had only <u>delivered</u> 90 million out of an objective of 2 billion doses.
- Pharmaceutical companies which were holders of relevant IP <u>failed</u> to engage with the WHO's voluntary COVID-19 Technology Access Pool (C-TAP).
- As pharma dallied, the <u>global excess mortality</u> associated with COVID-19 was 14.91 million in the 24 months between 1 January 2020 and 31 December 2021.

The International Commission of Jurists (ICJ) <u>issued</u> an expert legal opinion in November 2021 calling on States to stop blocking the TRIPS Waiver:

"The proposed TRIPS waiver should be understood as an effort by the States proposing and supporting the waiver to comply with their human rights obligations in terms of the rights to health, equality, scientific benefits and life by initiating necessary coordination and solidarity in line with their obligations relating to international assistance and cooperation. Conversely, those States actively opposing or otherwise blocking or inhibiting international agreement at the WTO in respect of the waiver must be understood as contravening their obligations to respect and fulfil the same human rights. Further, by failing to take measures to effectively regulate private actors in health operating on a multinational level where their operations compromise access to COVID-19 diagnostics, medications, vaccines, therapeutics and other relevant health products, States contravene their obligations to protect human rights."

Concerted effort to limit the TRIPS Decision to vaccines with conditions

As stated in *part 3* of our Belgium <u>shadow report</u>, the TRIPS Decision reflects the obstructive positions of the UK, EU and Switzerland and the US's insistence that the Decision should be limited to vaccines. During the negotiations of the WTO Director-General's (DG) text on the Decision, the UK and Switzerland, with EU support, made constant attempts to limit the scope of the decision. Below are examples of these States' regressive conduct.

The DG's text centered around making changes to Article 31(f) of TRIPS, the provision on compulsory licenses related to exports. **The UK, EU and Switzerland working in concert**, proposed a series of amendments to the DG's text to limit the scope of the decision, including the following moves:

- The DG's text originally covered 'subject matter of a patent' which included ingredients and processes necessary for the manufacture of the COVID-19 vaccine. The UK made several regressive proposals to create an exhaustive list of "patented" subject matter for which a non-voluntary (compulsory) license may be issued under the Decision, even though determining the patent landscape of any aspect of a vaccine is a Herculean task, if not impossible. The UK's suggestion would also have excluded other tools important for the manufacture of COVID-19 vaccines such as single use bio-bags, single use filters, micro fluid and nanofluid mixers for lipid nanoparticles etc., even as the world has seen a shortage of many of the tools needed for manufacturing due to the high concentration in their production.
- The text sought to waive Article 31(f) of TRIPS, thereby doing away with the requirement that any compulsory/government use license issued should be predominantly for the supply of the domestic market of the WTO Member authorizing such use. This opens the way for export of the products in question. The UK sought to limit the application of the waiver to only COVID-19 vaccines, excluding application of the exportation waiver to tools such as ingredients to produce the vaccines, making the entire decision unworkable.
- Switzerland proposed a nullification of the existing flexibility related to protection of undisclosed information under Article 39.3 of the TRIPS Agreement. Paragraph 4 of the DG's text had stated: "Nothing in Article 39.3 of the Agreement shall prevent an eligible Member from taking measures necessary to enable the effectiveness of any authorization issued as per this Decision". This text was provided to overcome the test data protection or data exclusivity barriers related to the regulatory approval of a pharmaceutical product. Article 39.3 as it stands provides flexibility to countries to disclose tests and other data submitted for domestic marketing approval, to protect the public or take measures against unfair commercial use. Switzerland proposed text to nullify the existing flexibility under Article 39.3.

- An attempt was also made to impose an obligation to notify the TRIPS Council prior to the shipment of vaccines produced under the Decision. Pre-shipment notification is not a requirement of Article 31 of TRIPS Agreement and hence is TRIPS Plus and would cause delay in the supply of vaccines.
- Applying the Decision to therapeutics and diagnostics is absolutely necessary from a public health perspective and yet it was one of the most contentious aspects of the negotiations and deferred in the Decision.

These obstructive actions by the States concerned contradict their earlier avowed positions of global solidarity. These States, including Switzerland, failed in their extraterritorial obligation to ensure equity in the terms of supply contracts, as shown in the Drugs for Neglected Diseases initiative report: "Public and philanthropic R&D funders could have secured terms and conditions with private companies to ensure open collaboration and transparent sharing of the IP, research knowledge, and data that would have been necessary to safeguard affordability, production, supply, and equitable allocation...[I]t appears that funders either did not include such conditions, or did not choose to exercise them. Instead, a combination of national interests and private commercial interests inevitably led to gross inequities". Governments must make different political and commercial choices that lead to equitable access to health products and technologies.

5. Switzerland has a duty to ensure equitable and human rights-compliant manufacture and distribution of COVID-19 treatments by its companies

It is now crucial that the Decision, limited as it is, be extended to other medical products, especially diagnostics and therapeutics. In this regard, we draw the Committee's attention once again to part 3 of our Belgium shadow report. We wish further to detail here the facts concerning various therapeutics which have been approved for COVID-19 treatment. We reiterate that most of the limited supply of COVID-19 therapeutics has been procured mainly by wealthy countries that represent a mere 16% of the global population. Even when available, they are unaffordable to most developing countries. Further, although voluntary licenses (VLs) have been offered by originator companies to some developing country manufacturers, there are countries which have been left out of these voluntary licenses and hence distribution will not be global. VLs can also be subject to various conditions that are often difficult to comply with. Supply constraints are expected to continue for most of 2022 even for products where VLs exist.

WHO has <u>recommended</u> the following 3 medicines (one of which is manufactured by a Swiss company) for COVID-19 treatment but the severe limitations of relying on VLs result in very limited access for developing countries and LDCs.

Tocilizumab

Tocilizumab is a strongly recommended treatment for patients with severe and critical COVID-19. It is a biological medicine manufactured by Roche, headquartered in Switzerland. Tocilizumab is in fact a repurposed drug, having been used for inter alia rheumatoid arthritis since it was first marketed. Its main patents expired in 2017. However, subsequent patent applications for other features have been filed leading to the extension of toxilizumab's patent thicket until 2028 for some jurisdictions in the world. These are known as "evergreening" patents. Although Roche voluntarily said that it would not enforce its patents in some developing countries and LDCs (noting that LDCs have the right to not implement TRIPS for the time being anyway), it leaves out key manufacturing countries¹⁶. In South Africa, despite an expert panel finding that tocilizumab reduced deaths, the recommendation was for the medicine to not be used because it is "not affordable at the current offered price". The life-saving therapy is largely out of reach for African populations at a cost of around 2,000 dollars per patient. The cost to manufacture tocilizumab is estimated to be as low as 40 dollars per dose of 400 mg. Further, the demand for tocilizumab far outstrips its limited supply, jeopardising the treatment not only of COVID-19 patients but also those who use the drug for the other indications available.

The guidance from Médecins Sans Frontières (MSF) is instructive with regards to the kind of action required to enable the ramping up of tocilizumab for equitable access in all countries that require it for COVID-19 treatment:

- Non-assertion of patents to be applicable to all countries -- and not just to low- and middle-income countries as defined by Roche -- so that wherever biological production capacity exists, alternative producers can speed up development and production of biosimilars (generic version of the originator);
- Full disclosure of all remaining secondary (evergreening) patents and any pending patent applications, and these should be withdrawn in order for there to be full freedom to operate and legal certainty for biosimilar producers;
- Ensure quick and independent production and supply of tocilizumab by additional manufacturers, through open, transparent and unrestricted transfer of master cell lines. The regulatory dossier and any other manufacturing information; and
- The price of tocilizumab <u>must be lowered</u> to make it affordable and accessible for everyone who needs it.

Baricitinib

This therapeutic is widely <u>patented</u> in more than 50 countries, with patents only expiring in 2029. Again, it is priced out of reach in most developing countries.

¹⁶In countries where there is no such waiver of patent implementation, it is reported that Roche has kept the price of this therapeutic very high in most countries, ranging from 410 dollars in Australia, 646 dollars in India to 3,625 dollars in the USA per dose of 600 mg for COVID-19.

Generic versions of baricitinib are available for under 7 dollars per 14-day treatment course in India and Bangladesh, in comparison to patent holder Eli Lilly's prohibitive price of 1,109 dollars per 14-day treatment course in the US. Eli Lilly's VL to Indian generic companies is restrictive. It inhibits the supply of generic versions of the drug to any other country outside of India¹⁷, demonstrating again that VLs and voluntarism is not the answer.

Paxlovid

<u>Paxlovid</u> is an antiviral, a combination of two medicines, nirmatrelvir and ritonavir (an existing therapeutic long used for HIV treatment). Pfizer has <u>entered</u> into a license agreement with the Medicines Patents Pool to supply a generic version to 95 countries but exclude almost all of Latin America, and many developing countries in Asia and Africa. This means those countries will not be allowed to buy generic versions of this oral drug that are produced under the deal. The drug also has patents pending in most of those countries¹⁸. This will leave countries solely dependent on Pfizer's supply and pricing decisions¹⁹.

As <u>MSF</u> stressed, VLs "just continue to feed into the monopoly situation; it excludes producers and other manufacturing countries, where they already have manufacturers that are ready and capable to produce these types of medicines".

The world cannot depend on industry's conditional voluntarism. IP is a privilege that the State grants but the current IP regimes have been distorted to put profits before lives and health. Therefore it is incumbent on States to comply with their responsibilities and human rights obligations.

The IP regime is not sacrosanct. As <u>Dr Hyo Yoong Kang</u>, Reader in Law at Kent University, argues:

"Intellectual Property rights are not absolute rights. They are granted and recognised under the condition that they serve the public interest. Right now, it is in the global public interest to provide access to vaccines and the technologies to produce them in the regions that need them. This is a global, not a local pandemic, and we will keep seeing the virus spread and new variants emerge if we fail to share knowledge in this way."

¹⁷ See an MSF map of countries shut out in baricitinib licensing deals.

¹⁸For example, if patents are granted in Latin American countries, they would not expire in many countries until 2041.

¹⁹ See an MSF map of countries shut out in paxlovid licensing deals.

6. Switzerland's extra-territorial obligations include imposing binding obligations on its companies to facilitate open sharing of **COVID-19 medical products**

Replying to question 6 of the Committee's List of Issues Prior to Reporting, Switzerland pointed out the adoption of its national action plan (NAP) for the implementation of the United Nations Guiding Principles on Business and Human Rights (UNGPs). Yet, the Swiss NAPs were assessed as failing to provide a solid framework for ensuring that Swiss companies respect human rights in their activities domestically and abroad.²⁰ The Swiss NAPs also fall below recent States practices on adopting mandatory human rights due diligence, including multiple European jurisdictions.²¹

Overall, the Swiss NAP is based primarily on voluntary approaches, rather than balancing different approaches within the 'smart mix' recommended by the UNGPs and the Working Group on Business and Human Rights,²² which ought to include a mix of mandatory and voluntary mechanisms. In comparison, other European countries such as France and Germany have set in place mandatory due diligence obligations.²³

Moreover, on 29 November 2020, the Responsible Business Initiative was rejected at the ballot box despite gaining 50.7% of the popular vote, bringing into force a counter-proposal that requires companies to report on human rights and environmental standards, yet does not include a liability clause in case of non-fulfillment. Thus Switzerland has yet to establish effective measures on corporate human rights and gender impact assessments, as requested by the Committee.24

In the context of COVID-19 and in line with the UNGPs, the private sector is required to respect human rights and prevent adverse human rights impacts related to their provision of goods and services during the pandemic (Principle 17). Thus pharmaceutical companies have responsibilities regarding the realization of the right to health, particularly in relation to access to diagnostics, vaccines and therapeutics.

https://vigilance-plan.org/the-law/#:~:text=A%20pioneering%20law&text=It%20requires%20French%20companies%20to.of%20indiv iduals%2C%20and%20the%20environment.; European Directive on corporate sustainability due diligence https://ec.europa.eu/commission/presscorner/detail/en/ip 22 1145; German mandatory human rights due diligence law

https://www.business-humanrights.org/en/latest-news/german-due-diligence-law/

and https://www.circularise.com/blog/german-supply-chain-act-due-diligence-obligations-explained#:~:text=The%20law%20imposes %20due%20diligence,to%20serious%20liabilities%20upon%20violations

²⁰ See for example: 2016 Analysis and comments by the Swiss Coalition for Corporate Justice on the Swiss National Action Plan on Business & Human Rights, available at

https://www.business-human rights.org/es/%C3%BAltimas-noticias/analysis-and-comments-by-the-swiss-coalition-for-corporate-justing the substitution of the substitutice-on-the-swiss-natl-action-plan-on-business-human-rights/. See also comments on 2020 NAP at:

https://globalnaps.org/wp-content/uploads/2020/05/stakeholder-analysis-swiss-nap-2020-2023.pdf ²¹ See: French Duty of Vigilance Law

²² See for example the references to the 'smart mix' under the UNGPs, principle 3 on State obligations, available at: https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf

²³ See Footnote 22

²⁴ Raised in paragraph 6 of CEDAW's List of Issues Prior to Reporting.

The human rights due diligence that is part of businesses' responsibilities should apply to companies' decisions regarding pricing and distribution and should consider the adverse impacts such decisions could have on access to medicines, particularly for low-income and marginalized individuals including women. UN Human Rights experts had underlined that "pharmaceutical companies should: discharge their responsibilities, including by exercising human rights due diligence to identify and address adverse impacts on the rights to life and health as set out in the Guiding Principles on Business and Human Rights. In particular, they should refrain from causing or contributing to adverse impacts on the rights to life and health by invoking their IP rights and prioritizing economic gains".

The conduct of pharmaceutical companies throughout the pandemic clearly does not align with these responsibilities. Amnesty noted in April 2022 that with the WHO's "global target of a 70% vaccination rate in every country by July 2022 on course to be missed by a significant margin, pharmaceutical companies continue to obstruct fair access to COVID-19 vaccines by monopolizing technology, blocking and lobbying against the sharing of IP, charging high prices for vaccines, and prioritizing supplies to wealthy countries".

To effectively fulfill the responsibilities of businesses, human rights experts have underlined that transparency of contracts on vaccine development, procurement and provision is crucial, as well as a thorough human rights impact assessment of all vaccine-related company activities. This is in line with the question posed by the Committee on how Switzerland is ensuring that trade and investment agreements negotiated by corporations registered or domiciled in Switzerland comply with the State party's obligations under the Convention and explicitly consider their impact on women's rights.

Moreover, human rights experts had underlined that '[p]ledges and voluntary licenses ... are not enough in view of the current situation. "Binding commitments to facilitate the open sharing and right to use technologies, know-how, data and global non-exclusive rights to use and produce COVID-19 medical products" should be put in place immediately.'²⁵ As discussed in Section 4, Switzerland took a contrary position in the TRIPS Waiver negotiations.

7. Recommendations

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Therefore, we respectfully request that, in accordance with Switzerland's CEDAW obligations, the Committee encourages Switzerland to unequivocally:

- (i) Support the expeditious extension of the June 2022 TRIPS Decision, that was the outcome of the negotiations on the TRIPS Waiver proposal, to the production and supply of COVID-19 diagnostics and therapeutics without any further conditions. Paragraph 8 of the Decision states: "No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics";
- (ii) Support the full use of existing TRIPS flexibilities such as compulsory licensing of patents and adequate exceptions to protection of undisclosed information, copyright and industrial designs;
- (iii) Pledge not to use the dispute settlement mechanisms of the WTO and other trade and investment agreements, or other means to stop or dissuade countries from using any TRIPS flexibilities for producing, using, exporting or importing medical technologies and products;
- (iv) Refrain from making any TRIPS Plus demands in its trade agreements and negotiations with developing countries;
- (v) Where public funds are involved in R&D, include clear and transparent terms and conditions that ensure sharing of research data, knowledge, and technology on a non-exclusive basis, enabling adequate production scale-up to ensure sufficient supply, equitable allocation, and affordability;
- (vi) Put in place a solid framework for ensuring that Swiss companies respect human rights in their activities domestically and abroad, which should include effective measures pertaining to corporate human rights and gender impact assessments before making investment decisions, which are compliant with its international obligations;
- (vii) Provide for legally enforceable measures within its territory for human rights abuses within its own jurisdiction. In the context of COVID-19, include measures requiring transparency on the development, procurement and provision of COVID-19 health technologies.
- (viii) Require full disclosure of "evergreening" secondary patents and pending patent applications, and their withdrawal to enable scaled-up production of generics/biosimilars of vaccines and therapeutics.

As stated in our <u>Belgium shadow report</u>, we reiterate the need to strengthen a "global public goods" perspective to health, which is based on international cooperation and

collaboration to improve global health, in particular the health of the poor. Global public goods are, *inter alia*, programmes, policies and services that can be enjoyed by anyone repeatedly without lessening their benefits to others. The benefits of such goods also accrue to future generations and merit the cost expended on them in the present. Health is a quintessential public good and the time is now for international mechanisms to recognise this framing as essential to the fulfillment of human rights obligations.