



**FEMINISTS  
FOR A PEOPLE'S  
VACCINE**



**DAWN  
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Third World Network



# **TRIPS IS A BROKEN MODEL OF HEALTH INNOVATION**

**ENSURING STATE ACCOUNTABILITY FOR  
HUMAN RIGHTS-BASED PANDEMIC  
PREPAREDNESS FOR THE FUTURE**

**Shadow Report to the  
74<sup>th</sup> session of the CESCR**

**Shadow report to the 74<sup>th</sup> session of the UN  
Committee on Economic, Social and Cultural Rights  
Session (CESCR) for the review of France**

# **TRIPS IS A BROKEN MODEL OF HEALTH INNOVATION**

**ENSURING STATE ACCOUNTABILITY  
FOR HUMAN RIGHTS-BASED  
PANDEMIC PREPAREDNESS  
FOR THE FUTURE**

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Third World Network (TWN)**

**on behalf of the Feminists for a People's Vaccine Campaign (FPV)**

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# Summary

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# 1. Background

On May 5<sup>th</sup> 2023, the World Health Organization (WHO) *announced* the end of COVID-19 as a public health emergency of international concern (PHEIC). The WHO Director-General's announcement called for caution, although COVID-19 was killing one person every three minutes just the week before his announcement. Three months on, the *decreasing* numbers of infections, hospitalizations and deaths are deceptive as only 25% of WHO countries continue to report infections and deaths whilst only 11% report hospitalization.

Although we do not experience the effects of COVID-19 as before due to vaccination programs, the SARS-CoV-2 virus has proven its resilience and mutability, thus making COVID-19 a continuing health risk.

On August 24<sup>th</sup>, the WHO announced that a *highly mutated* COVID-19 variant called BA.2.86 had been detected in Switzerland and South Africa in addition to Israel, Denmark, the US and the UK. Experts caution that the potential risk must still be taken seriously. Shortly before that, another variant EG.5 was *classified* as a variant of interest and while its mutation poses little risk, its immunity-evading characteristics threaten vulnerable populations. We must therefore continue to be vigilant around the lifting of all measures against the spread of COVID-19 and the ongoing unequal distribution of tests, treatments and vaccines. We also note for instance that whilst populations are being advised not to maintain any COVID-19 protocol, COVID-19 testing is mandatory to enter the *White House* and at the World Economic Forum in *Davos*.

Among the key causes that prolonged the pandemic are intellectual property (IP) barriers which prevent equitable and non-discriminatory access to COVID-19 vaccines, diagnostics and therapeutics. This has resulted in continued inequality in vaccination between regions. **Approximately 1 billion people in developing countries remain unvaccinated and also face serious challenges to accessing important therapeutics and diagnostics with detrimental consequences to public health.** As new variants emerge, new diagnostic tests and even vaccines may be needed while therapeutics continue to be worked on.

This call has been echoed by the WHO Director-General himself, who has repeatedly *appealed to WTO member states* to reach an agreement on the extension of the World Trade Organization’s Ministerial Decision of June 2022 relating to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Decision), described in further detail below, for diagnostics and therapeutics. **He stressed that local production of vaccines, diagnostics and therapeutics is key not only to ending the pandemic but also to strengthening preparedness for future emergencies.**

The *Office of the High Commissioner for Human Rights* (OHCHR) has also noted with concern that “*Vaccine equity and access to diagnostics and therapeutics is a fundamental component of the full realization of the right to health. Vaccines, diagnostics and therapeutics must not only be produced and made available - they must also be accessible to all persons. Yet, access to vaccines, diagnostics and therapeutic remains disturbingly uneven in many places*”.

This Parallel Report submitted to the UN Committee on Economic, Social and Cultural Rights (CESCR) for the review of France by the *Feminists for a People’s Vaccine Campaign* focuses in particular on the impact of TRIPS, administered by the WTO, and the opposition by a minority of countries, including France, as a member of the European Union (EU), to a comprehensive temporary waiver from TRIPS implementation of intellectual property (IP) on COVID-19 vaccines, diagnostics, therapeutics and other needed medical products.

This submission also focuses on the right to timely and appropriate healthcare and the denial of this right by France through its actions in critical political and policy decision-making spaces, notably the EU and the WTO. Through its actions (described in greater detail in the next sessions), France fails to meet its:

- (a) extraterritorial obligations under CESCR, including duties to meet the standards in relation to creating an enabling global environment for the realisation of the right to health when operating within the multilateral system and as a member of the EU and the WTO;
- (b) duties to international cooperation and assistance, including refraining from infringing on the ability of other States to fulfil their own human rights obligations;

**In particular, and for the reasons detailed below, we respectfully request the CESCR Committee to recommend that as a member of the EU, France:**

- 1.** Refrain from requiring “TRIPS-Plus” proposals that undermine pharmaceutical manufacturing capacity and timely access to affordable vaccines and medicines in current and future negotiations with developing countries.

These demands in the wake of COVID-19, which ravaged these nations, show a complete disregard for obligations of France/EU under international human rights instruments.

**2.** Require national pharmaceutical companies to stop all anti-generic strategies and comply with their responsibilities under international human rights law, including the impact of their activities abroad, aligning national reform as recommended by the European Parliament and European Commission with its extraterritorial obligations. France needs to compel its corporations to be more proactive in respecting human rights and consider strongly what positive duties they may carry in terms of international human rights law in their dealings abroad.

**3.** Comply with its extraterritorial obligations to respect, protect, and fulfill the Right to Health in its actions within the multilateral system, including refraining from any action that will limit the full implementation of existing TRIPS flexibilities such as compulsory licensing of patents and the exclusion from patentability of inventions that jeopardise the Right to Health.

**4.** Support the expeditious unconditional extension of the June 2022 WTO Decision on COVID-19 vaccines to include COVID-19 diagnostics and therapeutics.

In this report, we also call for the rethinking of the operationalization of the Right to Health, looking at the systemic and structural defects of the current health innovation system which perpetuates and exacerbates historical inequities.

**We therefore respectfully request the CESCR Committee to consider commencing a process of elaborating a General Comment on IP regime reform building on its own existing analysis as well as the analysis of various UN agencies and the European Commission:**

*– with the experiences of HIV, Ebola, COVID-19, Monkeypox and the realization that the current IP regime is flawed, there needs to be a fundamental reform of TRIPS and national laws.*

Through this process we also believe that the Committee can ensure that ongoing and future negotiations of bilateral and regional trade/economic agreements as well as multilateral negotiations, including at the WHO, WTO and UN General Assembly are consistent with the full realization of the Right to Health.

## 2. Current inequities in the global health architecture

Current health innovation is underpinned by the IP regime codified in the TRIPS Agreement, the first global standard-setting treaty of its kind. It is increasingly recognised, however, that TRIPS can impede innovation and COVID-19 showed us that TRIPS can be a stumbling block to much-needed production and access to life-saving medical tools – driving, rather than alleviating, health inequities.<sup>2</sup>

In the Doha Declaration on TRIPS and Public Health adopted in 2001, WTO Members affirmed that the TRIPS Agreement “*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.*” However, responses to the HIV, COVID-19 and Monkeypox health emergencies show that developed countries have failed time and time again to honour their extra-territorial obligations towards the concrete realization of poorer nations’ right to health, even in times of crisis.

Experts at the 2022 International AIDS conference, including scientists, economists and heads of AIDS programmes globally attested that “*As the [latest data reveals](#) progress in the HIV response is stalling, putting millions of lives in danger, as the COVID-19 crisis drags on, and as Monkeypox presents new risks, all are being held back by inequalities, and all three viruses are in turn further exacerbating those inequalities.*”<sup>3</sup>

Winnie Byanyima, Executive Director of UNAIDS, and Under-Secretary-General of the United Nations stated: “*There are Monkeypox vaccine doses in Europe but none in Africa. Most people at risk of dying from COVID-19 in lower-income countries have still not received a COVID-19 vaccine. New game-changing prevention medicines for HIV will not be widely available in lower income counties for years unless there is a dramatic course correction.*”<sup>4</sup>

As early as 2005, the CESCR Committee in its [General Comment 17](#) stated clearly that human rights are fundamental as they are inherent to the human person, that IP regimes “*primarily protect business and corporate interests and investments*” and “*It is therefore important not to equate*” IP rights and human rights (Paragraphs 1 to 3). The Committee called for the use of flexibilities in Article 27 to exclude inventions from patentability whenever their commercialization would jeopardize the full realization of human rights including the rights to life and health (Paragraph 35).

Elaborating on the above in April 2021 in relation to COVID-19, the CESCR Committee noted that most of the vaccines approved are subject to an IP regime and had received “*huge financial support from public funds*”, and recalled that IP rights “*are not a human right, but a social*

product, having a social function. Consequently, States parties have a duty to prevent IP and patent legal regimes from undermining the enjoyment of economic, social and cultural rights”.<sup>5</sup>

While reiterating that “States parties should use, when necessary, all the flexibilities of the TRIPS Agreement, such as compulsory licenses, to ensure access to a COVID-19 vaccine for all ...” the Committee also acknowledged that “These flexibilities will in all likelihood, however, be insufficient to face adequately the pandemic, especially in developing countries.”<sup>6</sup> Disregarding the calls above and perpetuating the myth that current skewed IP regimes are needed to protect health innovation, governments of developed countries, including France and other EU Member States, strongly opposed the TRIPS Waiver.

The EU played a substantial role in the global vaccination effort through huge public investments: it was home to three out of the first four safe and effective COVID-19 vaccines and was the first producer and exporter of mRNA vaccines.<sup>7</sup> Yet, despite proclamations that COVID-19 vaccines would be global public goods, their lack of will allowed the corporations involved to earn super profits to the detriment of millions of lives, even though the public sector invested heavily in the development of vaccines. In January 2021, a kENUP Foundation report found that in the first eleven months of the pandemic, the public sector had invested heavily in the development of vaccines with a commitment of 95% of the total spending, amounting to 86.5 billion euros. The majority of the public funds came from vaccine developers from high-income countries, with 32% invested by the US, 24% by the EU, and 13% from Japan and South Korea.<sup>8</sup> Contributing states failed to attach pre-conditions to these public investments to ensure public returns and equitable distribution of the resulting medical goods.

Although claiming to support the TRIPS Waiver proposal, France’s President Emmanuel Macron was also reported to have insisted that the priority for developed nations was to ensure that **donations** of vaccines were sufficient for the rest of the world. Charity, which entrenches dependency of the developing world on the global North, is clearly not the answer. Firm, legal obligations towards “reparative redistribution” from the North to the South should be the practice and the norm.<sup>9</sup> Healthcare cannot be left to market forces that are monopolistic in the pharmaceutical sector and voluntary mechanisms - the purchase of vaccines itself propels countries of the global South further into debt. *“Given the detrimental neocolonial implications of debt, with a long history of loan conditionalities through structural adjustment programmes, increasing debt to service health needs contributes to the worsening of inequalities between the Global North and Global South. These programmes may increase debt and undermine development in ways that limit the realisation of the right to health. The World Bank has set aside US\$12 billion and has already disbursed loans of US\$500 million for vaccines in low-income and middle-income nations; poorer nations, instead of servicing already depleted health systems, are forced to divert additional funds to servicing debt.”*<sup>10</sup>

The above is compounded by the fact that inequitable access to vaccines translates into further disparities in post-COVID economic recovery. UNDP illustrates the magnitude of the problem. In low-income countries, where vaccination rates are still lagging, the path to recovery will be long and uncertain unless urgent action is taken now by the global community. By September 2021, only 2.33% of people in low-income countries had been fully vaccinated. UNDP's analysis suggests that had the vaccination rate been equal to that of high-income countries (54.3%), the GDP of low-income countries would have increased by \$16.27 billion which represents an increase of 5.16 percentage points in 2021, which could have been used toward other development priorities.<sup>11</sup>

COVID-19 exposed the structural flaws in society, amplifying primarily economic disparities, patterns of marginality, and the inadequacies and inequalities in health systems worldwide. Despite repeated calls for global solidarity and a global response to the pandemic, the world left the poor behind.

Meanwhile, the European *Commission Directorate-General for Health and Food Safety* commissioned a study on the availability of medicines and vulnerabilities in pharmaceutical supply chains, as reliance on a limited number of manufacturers and suppliers grows. The study confirmed what COVID-19 glaringly revealed - that left to the hands of corporations, pharmaceutical supply is, at the end of the day, determined by commercial considerations. The Commission found that: *“This study has confirmed that shortages often are not so much a problem of whether a medicine is available but one of where it is available. Even in the context of the European Union, founded on principles of solidarity, some countries are fighting shortages daily whereas others hardly experience them at all. This points towards some fundamental issues that have little to do with sourcing and manufacturing and much more with commercial decisions by suppliers on the one hand and national policies on the other. Here, many parties share responsibility. Suppliers make decisions based on considerations of profitability, selecting markets to supply based on willingness and ability to pay and ignoring others. Governments have also put pressure on prices which has led to supply chains that are lean to the point of vulnerability. This requires critical reflection on the part of all stakeholders not only of the roles of others but also of their own responsibilities.”*<sup>12</sup>

The EU Parliament has made extensive recommendations for reform of pharmaceutical and IP regulations, recognising that the IP regime lends itself to abuses and that the over-restrictive pursuit of IP separate from public health and interest concerns is harmful.

### **3. “Trips Plus” – Contradictions between The EU’s national and international positions**

Despite the EU Parliament’s recommendations and the reforms that the European Commission is taking regionally to ensure supply chain resilience and health for all of its citizens,<sup>13</sup> the bloc, of which France is a member, continues to pursue disproportionate obligations going beyond TRIPS in their trade dealings with countries of the global South. These demands jeopardise the realization of the right to health.

In their negotiations with India<sup>14</sup> and Indonesia, the EU has put TRIPS Plus obligations (data exclusivity and patent term extensions) on the table<sup>15</sup> raising concerns that access to affordable treatment and healthcare in developing countries will be greatly impacted. India and Indonesia both have generic medicines manufacturing capacity. India, especially, has long been known as the “pharmacy of the world” supplying the global South in particular. In 2018, it was the single largest supplier of pharmaceutical products to Africa and accounted for a fifth of the continent’s pharmaceutical imports.<sup>16</sup>

It is reported that India has pushed back on these demands, stating that data exclusivity and patent term extensions are “redlines” for India in the negotiations.<sup>17</sup> Even so, as Ban Ki-Moon, former UN Secretary-General, and Winnie Byanyima, UNAIDS Executive Director, point out, the EU should never have demanded such changes in the first place.

The implementation of these TRIPS Plus provisions can be disastrous for developing countries as seen from bilateral trade agreements with the United States. In Jordan, data exclusivity delayed the introduction of cheaper generic alternatives for 79% of medicines between 2002 and 2006, and ultimately the higher medicine prices threatened the financial sustainability of government public health programs. Consequently, medicine prices in Jordan are 800% higher than in neighbouring Egypt, for example. In Colombia, data exclusivity increased the costs to the public health system by US\$396 million between 2003 and 2011. In Peru, data exclusivity is expected to contribute to an increase of about US\$459 million in total pharmaceutical expenditure by 2025. In Guatemala, the data exclusivity duration of 15 years significantly reduced competition, so medicines readily available in most countries at affordable prices were simply not available in Guatemala.<sup>18</sup> In 2006, the Korean National Health Insurance Corporation calculated that a 3-year patent extension would cost US\$529 million and US\$757 million for 4 years.<sup>19</sup>

Pursuit by the EU, with France as a member state, of the same TRIPS Plus provisions, would bring about similar impacts.

As far back as 2009, the UN Special Rapporteur on the Right to Health cautioned that:

TRIPS and free trade agreements (FTA) have had an adverse impact on the prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health.

Developing countries and Least Developed Countries (LDCs) should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into FTAs that contain TRIPS-plus language and should be mindful of actions that may infringe upon the right to health.

In light of its detrimental effects, the EU must drop TRIPS-plus proposals in its trade negotiations with developing countries and refrain from raising them in the future. These demands coming especially in the wake of COVID-19, which ravaged these nations, show a complete disregard for the EU's obligations under international human rights instruments.

It is important to underscore that France's pharmaceutical corporations have been prominent in anti-competition cases for their IP abuses to prolong monopoly and high prices. French manufacturer Servier's blockbuster hypertension drug perindopril (marketed as Coversyl), is one such example. The European Commission found that Servier had an anti-generic strategy, some elements of which flouted the EU anti-competition rules (specifically Articles 101 and 102 of the Treaty on the Functioning of the European Union). The compound patent for perindopril expired around 2003/2005 (in different EU member states), upon which generic perindopril should have entered the market. However, it was only around 2007 that the UK became the first country in Western Europe where entry was made possible. This delay, the European Commission found, was because of Servier's conduct as part of the anti-generic strategy documented in Servier's internal documents. The strategy included "blocking patents", which in Servier's own assessment involved "zero inventive activity". Servier further acquired active pharmaceutical ingredients (API) technologies and removed them as a competitive source from the market. Servier also engaged in patent disputes with its generic competitors. The European Commission found that, as a result, there was no single generic producer that could enter the market without being challenged in one way or another. These challenges led to patent settlement agreements with the (most) advanced generic contenders, save one, covering all EU member states. In total, Servier's payments to the generic companies exceeded 120 million euros.<sup>20</sup> The High Court of London ruled against Servier recently on this matter, granting damages to the National Health Service in excess of 250 million pounds for breaches of EU and UK competition rules on the basis that Servier entered into "pay-for delay" (or reverse patent settlement) agreements.<sup>21</sup>

France must require its pharmaceutical companies to stop all anti-generic strategies and comply with their responsibilities under international human rights law, including the impact of their activities abroad. France needs to compel its corporations to be more proactive in respecting human rights and consider strongly what positive duties they may carry in terms of international human rights law in their dealings abroad. As the CESCR Committee noted, *“Business entities, including pharmaceutical companies, have the obligation, at a minimum, to respect Covenant rights ... In particular, pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities with regard to access to medicines, comprising active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other related health-care technologies.”*<sup>22</sup>

#### **4. Trips a broken model of health innovation: Profitability driving innovation and supply while violating the covenant**

*“Crises may erupt overnight, often triggered by an exogenous event, but they do not build up overnight. They are the product of underlying structural forces involving contestations of ideas and classes over long periods. Crises are also periods when change can and sometimes does happen”* and must happen.<sup>23</sup>

The call to revamp TRIPS is not new. For example, in relation to access to HIV medicines, in 2012, the Global Commission on HIV and the Law found that *“[a] growing body of international trade law and the over-reach of intellectual property (IP) protections are impeding the production and distribution of low-cost generic drugs. IP protection is supposed to provide an incentive for innovation but experience has shown that the current laws are failing to promote innovation that serves the medical needs of the poor. The fallout from these regulations—in particular the TRIPS framework—has exposed the central role of excessive IP protections in exacerbating the lack of access to HIV treatment and other essential medicines. The situation is most dire in low- and middle-income countries but reverberates through high-income countries as well.”*

More than 10 years later, the world found itself at the exact same place in the fight against COVID-19. At the same time, with the escalation of non-communicable diseases, the prohibitive prices of medicines for cancer, diabetes and cardiovascular diseases caused by multiple patents and other IP on each medicine are straining public health budgets and driving up patients’ out-of-pocket expenses across the world, especially in developing countries.

The CESCR Committee, and other UN human rights Treaty Bodies and mandate holders, are uniquely positioned to guide States on how to correct course and ensure a human rights-based

approach to operationalize the right to health and access to medicines, including transitioning away from the TRIPS regime and towards a global public good approach.

There has always been wide concurrence that at the early stages of development, IP must be limited in order to promote technology transfer and the dissemination of knowledge and know-how.

*“After it declared independence, the United States, a net importer of technology at the time, did not allow foreigners to file patents for the first 37 years of nationhood. When the restriction on foreigners was eventually lifted, patent fees for foreigners were approximately tenfold higher (with an additional 65% charge for British nationals). Switzerland suspended its patent system from 1802 until 1888, when it re-established it under threat of trade sanctions from Germany. When a new law was passed, it contained a strong compulsory licensing mechanism and excluded certain products, including chemicals, from patent protection”.<sup>24</sup>*

Up until the 1990s, many patent regimes, including those in some developing countries, excluded medical and agricultural technologies. The majority of countries did not allow for product patents – while distinct technologies deserving of a patent would be granted one, a product that can be arrived at through different technological pathways would remain unencumbered. Historically, nations determined their own IP standards, including the fields to be covered and the duration of patents, depending on each country’s stage of development. Shadlen, Sampat and Kapczynski (2020)<sup>25</sup> highlight the following:

Before the mid-1970s, pharmaceutical products were eligible for protection in only a few countries such as the UK and USA;

From the mid-1970s to the early 1990s, pharmaceutical patenting became more widespread in the “Global North”. In the 1970s, Italy, Sweden and Switzerland did not grant patents for pharmaceutical products. Spain only offered patent protection for pharmaceuticals as late as 1992. France itself excluded the patentability of pharmaceutical products for a long time, from 1844 to 1960.<sup>26</sup> In 1986, when the negotiations leading to TRIPS opened, as many as 50 countries provided no patents for pharmaceutical products;

From the mid-1990s onward pharmaceutical product patents became nearly universal (in 130 countries) due to WTO membership that requires TRIPS implementation.

India, the “pharmacy of the world”, implemented a policy in 1970 that declared pharmaceutical products and processes non-patentable. This allowed India to reverse engineer pharmaceutical products leading to the development of a strong local

pharmaceutical sector. Competition from generics made medicines affordable and has proven critical to scaling up access to therapeutics.

It is misleading and even a fallacy to argue that pharmaceutical innovation is only possible with strong IP protection for the industry. Public investment in basic research especially in the Global North has been, and remains, a crucial financing source. *The WHO Report of the Commission on Public Health, Innovation and Intellectual Property Rights (2006)* extensively reviewed literature and practice and highlighted that:

*“In successive phases of the innovation cycle – from fundamental research to the discovery, development and delivery of new products – the multiplicity of financial and other incentive mechanisms, and the scientific and institutional complexities of biomedical innovation have had to be considered. At each phase, intellectual property rights may play a greater or lesser role in facilitating the innovation cycle. Other incentive and financing mechanisms to stimulate research and development of new products are equally necessary, along with complementary measures to promote access.”*

Essentially the question is how research is to be motivated and financed. To that end, patent law is a tool of regulatory policy and must not be conflated with actual property rights. Put into its correct perspective, the objective of IP rights law is not to provide the maximum possible return to rights holders but to strike the proper balance between the rights of investors and international human rights law and public health needs.<sup>27</sup> The right policies are required to ensure that IP is granted to truly deserving applicants for an appropriate period and that flexibilities and exemptions and exclusions are provided to safeguard vital public interests.<sup>28</sup>

### **More than 20 years of implementation of TRIPS have shown that:<sup>29</sup>**

The negative impacts of IP have been recognised by the CESCR Committee under paragraph 61 of General Comment No. 25 (2020) on science and economic, social and cultural rights, relating to Article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights.<sup>30</sup> Article 61 reads: “Firstly, intellectual property can sometimes create distortions in the funding of scientific research as private financial support might go only to research projects that are profitable while funding to address issues that are crucial for economic, social and cultural rights might not be adequate, as these issues do not seem financially attractive for business. This has been the case with the so-called neglected diseases. Second, some intellectual property regulations limit the sharing of information on scientific research for a certain period, as is the case with data exclusivity for patent holders included in some of the “trip-plus” treaties ... Third, although intellectual property provides positive incentives for new research activities and thus plays an important role in contributing to innovation and the development of science, it may, in some cases, pose significant obstacles

for persons wishing to access the benefits of scientific progress, which may be crucial for the enjoyment of other economic, social and cultural rights, such as the right to health. Patents give patent holders a temporary exclusive right to exploit the product or service they have invented. Thus, they can determine the price for these products and services. If prices are set very high, access to these products and services becomes impossible for low-income persons or developing countries, as has happened with new medicines that are essential for the health and life of persons with certain diseases”.

The move away from the TRIPS regime is also supported by experts within the field. For example, T.N. Srinivasan, an economics professor at Yale University advocated taking TRIPS out of WTO altogether or at least renegotiating some of its provisions.<sup>31</sup> The well-known free trade economist, Jagdish Bhagwati, an economics professor at Columbia University wrote in a letter to the Financial Times in 2001 that “we were turning the WTO, thanks to powerful lobbies, into a royalty-collecting agency by pretending, through continuous propaganda that our media bought into, that somehow the question was ‘trade related’.” He advocated that the TRIPS Agreement be removed from the WTO.<sup>32</sup>

The way forward based on non-IP models has been set out in General Comment No. 25 (2020), specifically paragraph 62. The same paragraph enjoined that States should make every effort, in their national regulations and in international agreements on IP, to guarantee the social dimensions of IP, in accordance with the international human rights obligations they have undertaken (E/C.12/2001/15, para. 18). In addition paragraph 69 reiterated the Doha Declaration 2001 that the intellectual property regime should be interpreted and implemented in a manner supportive of the duty of States “*to protect public health and, in particular, to promote access to medicines for all*”. The Committee concluded that “*States parties should use, when necessary, all the flexibilities of the TRIPS Agreement, such as compulsory licences, to ensure access to essential medicines, especially for the most disadvantaged groups*”.

With the record of the pharmaceutical industry in abusing the IP regime and employing other anti-competitive market strategies Paragraph 84 of the General Comment is also crucial: “*State parties also have an extraterritorial obligation to regulate and monitor the conduct of multinational companies over which they can exercise control, in order for the companies to exercise due diligence to respect the right to participate in and to enjoy the benefits of scientific progress and its applications, also when acting abroad. States parties should provide remedies, including judicial remedies, for victims of these companies.*”

The target should be the sharing of knowledge and know-how and the development and diversification of production to the global South, moving towards placing substantive equality in the centre of the operationalization of the right to health, looking at the systemic and structural defects of the current health innovation system which promotes and exacerbates historical inequities.

# ANNEX

*Busfield J. Documenting the financialisation of the pharmaceutical industry. Soc Sci Med. 2020 Aug;258:113096. doi: 10.1016/j.socscimed.2020.113096. Epub 2020 Jun 1. PMID: 32563788.*

**1.** The pharmaceutical sector is becoming more financialised. This paper studied the consequences of corporate financialization in the pharmaceutical industry, highlighting that the focus on shareholder primacy results in:

companies becoming short term oriented in seeking to maximise immediate shareholder returns. “Lazonick and colleagues (2017) analysed data on the eighteen US pharmaceutical companies over the period 2006-15 included in the Standard and Poor’s top-500 Index in January 2016 and found that over this period they distributed 99 percent of their profits to shareholders, 49 per cent as dividends and 50 per cent as share buybacks.”;

Increased product prices as companies raise the prices of pharmaceutical products to pay for costly share buybacks and dividends;

due to the focus on revenue maximisation more money is usually spent on marketing and advertising in order to push up sales;

if more money is spent on dividends, share buybacks, managers’ pay and marketing, less is available to invest in R&D and the development of new drugs;

the weakening of R&D capability due to closures of older R&D facilities and the breakup of research teams to cut the costs of production and manufacturing.

“Instead of profits being retained and reinvested in the company to the benefit of population health, they are often used for unproductive financial activities that benefit senior managers, shareholders and the financial sector.”

**2.** Over 50% of new medicines reaching the market do not present any added therapeutic advance for patients;

**3.** Critical health needs are not being met or are sidelined. Production focuses on drugs that offer better sales prospects and which are lucrative. Disease prevention, vaccines, antibiotics and much-needed new cures are often sidelined in favour of high-incidence chronic or life-long treatments (such as diabetes), and there is a severe lack of investment for conditions that mainly affect people in low-income countries;

4. Patenting is increasingly moving upstream in the research process. Not only are products being patented, but the tools and processes for research that might lead to those discoveries are being patented as well;

5. The pursuit of profits leads to compromises on patient safety: “All businesses are motivated by profit, but the power of shareholders and the reward of patent monopolies can align to encourage pharmaceutical-industry behaviour that is directly at odds with patient safety. In this case, private incentives to profit interfered with and subverted the public interest.” Such was the case of OxyContin, a prescription opioid that was marketed by Purdue Pharmaceuticals as being less addictive and less prone to abuse than other painkillers. An investigation by the U.S. Department of Justice (DOJ) however tells a different story. Purdue in fact knew of “significant” abuse and suppressed that information in their marketing of OxyContin as a safer alternative to other painkillers. In it all, Purdue has fought to keep its patents on OxyContin up to 2030, although it was originally to expire in 2013. Figures in 2017 show that at least 200,000 lives have been lost in the opioid epidemic that continues. The Roosevelt Institute writes that it was the monopoly given to Purdue by virtue of its patents, that gave Purdue significant financial incentive to push its drug, regardless of its risks.

## Endnotes

1- *“TRIPS Plus” refers to obligations in trade and economic agreements that require developing countries to provide intellectual property protection that are more expansive than TRIPS, resulting in loss of national policy space called “TRIPS flexibilities” and extended market monopolies, thereby reducing access to affordable treatment.*

2- See pages 4-6 in *Governing health innovation for the common good—The WHO Council on the Economics of Health for All—Council Brief No. 1.*

3- UNAIDS. *Pandemics are not fate: Concrete actions to tackle inequalities can overcome AIDS, Monkeypox and COVID-19.* 10 August 2022.

4- UNAIDS. *Pandemics are not fate: Concrete actions to tackle inequalities can overcome AIDS, Monkeypox and COVID-19.* 10 August 2022.

5- United Nations Committee on Economic, Social and Cultural Rights (CESCR). *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property.* 23 April 2021.

6- United Nations Committee on Economic, Social and Cultural Rights (CESCR). *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property.* 23 April 2021.

- 7- [European Parliament Special Committee on the COVID-19 pandemic: lessons learned and recommendations for the future report](#). 26 June 2023.
- 8- The study was by the kENUP Foundation, a European non-profit supporting research-based innovation in health industries and can be found in [Health Policy Watch](#). [93 billion euros spent by public sector on COVID vaccines and therapeutics in 11 months, research finds](#). 12 Jan 2021.
- 9- Sekalala S, Forman L, Hodgson T, Mulumba M, Namyalo-Ganafa H, Meier BM. [Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine](#). *BMJ Glob Health*. 2021 Jul;6(7):e006169. doi: 10.1136/bmjgh-2021-006169. PMID: 34253631; PMCID: PMC8277484.
- 10- *Ibid*.
- 11- UNDP. [Impact of Vaccine Inequity on Economic Recovery](#). Updated Feb 2022.
- 12- See page 6 in European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. (2021). [Future-proofing pharmaceutical legislation : study on medicine shortages: final report \(revised\)](#), Publications Office of the European Union.
- 13- France recently announced that it would call its producers home to ensure local production to avoid shortages in its pharmacies of a core list of 50 drugs. See [\[online\]](#).
- 14- MSF Access Campaign. [News Update: EU-India FTA negotiations could have negative impact on access to medicines](#). 14 March 2023.
- 15- *Data exclusivity: At its most severe, it prevents the Ministry of Health from registering a generic version of the medicine on the basis of the originator's data for a period of often 5-6 years. This means the generic version cannot be sold for this period because to get registration if there is data exclusivity, the generic medicine applicant would have to repeat the clinical trials, which can take a number of years. Data exclusivity also provides a monopoly even when there is no patent. If there is a patent, data exclusivity may prevent a compulsory licence from working because if a compulsory licence is issued and the medicine is imported or produced, it cannot be registered until the data exclusivity period is over. Patent Term Extension: Links medicine registration to patent status. Patent status is irrelevant to medicine registration which is determined on the criteria of safety, efficacy and quality. See [online].*
- 16- *Ibid*.
- 17- The United Kingdom is also making TRIPS Plus demands on India in their bilateral trade negotiations. More than 120 health experts and civil society organisations from Africa, Asia and Latin America sent a strong objection [letter](#) to the UK trade minister. India is reportedly [pushing back](#) on TRIPS Plus.
- 18- [The Feminists for a People's Vaccine Campaign Shadow Report submitted to the 83rd CEDAW Session](#).
- 19- Hankyoreh. [U.S. FTA may cost drug industry \\$1.2 billion: gov't](#). 17 October 2006.
- 20- All of Servier's strategies are described in the Commission's decision in the following order, including: (1) filing a patent cluster (section 4.1.2.1); (2) publication of perindopril monograph in the European Pharmacopoeia (section 4.1.2.2); (3) acquisition of alternative technologies and accompanying intellectual property rights (IPRs) (section 4.1.2.3); (4) patent disputes and patent settlements (section 4.1.2.4); (5) distribution agreements with friendly generics (section 4.1.2.5); and (6) selective switch to the arginine salt (section 4.1.2.7).

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- 30- See [\[online\]](#)
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**FEMINISTS  
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