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UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND – EXTRA TERRITORIAL OBLIGATIONS

TRIPS IS A BROKEN MODEL OF HEALTH INNOVATION ENSURING STATE ACCOUNTABILITY FOR THE RIGHT TO HEALTH

SUBMISSION TO THE 77TH SESSION OF THE UN COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS SESSION (CESCR) FOR THE REVIEW OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND.

FEMINISTS FOR A PEOPLE'S VACCINE

Submission to the 77th session of the UN Committee on Economic, Social and Cultural Rights Session (CESCR) for the review of the United Kingdom of Great Britain and Northern Ireland.

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TRIPS IS A BROKEN MODEL OF HEALTH INNOVATION

ENSURING STATE ACCOUNTABILITY FOR THE RIGHT TO HEALTH

Submission by

Development Alternatives with Women for a New Era (DAWN)

International Women's Rights Action Watch Asia Pacific (IWRAW-AP)

Third World Network (TWN)

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

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BACKGROUND

1. The realisation of the fundamental right to health is necessary for the enjoyment of all other rights. Enshrined in the Constitution of the World Health Organisation (WHO) (1946), and the Universal Declaration of Human Rights (1948), further enumerated in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966), and CESCR General Comment No. 14, the right to health is more than just a right to healthcare. The concept of the right to health encompasses various socio-economic elements that foster conditions for a healthy life, as further elaborated in paragraph 2 of Article 12. It includes fundamental factors like access to adequate food and nutrition, housing, clean and safe water, proper sanitation, safe and fair working conditions, and an environment conducive to health.
2. Every State has ratified at least one international human rights treaty recognising the right to health (OHCHR, 2008). Yet, today, in adopting the United Nations Pact for the Future in September 2024, Member States agreed that the world finds itself in a “time of profound global transformation”. Our choices thus far have resulted in rising catastrophic and existential risks. Without a change of course, “we risk tipping into a future of persistent crisis and breakdown”.
3. Since the adoption of those key instruments in the 1940s to date, economic globalization with new legally binding economic rules and structures have severely reduced national policymaking, entrenching a new form of colonisation:
4. (i) At the World Trade Organization (WTO): the Uruguay Round agreements administered by the WTO have gone far beyond merely trade in goods into almost every aspect of national economies. **Particularly relevant, and the focus of this report, is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that entered into force in 1995 setting minimum standards for intellectual property rights (IPRs) to be implemented through national legislation by Member States. TRIPS has led to extreme concentration of technological investments and control in the global North and severely impacted the availability and affordability of essential life-saving treatments, especially for the Global South;**
5. (ii) Operational policies and lending conditionalities and practices of the World Bank, International Monetary Fund, and regional development banks, including fiscal consolidation and austerity measures have led to deregulation and privatization. Increased concentration in corporate wealth and the build-up of unsustainable debt in developing countries are key results. Health and economic recovery as well as efforts towards achievement of the 2030 Sustainable Development Agenda and its 17 goals have been derailed, deepening intersectional inequalities, particularly those of gender and race;
6. (iii) Private finance has grown exponentially and financial actors have become more concentrated and powerful, with borrowing costs of developing countries far exceeding those of developed countries. Developing regions can borrow at rates that are 2 to 4 times higher than those of the United States and 6 to 12 times higher than those of Germany, experiencing negative net resource transfer (Raja, 2024).

7. The above has deepened inequalities between and within countries. Together with the effects of the COVID-19 pandemic and wars, they have compounded the factors that exacerbate vulnerability - poverty, irregular migratory status, health status, and racism. In this polycrisis context, the right to the highest sustainable standard of physical and mental health remains a distant goal (Mofokeng, 2024).
8. **Global transformation is possible but it requires a necessary re-commitment to international cooperation based on respect for, and compliance with, international law. The challenges we face today, as per the Pact for the Future states, "can only be addressed collectively, through strong and sustained international cooperation guided by trust and solidarity for the benefit of all and harnessing the power of those who can contribute from all sectors and generations" (UN General Assembly, 2024).**
9. There must be greater resource allocation for the developing countries of the Global South with much-needed transfer of technology. Any obligations undertaken must be on the principle of common but differentiated responsibilities with **equity** underpinning international relations.
10. **As stated above, this parallel report will focus on the international intellectual property system, and the need for its fundamental reform including a narrowing of the scope of patentability. The United Kingdom (UK) as a State that is home to powerful corporate actors has obligations to ensure that its engagements and dealings further a human rights, public health approach in the pursuit of a more equitable international order.**
11. As evidenced by the UK's conduct during the negotiations on the TRIPS Waiver proposal before the WTO at the height of the COVID-19 crisis, and in the current negotiations for a Pandemic Agreement at the WHO, as well as in its trade dealings with developing countries, the UK has thus far failed to meet its:
12. (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 bi-laterally with developing countries;
13. (b) duties to international cooperation and assistance, including refraining from infringing on the ability of other States to fulfil their own human rights obligations.
14. **In particular, and for the reasons detailed below, we respectfully request the CESCR Committee to recommend that the UK:**
15. 1. Ensures that it or the corporations governed by UK law, within and outside its territory, do not invoke or apply intellectual property rights in a manner that is inconsistent with the right to health, including access to medicines, vaccines and other health products, or the right of States to fully exercise the flexibilities of the TRIPS agreement. This is recommended by the UN Office of the High Commissioner for Human Rights (OHCHR) in a recent study on key challenges in access to health (OHCHR, 2024).
16. 2. Refrain from requiring "TRIPS-Plus"[1] proposals that undermine pharmaceutical manufacturing capacity and timely access to affordable vaccines and medicines in any current and future trade or other negotiations with developing countries.
17. 3. Support Colombia's proposal submitted to the WTO TRIPS Council for a review of the Agreement on 15 April 2024, including calling for:

[1] "TRIPS Plus" refers to obligations in trade and economic agreements that require developing countries to provide intellectual property protection that is more expansive than TRIPS, resulting in loss of national policy space called "TRIPS flexibilities" and extend market monopolies, thereby reducing access to affordable treatment.

(i) a clarification that plants, animals, micro-organisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organisms should also not be patentable;

(ii) the strengthening of existing public-health safeguards within TRIPS to ensure that governments have the unambiguous right to override patents in the interests of public health;

(iii) the adoption of a pro-public health interpretation of TRIPS through the flexible use of existing safeguards and exceptions. These include upholding the right of countries to grant compulsory licences for local manufacturing, import and export, and their right to implement parallel importation measures;

(iv) the removal of burdensome conditions that governments have to fulfil in the issuing of compulsory licences, so that licences can be granted on a 'fast track' basis for public-health purposes;

(v) the extension of the implementation deadlines within TRIPS for least developed countries in relation to patent protection (both product and process) for medicines;

(vi) agreeing not to exert bilateral or regional pressure on developing countries which take measures to exercise their rights under TRIPS to protect public health and promote access to medicines, nor to pressure them to implement unnecessarily strict and potentially harmful intellectual property protection standards or 'TRIPS-plus' measures;

(vii) the observation with immediate effect, of a moratorium on dispute settlement action against developing countries, which hinders their ability to promote access to medicines and protect public health (including the use of compulsory licence and parallel importation measures);

(viii) allowing developing countries the options of restricting the scope and length of patent protection, including an outright exemption of medicines from patenting on humanitarian or public health grounds, in order to meet the objectives of saving lives, countering and controlling epidemics, and ensuring that poor people obtain access to essential medicines for the treatment of poverty-related diseases. (World Trade Organization, 2024)

4. Ensure equity in the process of negotiations and the final substance of the Pandemic Agreement. The terms of the Agreement must provide for stronger commitments on technology transfer and the removal of intellectual property barriers, concrete obligations on the sharing of essential medical products, a legally binding fair, transparent, accountable and effective Pathogens Access and Benefit Sharing System (PABS), expanding manufacturing capacity in the Global South and strict conditions that any product resulting from publicly funded research and development must be a global public good to be equitably shared.

5. Commit to adequately supporting low- and middle-income (LMICs) countries in meeting their obligations under the Pandemic Agreement through the principle of common but differentiated responsibilities (Global Justice Now, 2024).

Further, we respectfully request the CESCR Committee to consider commencing a process of elaborating a General Comment on IP regime reform, including a shrinking of the scope of patentability, building on its own existing analysis as well as the analysis of various UN agencies.

Through this process we also believe that the Committee can contribute towards ensuring that ongoing and future negotiations of bilateral and regional trade/economic agreements as well as

multilateral negotiations, including at the WHO, the WTO and the UN General Assembly are consistent with the full realization of the right to health.

TRIPS: COMPOUNDING INEQUITIES IN GLOBAL HEALTH ACCESS

30. Everyone has the right to enjoy the benefits of scientific progress and its applications (Article 15(1)(b) ICESCR). However, States have for decades used TRIPS to justify abusive monopolies on access to medicines that disproportionately impact LMICs. This conflict was addressed in a 2000/7 OHCHR resolution on IP rights and human rights (UN, 2000) and has now been reiterated in its most recent report published in July 2024 . The OHCHR reminds us that,
31. [a]ccess to medicines, vaccines and other health products is deeply unequal in many countries owing to structural barriers, social determinants of health and other factors affecting various populations that are marginalised. These inequalities are further aggravated in contexts of fragility, conflict and violence[…] This impact is most dramatic in low- and middle-income countries[…] Children, women and girls, older persons, migrants, persons in geographically remote areas and persons with disabilities are among those who are disproportionately affected by limitations on access to medicines. Frequently, intersectional and multiple discrimination has a compounded differential impact. (OHCHR, 2024)
32. One of the recommendations which the OHCHR then makes is that States are "to ensure that intellectual property rights are not invoked and applied in a manner that is inconsistent with the right to health, including access to medicines, vaccines and other health products, or the right of States to exercise the flexibilities of the TRIPS agreement" (OHCHR, 2024).
33. 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" (WTO, 2001). However, the inequitable access of medical products in the response to the HIV, COVID-19 and mpox health emergencies show that developed countries have failed time and time again to honour their extraterritorial obligations towards the concrete realization of poorer nations' right to health, even in times of crisis.
34. 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" (UNAIDS, 2022b).
35. Winnie Byanyima, Executive Director of UNAIDS, and Under-Secretary-General of the United Nations stated:
36. 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. (UNAIDS, 2022b)

37. 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) (UN Economic and Social Council, 2006).
38. **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" (Committee on Economic, Social and Cultural Rights, 2021).**
39. 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" (Ibid, 2021). This underscores the urgent need for fundamental reform of TRIPS, including the shrinking of the scope of patentability.

UNDERMINING THE RIGHT TO HEALTH

40. Despite international law precedents and the UK's agreement, as a WTO Member State, that TRIPS "does not and should not prevent member governments from acting to protect public health" (World Trade Organization, 2011), the UK, which made huge public investments in vaccine development, consistently acted to undermine the right to health, particularly in LMICs (Government of the UK, 2023). The UK imposed export restrictions on health products that could have been relevant to COVID-19 treatment (Evenett, 2020), and hoarded vaccines, causing implementation challenges to the COVAX facility (Gavi, 2021)[2].
41. Further, the UK, together with the European Union, led by Germany, and Switzerland, continuously adopted intransigent positions on the TRIPS waiver proposal submitted by India and South Africa in 2020 at the WTO during the COVID-19 pandemic (WTO, 2020; 2021): blocking much-needed scaling up and diversification of global manufacturing of health products and technologies for the prevention, treatment and containment of COVID-19. In so doing, the UK took positions which protected the monopolies and massive profits of large pharmaceutical companies domiciled within its boards, resulting in enormous loss of lives globally (Kanth, 2021) and prompting a letter by southern civil society organisations to then Prime Minister, Boris Johnson, to act in solidarity with more than 100 countries that supported the proposal.
42. The TRIPS waiver negotiations ended with the WTO failing to deliver a comprehensive multilateral solution on diagnostics, vaccines and therapeutics for the COVID-19 pandemic at its 13th Ministerial Conference (Kanth, 2024).

[2] COVAX is a cooperation between the WHO and other international institutions such as the Global Alliance for Vaccines and Immunization, which aimed to provide equal access to vaccines globally by pooling resources. See also Pushkaran et al (2023). , Vijay Kumar Chattu and Prakash Narayanan, 'A critical analysis of COVAX alliance and corresponding global health governance and policy issues: a scoping review' (023) *BMJ Global Health*.

43. Instead of cooperating towards equitable access to COVID-19 health technologies and products, the UK announced donations of COVID-19 vaccines in July 2021, which drew criticism as a substantial amount of vaccines expired in September of the same year (Sewey, 2021). Charity, which entrenches dependency of the developing world on the global North, is not the answer. Firm, legal obligations towards “reparative redistribution” from the North to the South should be the practice and the norm (Sekelala et al, 2021). Healthcare cannot be left to market forces that are monopolistic in the pharmaceutical sector and voluntary mechanisms - furthermore, the purchase of vaccines at monopolistic market prices itself propels countries of the Global South further into debt.
44. 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. (Ibid, 2021)
45. **The UK also continues to thwart efforts at ensuring that equity is restored into multilateral efforts and processes in health emergency preparedness and response whether in negotiations that were recently concluded on the amendments to the International Health Regulations 2005 (IHR 2005) or for the ongoing Pandemic Agreement negotiations.[3]**
46. In the former, at the Working Group on the Amendments to the IHR’s (WGIHR) mandated under the WHO Executive Board Decision 150(3) to tackle equity gaps in IHR 2005, the UK acted to dilute proposed equity-related text.
47. In the latter, opposing the adoption of the principle of common but differentiated responsibility, a core tenet of sustainable development, in the implementation of pandemic prevention, preparedness and response, in the first week of negotiations at the 9th meeting of the Intergovernmental Negotiating Body (INB), developed country delegations, including the UK, contested the concept of "international solidarity”. This took the discussions to a stage where the WHO legal counsel had to refer to dictionaries and WHO resolutions to explain the meaning of the principle of international solidarity, according to a developing country delegate” (Third World Network, 2024). Although negotiations on amendments to the IHR have concluded, negotiations for the Pandemic Agreement continue. Achieving broader consensus among WHO Members has proven to be an uphill battle. Progress has been painfully slow and developing countries are increasingly alarmed that the Pandemic Agreement lacks meaningful provisions that will shift the status quo towards an equitable response during health emergencies. They advocate for tangible

[3] These are two separate processes addressing different subject matters; proceedings before the INB on the Pandemic Agreement focuses on pandemic prevention, preparedness and response, while IHR 2005 deals with all types of public health emergencies, pandemic or non-pandemic in nature.

commitments like technology transfer, diversifying production and timely equitable access to medical products.

48. In contrast, developed countries including the UK have shown little interest in adopting concrete measures that meaningfully operationalize equity. Instead, their focus remains on reflecting obligations for multisectoral surveillance, data sharing, and the exchange of biological materials. The divide between the Global North and South is starkly apparent (Ramakrishnan & Shashikant, 2024).

"TRIPS PLUS"

49. In its trade negotiations, such as the UK-India free trade agreement (FTA), the UK has pursued "TRIPS Plus" provisions. Not only are the negotiations being carried out in a non-transparent manner, the UK's proposed provisions would water down transparency and robust patent opposition mechanisms in India's IP regime while extending the patent term beyond 20 years, and allow for the granting of market exclusivities over clinical data. India is renowned for its dynamic IP system, which is seen as achieving a good balance between promoting innovation while ensuring IP protection. India is a global provider of affordable generics used by the NHS itself (Ivanova, 2022). Based on our information, the TRIPS Plus proposals were withdrawn due to global pressure; however, the UK's proposed provisions would have allowed for greater abuse of the Indian patent system, likely resulting in 'evergreening' of patents, thereby impacting global supply of affordable generic pharmaceuticals.
50. The UN Special Rapporteur on the right to health has emphasised in its report that "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 TRIPS Plus FTAs and should be mindful of actions which may infringe upon the right to health (UN Human Rights Council, 2009). CESCR Committee Member Preeti Saran at CESCR's 74th session during the review of France on 2nd and 3rd October 2023 (referring to the Committee's statement of April 2021, in the wake of COVID-19 pandemic) reiterated this point recognizing that provisions such as data exclusivity or patent term extensions can impede access to affordable health in the Global South.
51. The UK's own historical experience shows that a "strong" IP regime, in the sense of providing strong protection of private IP rights, was not an essential condition for its economic development. The UK itself established a strong IP regime only in the mid-19th century. It is very important to note that in relation to pharmaceutical patents especially, few of the developed countries today allowed patents on chemical and pharmaceutical substances (as opposed to the processes) until later in the 20th century[4]. The UK's efforts to impose more stringent IP protections in the national laws of India, therefore, be interpreted, at best, as a double standard, and at worst a deliberate attempt to protect the wealth of the UK and its pharmaceutical industry

[4] Chemical substances remained unpatentable until 1967 in West Germany, 1968 in the Nordic countries, 1976 in Japan, 1978 in Switzerland, and 1992 in Spain. Pharmaceutical products remained unpatentable until 1967 in West Germany and France, 1979 in Italy, and 1992 in Spain. Pharmaceutical products were also unpatentable in Canada until the early 1990s. See Chang (2001).

at the expense of the right to health and right to development of other countries (Chang, 2001, p. 35).

52. As raised by CESCR Committee Member Preeti Saran at CESCR's 74th session during the review of France on 2nd and 3rd October 2023 (referring to the Committee's statement of April 2021, in the wake of COVID-19 pandemic) States should not impose TRIPS Plus provisions such as data exclusivity or patent term extensions that impede access to affordable health in the Global South[5].
53. The implementation of these TRIPS Plus provisions can be disastrous for developing countries as seen from bilateral trade agreements.
54. 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. 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. (Feminists for a People's Vaccine, 2022)
55. Pursuit by the UK of the same TRIPS Plus provisions, would bring about similar impacts.
56. **In light of their detrimental effects, the UK 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 UK's obligations under international human rights instruments.**
57. In addition, we underscore that UK's pharmaceutical corporations have been prominent in abusing the TRIPS regime, and taken to task by authorities for their IP abuses to prolong monopoly and high prices. For example, Astrazeneca was found guilty by a Dutch court in 2018 for "evergreening" of its patent on an extended-release form of Seroquel, a medicine used for the treatment of psychosis. Despite the fact that a British court had ruled that the patent on the new formulation was invalid in 2022, the company nevertheless continued to take legal action against generic competitors in the Netherlands (t' Hoen, 2020). Evergreening refers to additional patents granted for often trivial changes that have no significant additional therapeutic value, thereby prolonging market monopolies beyond 20 years.

[5] [Our transcripts] "On the last issue of business and human rights, since I had the floor, I thought I'd just also seek further clarification on the impact assessment, if any, that has been undertaken by France on the various international agreements, bilateral and multilateral on the parties that are in line with the covenant provisions to the issuing party. In particular, I would like to draw attention to this Committee statement that was made in the wake of COVID-19. You had said that, you know, you had worked nationally on a lot of steps taken... But, you know, in April 2021, we too had issued a statement particularly urging pharmaceutical companies, including innovators, genetic and biotechnology companies, etc., to ensure affordable access to medicines, pharmaceutical ingredients, diagnostic tools, etc.. And so I wanted to know whether any TRIPS Plus obligations are being imposed upon, you know, new agreements that are being signed or by the pharmaceutical companies are being urged to stop anti genetic strategies, you know, such as data exclusivity or patent term extensions that impede access to affordable health in the global South. So this was my first question."

58. **The UK 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. The UK 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" (Committee on Economic, Social and Cultural Rights, 2020).

TRIPS, A BROKEN MODEL OF HEALTH INNOVATION: PROFITABILITY DRIVING INNOVATION AND SUPPLY WHILE VIOLATING THE COVENANT

59. In March 2024, after 30 years of TRIPS implementation, Colombia tabled a proposal under Article 71 of TRIPS, for, among other things, a review of the implementation of the agreement. Implementation has been controversial and after 30 years, requires a reality-check by WTO Members, supported by metrics and data on best practices, identifying obstacles and potential implementation improvements, and to consider narrowing the scope of patentability scope. The Colombia proposal provides this crucial opportunity and the UK must now support it.
60. A summary of the impacts of TRIPS is as follows[6]:
61. (i) the jacking up of prices of consumer products (including essential items such as medicines) by companies owning IP rights, reducing consumers' access and affecting their welfare, health and lives;
62. (ii) the high cost to firms of developing countries which have to pay big royalties for use of technology, or are unable to get permission from IPR holders to use modern technologies, this affecting a country's ability to modernise and upgrade their technology;
63. (iii) biopiracy, where individuals or corporations (mainly of the North) have sought to patent biological sequences and the knowledge of their uses. Farmers and indigenous peoples (especially on the South) have their knowledge appropriated. E.g. a US patent for the use of turmeric for healing wounds (successfully challenged by the government of India as it is a traditional treatment in India) and the patenting by American scientists of a protein from Thai bitter gourd after Thai scientists found its compounds could be used against the AIDS virus.
64. (iv) Over 50% of new medicines reaching the market do not present any added therapeutic advance for patients;
65. (v) Critical health needs are not being met or are sidelined as 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; and

[6] Here reference is also made to the observations of 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

66. (vi) 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.
67. (vii) Developing countries coming under severe pressure from corporations and/or the governments of the North for using TRIPS Flexibilities to expand access to essential medicines, leading to an unnecessarily cautious approach in the utilisation of legimite responses and tools.[7]
68. The above has been recognised by the UN High Commissioner on Human Rights. In his report to the 56th Session of the Human Rights Council (2024) titled "A review of the key challenges of ensuring access to medicines, vaccines and other health products concerning everyone's right to enjoy the highest attainable standard of physical and mental health", the High Commissioner made the following key recommendations, among others:
69. (a) cooperation between States, the private sector, civil society and other stakeholders to improve access to medicines, vaccines and other health products;
70. (b) improving global, regional and local health governance;
71. (c) supporting investment in the research and development of new medicines and vaccines through public-private partnerships and innovative funding;
72. (d) promoting research and development to improve access to medicines, vaccines and health products for limited markets, for example, neglected tropical diseases and other global public health challenges,
73. (e) introducing measures to encourage mutual learning and technology transfer to ensure the widest possible access to medicines, vaccines and other health products, thereby ensuring that States comply with their international law and international human rights law obligations,
74. (f) ensuring that intellectual property rights do not limit people's right to health. This includes stopping intellectual property rights from being used to limit access to medicines, vaccines and other health products, or to limiting a State's right to exercise the flexibilities of TRIPS. (Office of the United Nations High Commissioner for Human Rights, 2024)
75. In addition, the Committee for Development Policy (CDP) to the 26th session of the United Nations Economic and Social Council (ECOSOC) which was convened in March 2024, drew the following conclusions (among others) in its report "Innovation Ecosystems for Development, Structural Change and Equity" recognized that although technology can increase productivity, advance inclusion, build resilience against crises, and address urgent global priorities such as climate change, infectious diseases, food insecurity, and gender and other social inequities, its potential has not been fully realized. The Committee identified critical gaps as including
76. the undersupply of technologies for many development priorities; extreme concentration of global science, technology and innovation investments and capacity in a few countries; and weak science, technology and innovation capacity and knowledge assets in most developing countries, despite the emergence of China and other Global South countries as poles of innovation. (Committee for Development Policy, 2024)
77. It specifically noted the long-standing challenges faced by developing countries in the 21st century knowledge economy are acute due to the dominance of intellectual property monopolies. The Committee specifically states that:

[7] See MSF (2017); I-MAK (2022); Florio et al. (2021).

78. the myth that the stronger the patent protection, the better, is not grounded in evidence. Strong patent protection can also create obstacles to innovation and limit the diffusion of the benefits of scientific progress. The current intellectual property system (national, regional and international frameworks) is dysfunctional in many ways for the purposes of equitable and sustainable development. The existing rules and institutions were not formulated with a view to supporting innovation or the dissemination of new technologies for development purposes or for facing planetary-scale shocks. They are biased towards rewarding innovators over users. Intellectual property protection often far exceeds what would be necessary to incentivize innovation, leading to high prices and an undersupply of public goods and reducing the global dissemination of the benefits of innovation, which contributes to new inequalities. (Ibid, 2024)
79. Whilst, TRIPS contains policy space/flexibilities for governments to balance the goals of innovation and access, nevertheless, “developing countries face obstacles in making use of flexibilities owing to gaps in information, trade sanctions and other forms of political pressure, and incompatible national legal frameworks” (Ibid, 2024).
80. Finally, the Committee states that
81. the implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) provisions for technology transfer and to support development have not had the desired impact. The challenges of science, technology and innovation and the role of intellectual property frameworks are a neglected issue in international organizations with a mandate for development. Such organizations should provide developing countries with proactive support at the country level for the development of intellectual property architecture and policy frameworks, for the deployment of intellectual property as a development policy tool, and for the implementation of TRIPS flexibilities and other measures to pursue public interest. That includes providing policy analysis on alternative approaches. International organizations should also expand their work on global governance for the ethical use of new technologies. (Ibid, 2024)
82. In the United Nations Pact for the Future, Global Digital Compact and Declaration on Future Generations (2024), UN Member States recognized the need to increase efforts to support developing countries, with capacity-building in science, technology and innovation through policy exchanges, knowledge-sharing, technical assistance, financing, joint international research and personnel training tailored to specific needs, policies and priorities of developing countries, integrating a human rights perspective into regulatory and norm-setting processes for new and emerging technologies, calling on private sector compliance in contributing to the full enjoyment of human rights by all.
83. 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. As touched on above, 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 (Kenneth et al, 2020). **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:

84. 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. (Commission on Intellectual Property Rights, Innovation and Public Health, 2006)
85. 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 (Global Commission on HIV and the Law, 2012). 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 (Khor, 2005).
86. **However, perhaps disruption is needed and WTO members should seriously reconsider whether TRIPS belongs to the WTO. IPRs is not a trade issue. IPRs being private rights are to be enforced by their holders under national legal systems instead of turning the WTO into a "royalty-collection agency" (Khor, 2001)**. As Khor (2001) points out,
87. High IPRs standards constitute a form of protection that prevents or constrains the international transfer of technology; they constitute the institutionalising of monopoly privileges that result in rentier incomes and that restrains competition and promotes anti-competitive behavior. It is an aberration that TRIPS is located in a trade organization whose main functions are supposed to be the promotion of trade liberalization and conditions of market competition, whilst TRIPS is protectionist and curbs competition. The reality is that TRIPS was placed in the WTO because the developed countries wished to make use of its dispute settlement system in order to ensure effective enforcement of disciplines on developing countries.
88. **Radder and Smiers (2024) have put forward concrete proposals for medical research without patents, properly recognizing the substantial contribution of public coffers through tax payer funds towards drug development. They show that such is not only scientifically, socially, and morally preferable. It is also economically and financially profitable, and socio-politically and organizationally practicable (Radder & Smiers, 2024).**
89. The world is not short of aspirations and the time for action is now. As said by the UN Secretary-General Antonio Guterres, "the SDGs aren't just a list of goals. They carry the hopes, dreams, rights and expectations of people everywhere" (Anderson, 2023).
90. For the reasons above, we respectfully call on the Committee to make the recommendations as enumerated in pages 4-6 of this report.

91. Who owns the patent on this vaccine? Quoting Jonas Salk famous phrase, we could answer: “The people[...] There is no patent. Could you patent the sun?”.

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