TRIPS WAIVER BRIEFING

Background

We are living through a two-tier pandemic which is putting us all at risk. Just one in twelve people in poor countries have received their first vaccine. The World Health Organisation recently highlighted that six times more booster shots are being administered daily around the globe than primary doses in low-income countries. The Omicron variant shows that where there are low vaccination rates in countries due to lack of access, this can lead to greater incidence of the virus, and risks of dangerous new variants emerging. This threatens control of COVID-19 for everyone everywhere, including Ireland. Many scientists have predicted that potentially deadly variants like Omicron will continue to arise as long as global vaccine inequity is allowed to continue. This was the key message heard at a recent meeting held with top scientists, health professionals and academics from Ireland and around the world. Following this event more than 400 leading scientists and medical professionals, including Prof Kingston Mills, Prof Sam McConkey, Prof Cliona Ni Cheallaigh and Prof Luke O'Neill signed a public statement urging the Irish Government to support the generic production of Covid-19 vaccines and treatments to address global vaccine inequity. This letter was handed in to the Taoiseach's office on Thursday 9th of December.

Explanation of what the TRIPS waiver will actually mean

The WTO TRIPS waiver was first proposed in October 2020 by India and South Africa (see here and here). The temporary waiver seeks to suspend the implementation of certain provisions in the TRIPS Agreement relating to copyrights, industrial designs, patents, and protection of undisclosed information for a period of three years for ramping-up the production of diagnostics, therapeutics, and vaccines across developing countries in combating the pandemic. However, a handful of countries led by the European Union have blocked attempts to finalize the decision on the temporary TRIPS waiver and even refused to engage in text-based negotiations so far. WTO DG Ngozi Okonjo-Iweala recently appealed to trade ministers to conclude multilateral decisions on the "WTO's response to the pandemic, including the TRIPS dimension" by the end of February 2022. Although negotiations have been going on for over a year UK, Switzerland and the EU are still blocking a move to text-based negotiations. The WTO claimed in June that text-based negotiations on the waiver would commence, but documents uncovered by Geneva Health Files reveal that these formal discussions still have not begun.

IP law - especially on patents and trade secrets - is a key barrier to vaccine equity, because to reproduce an IP-protected technology, a permission (licence) from the rightsholder is needed. Multiple IP rights apply over COVID-19 vaccines. To date industry has not engaged sufficiently with voluntary systems to license technologies to meet global demands. A report by the Economist Intelligence Unit states many poor countries will not achieve the WHO goal of 70% vaccination by 2023, 'possibly never'.

Voluntary proposals like the WHO's C-TAP aim to encourage industry to share IP rights and know-how to increase production for COVID-19 vaccines; yet it has not been supported by any vaccine

manufacturer. Meanwhile, COVAX which aims to donate vaccines to poorer countries, is a useful short-term way to deliver some vaccines on the ground. But COVAX relies on charity and does not increase production capacity to enable countries to have sustainable supplies. It has also continued to miss commitments for vaccine distribution.

In the absence of sufficient voluntary licensing the India-South Africa proposal to waive IP rights is vital. It would clear IP obstacles enabling greater production of vaccines in the global south. The proposal has the support of more than 100 WTO members, including the US, over 120 IP academics, and leading global figures such as Mary Robinson.

However, it is opposed by industry which claims that IP is '**inviolable**'. This is simply untrue. IP is a legal tool created by states to facilitate the public good. It gives rightsholders exclusivity enabling them to maintain an artificial scarcity of certain products, but it is justified only as a quid pro quo: companies risk their investments to fund R&D, in return they get a 20-year monopoly on resulting inventions. This justification is not sustainable for COVID-19.

The public – not the private sector – has borne most of the cost of the key R&D for the vaccines. The Moderna vaccine was **co-created** with the US National Institutes of Health, a government agency. Moderna also received $10bn from the US government, with BioNTech obtaining more than **400 million Euros** from the German government. The AstraZeneca vaccine was the product of **publicly funded research** at the University of Oxford. Even though the R&D was de-risked by public funds, governments left the IP to private companies.

In a pandemic, artificial scarcity is not the approach to take: it should be an 'all hands-on deck' situation, with all viable producers licensed to produce vaccines. That **productive capacity in countries like India, South Africa and Brazil** continues to go under-utilised is a scandal. The principal way that developing countries emerged from the HIV/AIDS epidemic was through facilitating generic drug production in countries like India and South Africa. For COVID-19 vaccines, IP rules are enabling protectionism and hindering generic production.

The legal effect of a waiver would be to limit IP rights internationally, but national rights would remain within each country's sovereignty. Thus, each country wishing to avail of the temporary TRIPS waiver would have to pass its own national laws to rescind existing IP protections. This is most likely to be only utilised by low-income states. Rich countries like Ireland have no domestic need to waive national IP even if an international waiver passes. Pfizer and Moderna's sales to rich countries are unlikely to be affected much, if at all, by the TRIPS waiver.

Thus, the TRIPS waiver will most likely lead to a two-trier market for vaccines, with generic production for low-income countries and existing production systems for rich countries- similar to what eventually transpired during the AIDS pandemic.

You can find out more about in this MSF over view of the TRIPS waiver and here.

EU counter proposal

The EU counter proposal to the TRIPS waiver is a distraction – it largely reiterates existing TRIPS provisions. The EU focuses on compulsory licensing (or flexibilities), which allows a country to produce a technology under patent, without permission. Yet compulsory licensing is cumbersome, and on its own is insufficient to deliver timely global vaccine access because it is a country-by-country, patent-by-patent approach. This would take too long. It also does not address other key IP rights for vaccines, like trade secrets. This means that generic producers would not be able to request the know- how or blueprints for how to produce vaccines. So a compulsory licence arrangement would give permission to produce vaccines (only after a timely

legal process) but would not empower generic producers to be given the relevant blueprints for how to produce the vaccines. Added to this is the political reality that low-income countries fear trade retaliation even if they could issue effective compulsory licenses. As a result, no country has used any the aspects of TRIPS, including compulsory licencing, put forward in the EU proposal. This is probably the clearest indication of that EU's proposal lacks any validity.

Despite clear and repeated directions from the European Parliament, the European Union has refused to engage in negotiations on a text and has instead proposed an entirely different position that seeks to protect the status quo. It's latest tactic is to turn the finger of blame on developing country waiver sponsors for blocking progress. In October, the European Commission, Trade Head of Unit Antonio Martos-Fernandez alleged that India's delegation "have not been amenable to compromise." At the start of December more than 180 charities, NGOs, unions, and campaign groups have signed a statement accusing EU negotiators of "dogmatically defending a status quo that has actively hindered global vaccination, testing and treatment efforts. The EU's warm words about solidarity and cooperation have been little more than a deflection exercise"

You can find out more about the flaws in the EU counter proposal by reading this MSF analysis of why EU counterproposal is adequate and listening to Dr. Aisling McMahon of MU.

Production capacity

It has been claimed by opponents of the TRIPS waiver that TRIPS will not result in any increased production or if there is it will take 2-3 years to bring untrue. Both these claims are incorrect. Experienced manufacturers who are willing to make hundreds of millions of doses have come forward from all over the world, including from Bangladesh, Pakistan, Senegal, Denmark and Canada. Biolyse in Canada (who have approached J&J and AstraZeneca) say they could be producing vaccines within 6 months; Incepta in Bangladesh (who estimate they can make between 600m to a billion doses), Teva in Israel (who report capacity ready to go) and Bavarian Nordic in Denmark have all asked to assist in the manufacture of vaccines. But IP is preventing them.

The Director General of the World Trade Organization, Ngozi Okonjo-Iweala has reported that the governments of Pakistan, Bangladesh, Indonesia, South Africa and Senegal have all said that they have facilities that could possibly be retooled to produce coronavirus vaccines. UNICEF data suggests that when counting only those manufacturers already involved in some way in Covid-19 vaccine manufacturing, only half of them are working to produce the approved vaccines. This suggests plenty of capacity that could be re-purposed.

In addition, Human Rights Watch, have identified an additional 125 vaccine manufacturers globally who have potential capacity for producing Covid 19 vaccines.

There has been much global media coverage about this issue. The most recent and most comprehensive evidence against these claims was published by the New York Times in October (it was front page news).

Legal implications

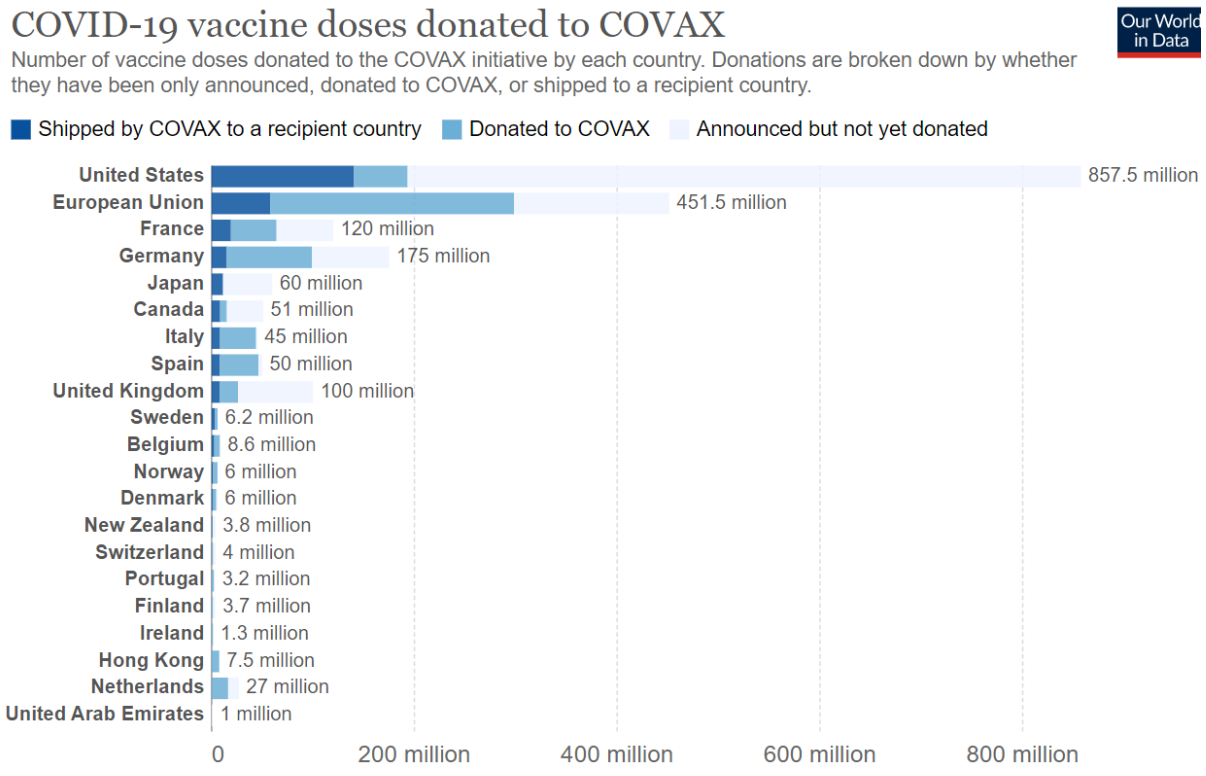
Ireland's continued opposition to the TRIPs waiver and its lack of endorsement of the WHO's C-TAP programme for sharing vaccine production and know how is greatly damaging Ireland's international reputation as a champion of poorer countries and as advocate for Human Rights. Last month a legal brief signed by leading jurists around the world asserting that "blocking" states like Ireland are breaching a number of covenant and treaty obligations under international human

rights law. Moreover, a petition to the UN Committee on the Elimination of Racial Discrimination (CERD), argues that countries opposing removing intellectual property barriers on all COVID-19 medical technologies through a TRIPS waiver are facilitating the inequitable and racially discriminatory rollout of the vaccine and other COVID healthcare technologies. As this is a test case, Ireland will be impacted by these deliberations.

Partnership agreements

The partnership agreements being developed by pharmaceutical companies, while welcome, are simply not enough to tackle the issue. These agreements still leave control of vaccine production in the hands of three or four companies, who will still get to decide production and distribution levels for the whole world. Commercial rather than human rights considerations will continue to inform such decisions and they have to date made little or no impact on tackling vaccine inequity. As Dr Tedros Adhanom Ghebreyesus, WHO Director General, 8th September 2021 said: "I will not stay silent when the companies and countries that control the global supply of vaccines think the world's poor should be satisfied with leftovers."

Why COVAX is not the solution



COVAX is a welcome and vital process, and it needs massively more support – but it alone is struggling to meet the scale of need. Covax is nowhere near its target of vaccinating 20% of people in developing countries by the end of this year. The Covax scheme's target was to deliver 2bn doses by the end of this month. And yet, by 5 December, well over a year since its launch, the Covax scheme had shipped only 669m doses to 144 countries, with just 250m donated to the poorest 95 countries. Not only is it way off track, millions of vaccine doses donated to African countries have passed their expiry dates and have either been sent back or destroyed.

Ultimately donations are neither a sufficient nor sustainable solution, especially as not enough vaccines are being produced and rich countries are reluctant to let go of supplies they may need for booster shots or tackling variants. The WHO has repeatedly said that the issue is not of finance but of supply. Charity is simply not going to fix the huge supply problem nor should people's lives in so many countries around the world be dependent on unpredictable and uncertain charitable giving from rich nations. Donations should never be a substitute for sharing the rights to produce these vaccines and ensuring distributed manufacturing around the world so that countries have their own supplies they can rely on. In April 2020, as the full gravity of the COVID-19 pandemic came into focus, world leaders, foundations, pharmaceutical corporations, & global health agencies came together. They launched a new initiative, known as the Access to COVID-19 Technologies Accelerator (ACT-A), to ensure rapid, affordable, and universal access to vaccines (and treatments and diagnostics) to overcome the disease.

In April 2021 the WHO established a Covid-19 mRNA vaccine technology transfer hub to try to speed up global manufacturing. All three mRNA vaccine manufacturers have refused to take part. If we want the world vaccinated with three doses, it will require the distribution of at least 20bn doses. Pfizer/BioNTech, whose vaccine requires ultra-cold storage which will require adequate notice and ongoing supply for planning in low-income settings, predicts it will expand production to 4bn doses at best by the end of 2022.

Experts are concerned that we will repeat the mistakes of last 2 years - rich countries will buy-up existing supplies for boosters and supplies of new, variant-adapted vaccines if not for the Omicron variant perhaps for a next one. We need a shift in emphasis from global access to vaccines to global access to all tools: vaccines, treatments and diagnostic.

Moreover, the current donations/charity approach is making the roll out of vaccines in poorer countries very difficult because of the lack of predictability & security of supply. To reverse vaccine inequity we must address its cause. We cannot donate our way out of this pandemic. Donating leftover vaccines to global south without a plan for increasing production in the global south is like putting a band aid on a machete wound.

Dealing with shortages of raw materials

If raw materials are in short supply then we need a more collaborative and co-ordinated government-led approach to fix this. And it's crucial to note that the shortage of many of the key inputs for the vaccines are also a result of intellectual property barriers and monopolies in production. The large plastic bio reactor bags for example are protected by over 1800 patents and produced by only one or two companies in the world. Waiving IP would also help diversify and ramp up the production of these key inputs.

Similarities to the HIV/AIDs crisis

As we saw in the HIV/AIDs pandemic it was only when generic production of essential life-saving medicines was allowed that the poorest and most vulnerable people in the world were able to get the treatments they needed. Pharmaceutical companies didn't come through for poor countries during that pandemic and we have seen no evidence that this will change during this pandemic. Dire warnings about the negative impact of generic production on innovation and future medicine production were also made during the HIV/AIDs pandemic. They never came to pass.

Increasing production by pharmaceutical companies will not solve the problem

Pharmaceutical companies have claimed that they are on track to produce a glut of coronavirus vaccines globally by 2022 and this will solve the issue. However, the issue isn't just over production, but fair distribution. Despite recent increases in production, sub-Saharan Africa having received only enough doses to vaccinate 1 in 8 people. We are about to repeat the mistakes of the last two years as western countries out-compete poorer countries for an artificially restricted supply of vaccines needed for boosters and potential new vaccines due to Omicron.

Vaccine Hesitancy

The issue of vaccine hesitancy in Africa has arisen in the last few days in some quarters as a reason not to support the TRIPS waiver. We think this is a dangerous and misleading new narrative we feel is being orchestrated by those with vested interests in protecting the status quo. Vaccine hesitancy is an issue everywhere, indeed higher in some rich countries than in Africa. Vaccine

hesitancy is an issue everywhere, but supply is not - and that is the issue our leaders must address. Yes we have been calling for more support in strengthening health systems, in challenging vaccine hesitancy but this needs to happen along with increasing the ability of countries to increase their own supply of life saving medicines.

In Africa, there is a high level of confidence in vaccines. Studies by the World Bank in several countries in Africa have found that the vast majority of people were happy to receive the vaccine. This study in Nature, specifically on COVID-19 vaccines, found "considerably higher willingness to take a COVID-19 vaccine in our LMIC samples (mean 80.3%; median 78%;) compared with the United States (mean 64.6%)".

Also, reasons for lack of vaccine uptake in Africa are not well understood and are much different than in western countries. The problem of lack of regular and adequate supply is the main factor - poor nations have only a tiny number of available vaccines right now. There are huge problems with the current donations/charity approach in terms of predictability and security of supply. Poor countries are dealing with difficult circumstances compounded by the fact they're often relying on last-minute vaccine donations about to expire.

At the height of the AIDS pandemic in the early 2000's when generic drugs was finally allowed to be produced these countries faced many challenges but they were able to mostly overcome them as generic production gave them affordable, secure & certainty of supply so they could undertake long term planning, and with the help of financial assistance, could undertake the necessary health system and logistics strengthening, as well as education outreach. This is a well balanced article of these issues.

Lack of support for the Government's position in Ireland

People in Ireland are not in support of the Irish Government's position on this issue. Oxfam Ireland undertook polling on this issue earlier in the year and 62% of adults in Ireland were in support of a TRIPs waiver.

The Examiner published this opinion piece in the Examiner last May dealing with many of these issues. It was authored by Oxfam Ireland's CEO Jim Clarken.

December 2021