Mr Thomas J W Peck

Office C74,

Law School,

Lancaster University,

LA1 4YT

t.peck@lancaster.ac.uk

**Response to: Call for Contributions – OHCHR analytical study on key challenges in ensuring access to medicines, vaccines, and other health products (HRC resolution 50/13)**

To the Registry of OHCHR,

My name is Thomas Peck. I am a postgraduate researcher at Lancaster University, Law School, UK. My research focuses on the right of access to medicines under international human rights law. Specifically, I consider the cost of pharmaceuticals, examining how price rises impact access to medicines, the obligations of states to protect from interferences with the right to health, and the responsibilities of pharmaceutical companies to respect the right to health therein. I submit to you my answers to the following of your questions:

***Questions (h) and (c): What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products? / Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?***

*The Rising Cost of Pharmaceuticals*

A key obstacle to ensuring equitable access to medicines and other health products is the rising prices of pharmaceuticals. The cost of essential medicines to individuals, insurers, and health providers continues to rise year on year far in excess of inflation. In the absence of publicly funded healthcare protection, these rising costs create distinct inequalities between individuals, with only those with the means to pay able to access essential services. Within publicly funded healthcare systems, rising costs place increasing strain on healthcare budgets, leading to resource allocation and rationing decisions which impact individual access to medicines.

*Issues in Domestic Regulation*

Significant regulatory deficiencies and ‘loopholes’ in domestic jurisdictions produce an environment where pharmaceutical companies are free to raise prices in an exploitative manner, increasing and exacerbating issues related to access to medicines. Here I will focus on two case studies in particular: The United States of America (USA) and the United Kingdom (UK). Traditionally ensuring access to medicines is viewed through the paradigm of poorer nations, whose broader national capacity to access medicines is limited. I do not seek to take away from these important case studies, rather, I use the case studies of the USA and UK in particular because they demonstrate that even in wealthy nations, which are often home to much of the pharmaceutical industry and development, issues of exploitative pricing are prevalent and directly impact upon an individual’s right to access essential medicines.

*The USA*

Whilst a system of publicly funded medicine exists within the USA (Medicare and Medicaid) the vast majority of US citizens access their healthcare through private insurance, requiring premium payments and co-payments. Those covered by private insurance are exposed to the impact of pharmaceutical price rises, as the cost of insurance premiums and co-payments continues to increase to cover the rising cost of medicines. Those without insurance, or coverage under Medicare or Medicaid, are fully exposed to the heightened cost of medicines. In the USA, the absence of sufficient price regulation allows manufacturers to raise drug costs significantly without justification or oversight.[[1]](#footnote-1) The recent ‘Inflation Reduction Act 2022’ has measures to increase direct negotiating power and influence, allowing a reduction in cost to the Medicare system. This however is of little help to those ineligible for care under the scheme, since there is no national system of Universal Healthcare.

*The UK*

In the UK the National Health Service (NHS) provides healthcare free at the point of use, with the majority of UK citizens and residents accessing healthcare in this manner.[[2]](#footnote-2) As such, many of the concerns regarding pharmaceutical pricing relate to the impact on the central healthcare budget and the allocation and rationing of resources.[[3]](#footnote-3) A degree of price regulation exists for so-called ‘branded’ medicines,[[4]](#footnote-4) which places constraints on potential price rises. However, a loophole exists in the context of ‘un-branded’ or ‘generic’ medicines.[[5]](#footnote-5) These medicines are, in theory, subject to the forces of the free market since they are not subject to patent protection. As such, there are no direct price controls placed upon them. However, medicines are not easily produced and entail significant hurdles in set-up and manufacture. As such, the de-branding of medicines acts as a loophole for pharmaceutical companies to avoid the price restrictions inherent in branded medicines since competition exists only in theory, not in practice.[[6]](#footnote-6) Given this, the UK has seen a significant rise in the costs of essential generic medicines placing increasing strain on NHS resources.[[7]](#footnote-7)

*Issues in the Clarity of International Human Rights Law*

A further barrier towards ensuring access to essential medicines is the current lack of clarity as to the obligations of states regarding ensuring access to medicines in the context of pharmaceutical price rises, in particular, the obligation to protect. My academic work looks to deliver such clarity, the main points of which I summarise below. However, the words of academics only go so far. As such, and as I reiterate in my recommendations below, it is essential that International Human Rights Institutions such as the OHCHR, HRC, CESCR and others make clear pronouncements endorsing these obligations of states to ensure that there is no remaining ambiguity as the expectations of the international community.

States must respect, protect and fulfil economic, social and cultural rights (ESCRs) including the right to health and the right to access essential medicines. Yet, there is a distinct absence of clarity regarding the obligation to protect ESCRs. I have argued that the obligation entails several core requirements upon states, those being:

(A) A requirement to act to prevent human rights abuses from third parties;

(B) A requirement to use the maximum available resources in protecting human rights, and

(C) A requirement to provide effective remedies and deterrence to future abuses.

In addition, in the context of transnational business activities, which include many activities of the pharmaceutical industry, I have argued that there are two additional requirements within the State obligation to protect, those being:

(D) A requirement to ensure corporate due diligence, in line with the UN Guiding Principles on Business and Human Rights, the OECD Guidelines and other relevant international standards; and

(E) An extraterritorial obligation to protect against abuses by corporate entities abroad, which are within the sphere of control and influence of the home state.

Through pronouncements endorsing and affirming the central importance and evident content of the obligation to protect, in the context of access to medicines, States may better understand their obligations and strive towards greater protection therein.

***Question (f) What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products? How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?***

How a State implements intellectual property law at a domestic level can directly impact the right to access medicines. Domestic and international intellectual property regulation thus represents a key tool through which a State may contribute towards greater compliance with the obligation to protect the right to health. The obligation to protect requires that States use the maximum of available resources to prevent violations of the right to access medicines. One such resource is their capacity, as parties to international treaties, to use the provisions of those treaties to their maximum potential in the pursuit of protecting the right to health. To this end, in the context of intellectual property law, States who are parties to the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (TRIPS) should, in line with the requirement to use the maximum available resources, engage with and use those ‘flexibilities’ confirmed in the Doha Declaration (2001) which are available to States to aid in the protection of the right to access medicines. In particular, States should consider:

A) Compulsory Licencing

Compulsory licencing occurs when a State allows a third-party access to a company’s patent, producing the product at a lower cost. Generally, the State will need to ask for voluntary surrender of the patent,[[8]](#footnote-8) with adequate remuneration paid to the patent holder.[[9]](#footnote-9) However, unilateral seizure can be achieved in situations of national emergency, extreme urgency or for non-commercial, governmental use.[[10]](#footnote-10) Yet these requirements do not pose much of a barrier to employing this mechanism. The grounds for using compulsory licencing are broad, and as the Doha Declaration clarifies, it is States that determine the threshold for an ‘emergency’ appropriate to unilaterally seize intellectual property.[[11]](#footnote-11)

When implemented successfully, compulsory licencing has been proven as an effective method of reducing the price of patented drugs and increasing access to medicines.[[12]](#footnote-12) Countries such as Thailand have used compulsory licencing as a deliberate element of the procurement strategy to facilitate lower drug costs and greater access to medicines.[[13]](#footnote-13) Several studies have concluded that the use of these licences increased access to medicines, decreased health-related expenditure and significantly improved patient outcomes.[[14]](#footnote-14) The *threat* of compulsory licencing may also be sufficient to comply with a state’s obligation to protect, what Hoen calls the ‘*Almost* Compulsory Licence’.[[15]](#footnote-15) In Brazil, studies have shown that the mere threat of compulsory licences has seen a decrease in drug prices from pharmaceutical companies.[[16]](#footnote-16) Similarly, in the US, the threat of issuing a licence for the anthrax drug ciprofloxacin in the wake of bio-terrorism attacks led the patent-holder Bayer to introduce price concessions.[[17]](#footnote-17) From a human rights perspective, the positive impact of compulsory licences arguably amounts to a form of preventative measure in line with the deterrent component of the obligation to protect. Given the clear increase in access to medicines, increasing the use of these methods remains a key recommendation of the WHO to tackle the rising cost of medicines.[[18]](#footnote-18)

B) Parallel Importation

Parallel importation refers to the import of goods from one state into another without the permission of the patent or intellectual property holder.[[19]](#footnote-19) Doing so allows for a State to import medicines at a more affordable price than would be available to them in the domestic market. There are however some aspects which States must be aware of in implementing these measures. The first is the potential for pharmaceutical companies to choose not to launch products in a State at all.[[20]](#footnote-20) Many companies operate based on profit and thus, where operating within a country is not seen as profitable, they may reassess their position. A further concern is the impact of lobbying and the influence of third countries opposed to the use of parallel importation. In 1998 the Pharmaceutical Manufacturers Association of South Africa (PMA) sought to challenge the Mandela government’s amendment to the *Medicines and Related Substances Control Act* which provided the legal basis for parallel imports into South Africa.[[21]](#footnote-21) Whilst the suit was dropped after public outcry, the US Government (after lobbying from the industry) placed pressure on the South African government, citing a threat to US-based intellectual property. Whilst eventually backing down, the US-backed campaign against the use of parallel imports has continued through a series of international trade agreements excluding its use.[[22]](#footnote-22) Perhaps due to pressure from the industry, or due to exporting nations such as the US’s negative view of the practice, parallel imports have been largely under-utilised by States.[[23]](#footnote-23) Nevertheless, in light of the positive impact of this practice, States should, in furtherance of their obligation to protect against harmful pharmaceutical pricing, employ and utilise their regulatory powers to implement parallel importation under a scheme of international exhaustion either in the form of actual imports, or the threat of imports as a deterrent.

***Question (e) From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?***

The above examples make clear that a significant barrier towards international cooperation is the power and influence of pharmaceutical companies, especially within those exporting nations, who view it in their national self-interest to protect the intellectual property rights of corporations which contribute towards their economic growth and development. As the 1998 case of US influence over South African parallel importation policy demonstrates, the pull of national and corporate self-interest can represent a significant challenge to the realisation of positive international cooperation towards the protection and promotion of the right to access medicines.

It is centrally important therefore to make clear the expectations and obligations of states concerning such international cooperation, assistance and protection. To this end, it is evident that states hold obligations towards international cooperation and assistance under Article 2(1) of the International Covenant on Economic, Social and Cultural Rights. In addition, it is also evident from both general international law and international human rights law that States have an obligation to protect human rights extraterritorially in the context of third-party interferences abroad.[[24]](#footnote-24) This has been confirmed and expanded upon several times, most notably under the *Maastricht Principles* in 2011.[[25]](#footnote-25) In the context of the right to health and access to medicines, the CESCR have made clear in General Comment 14 that States must “prevent third parties from violating [ESCRs] in other countries…”[[26]](#footnote-26) States should therefore be cognisant of these obligations and ensure that they are vigilant of any potential or actual infringements upon the right to access medicines by corporations under their control, influence or jurisdiction, taking appropriate action to prevent, protect or remedy.

***Question (i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?***

Considering my above analysis, I recommend the following:

1. States should ensure that their domestic regulation concerning the pricing of pharmaceuticals by private companies does not supply scope for exploitation by companies looking to raise their prices in such a manner as to directly infringe upon the rights of individuals to access essential medicines.
2. International Human Rights Institutions should adopt clear guidance and pronouncements on the content and application of the state obligation to protect the right to health and access to medicines in the context of pharmaceutical pricing. In particular, it should be made clear that the obligation to protect entails several requirements including:
	1. A requirement to act to prevent human rights abuses from third parties;
	2. A requirement to use the maximum available resources in protecting human rights,
	3. A requirement to provide effective remedies and deterrence to future abuses,
	4. A requirement to ensure corporate due diligence,
	5. A requirement to protect human rights extraterritorially.
3. States should ensure, where possible, that they utilise all available measures within the purview of their international obligations to ensure the protection of the right to access essential medicines. In particular, States parties to the TRIPS Agreement should, in light of the Doha Declaration, use all relevant TRIPS-Flexibilities to ensure continued access affordable to medicines for their citizens. These include, *inter alia*, compulsory licencing and parallel importation.
4. States should be cognisant of the pull or national or corporate self-interest when assessing their obligations towards international assistance and cooperation under Art.2(1) ICESCR. In particular, States should abide by their international obligation to protect human rights extraterritorially, in particular the right to access medicines, where actors within their control, influence, or jurisdiction pose a threat to the realisation of the right to health.
1. See for example: Eric J Yang and others, ‘Changes in Drug List Prices and Amounts Paid by Patients and Insurers’ (2020) 3 JAMA Network Open 1. [↑](#footnote-ref-1)
2. Marc A. Rodwin, 'How the United Kingdom Controls Pharmaceutical Prices and Spending: Learning From Its Experience' (2021) 51 International Journal of Health Services 229. [↑](#footnote-ref-2)
3. See: Daniel Wei Liang Wang, *Health Technology Assessment, Courts and the Right to Healthcare* (Routledge 2022) [↑](#footnote-ref-3)
4. Branded medicines are those subject to a protected patent, giving exclusive rights of manufacture to the patent owner. [↑](#footnote-ref-4)
5. Sarah Clarke, 'Bulletin 141: Branded generic drug saving' (2016) PrescQIPP Community Interest Company 1; Un-branded or generic medicines are not subject to patent protection. As such, they can be produced by any entity with the capacity to do so. [↑](#footnote-ref-5)
6. Diletta Danieli, 'Excessive pricing in the pharmaceutical industry: adding another string to the bow of EU competition law' (2021) 16 Health Economics, Policy and Law 64, 70. [↑](#footnote-ref-6)
7. See for example: <https://pharmaceutical-journal.com/article/news/generic-drug-price-increases-of-up-to-1700-have-cost-the-nhs-76m> [↑](#footnote-ref-7)
8. TRIPS (1994), Art.31b. [↑](#footnote-ref-8)
9. TRIPS (1994), Art.31h. [↑](#footnote-ref-9)
10. TRIPS (1994), Art.31b. [↑](#footnote-ref-10)
11. Doha Declaration (2001), para.5(c) and (d); Ellen´t Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (2016), 35. [↑](#footnote-ref-11)
12. Eduardo Urias and Shyama V. Ramani, 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3 Journal of International Business Policy 367. [↑](#footnote-ref-12)
13. Lybecker KM, Fowler E. ‘Compulsory Licencing in Canada and Thailand: Comparing regimes to ensure legitimate use of WTO rules’ (2009) 37 Journal of Law and Medical Ethics 222. [↑](#footnote-ref-13)
14. B. Tenni and others, 'What is the impact of intellectual property rules on access to medicines? A systematic review' (2022) 18 Globalisation and Health 1, 11; A. Mohara and others, 'Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand' (2012) 15 Value Health S95; I. Yamabhai and others, 'Government use licenses in Thailand: an assessment of the health and economic impacts' (2011) 7 Global Health 28. [↑](#footnote-ref-14)
15. Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 71-72. [↑](#footnote-ref-15)
16. Tenni and others, 'What is the impact of intellectual property rules on access to medicines? A systematic review', 40; C. T. Scopel and G. C. Chaves, 'Initiatives to challenge patent barriers and their relationship with the price of medicines procured by the Brazilian Unified National Health System' (2016) 32 Cad Saude Publica e00113815; Shyama V. Ramani and Eduardo Urias, 'When access to drugs meets catch-up: Insights from the use of CL threats to improve access to ARV drugs in Brazil' (2018) 47 Research Policy 1538. [↑](#footnote-ref-16)
17. Healther Stewart, Charlotte Denny and Andrew Clark, 'Bayer bow to pressure on anthrax antidote' *The Guardian* (23rd October 2001) <https://www.theguardian.com/business/2001/oct/23/anthrax.businessofresearch>; Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 71-72. [↑](#footnote-ref-17)
18. WHO Regional Office for South-East Asia Regional Committee, ‘Provisional Agenda Item 8.3: Access to Medicines’, (6th September 2017, 17th Session, Maldives, SEA/RC70/9), para.10. [↑](#footnote-ref-18)
19. M D Nair, 'TRIPS and Parallel Imports - Impact on Drug Prices' (2002) 7 Journal of Intellectual Property Rights 342. [↑](#footnote-ref-19)
20. Mehmet Sekip Altug and Ozge Sahin, 'Impact of Parallel Imports on Pricing and Product Launch Decisions in Pharmaceutical Industry' (2019) 28 Production and Operations Management 258, 274. [↑](#footnote-ref-20)
21. Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 13. [↑](#footnote-ref-21)
22. Muhammad Zaheer Abbas, 'Parallel importation as a policy option to reduce price of patented health technologies' (2021) 17 Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector 214, 217; United States-Morocco Free Trade Agreement, Art. 15.9(4), 15 June 2004; United States-Australia Free Trade Agreement, Art. 17.9(4), 1 January 2005. [↑](#footnote-ref-22)
23. Ibid, 217; Frederick M Abbott, 'Parallel trade in pharmaceuticals: trade therapy for market distortions' in Irene Calboli and Edward Lee (eds), *Research handbook on intellectual property exhaustion and parallel imports* (Edward Elgar Publishing 2016), 147. [↑](#footnote-ref-23)
24. See for example: Sigrun Skogly and Mark Gibney, 'Transnational human rights obligations' (2002) 24 Human Rights Quarterly 781, 786; Sigrun I. Skogly, 'Book Review: M. Salomon, ‘Global responsibility for human rights’ (OUP 2007)' (2009) 29 Oxford Journal of Legal Studies 827. [↑](#footnote-ref-24)
25. Maastricht Principles on Extra-territorial Obligations of States in the Area of Economic, Social and Cultural Rights (September 2011), https://www.fidh.org/IMG/pdf/maastricht-eto-principles-uk\_web.pdf (accessed 5th January 2023) (Maastricht Principles). [↑](#footnote-ref-25)
26. ComESCR, General Comment 14 on the Right to Health (E/C.12/2000/4, 2000) para.39. [↑](#footnote-ref-26)