AFTINET submission to the Department of Health and Aged Care:

Preparing for, and responding to, future pandemics and other international health emergencies - September 2023

How can international cooperation be improved to more effectively prevent, prepare for, and respond to, future pandemics and other international health emergencies?

The COVID-19 pandemic has demonstrated the necessity of a collective international approach to effectively prevent, prepare for, and respond to future pandemics. It has exemplified the limitations of the current International Health Regulations (IHRs), and the need for architecture such as the Global Pandemic Agreement and revised IHRs that include concrete actions and transformative norms to ensure governments comply with their responsibilities and report accurately on their capacities to ensure an effective response (Hannon et al., 2022).

The COVID pandemic has showcased structural power asymmetries in the global health system. The pharmaceutical industry and high-income countries largely determined the global health response to COVID, mainly through the intellectual property (IP) regime (Gleeson et al., 2023). IP rules gave a few pharmaceutical companies twenty-year patents on new COVID vaccines. This meant these companies controlled both the price and the quantity produced, essentially allowing them to control access to vaccines and treatments developed (Oxfam, 2022).

Existing international IP laws and voluntary mechanisms to waive IP rules failed to address inequities created by pharmaceutical monopoly power (Sekalala et al, 2021). Lobbying by the pharmaceutical industry protecting their interests, backed by a number of high-income countries, provided a substantial barrier to a waiver on IP rules for pandemic-related products. The majority of World Trade Organisation (WTO) members proposed a temporary waiver for all pandemic-related medicines on some aspects of the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in October 2020. This would have enabled increased global production of vaccines at affordable prices. After a long delay, the June 2022 WTO Ministerial decision fell far short of this proposal, applying a very narrow change to some aspects of the rules for vaccines only, and postponing a decision on treatments and tests, which still has not been made. Public health experts have questioned whether this small change has any practical effect and argued that a temporary IP waiver is still needed in the case of future pandemics (Amin and Kesslheim, 2022).

Without a waiver, the pharmaceutical industry monopolies continued, despite the fact that vaccines were developed with public funding. Governments invested over $100 billion in the development and manufacture of COVID vaccines and treatments (Mac-Lean, 2021). Pharmaceutical companies sold vaccines back to governments at very high profit margins. Pfizer, BioNTech, Moderna, and Sinovac were expected to make a total profit of around USD 90 billion from their COVID-19 related products during 2021 and 2022. Pfizer was expected to earn USD 35 billion of net profits, BioNTech and Moderna each USD 20 billion, and Sinovac USD 15 billion (de Hahn and ten Kate, 2023: p. 4).

Pharmaceutical companies ultimately held power over distribution of vaccines and prioritised the sales to rich countries which could pay inflated prices (Scholz et al, 2022). This was enabled by the nationalistic response of high-income countries which bypassed, and so undermined, efforts to coordinate an equitable global vaccine response through COVAX by negotiating bilateral deals with pharmaceutical companies, essentially paying to be front of the vaccine queue.

COVAX, a donor-funded mechanism is widely acknowledged to have failed in its aims of equitable distribution of COVID vaccines. Rich countries bypassed the mechanism, which meant it was underfunded and reliant on donations. While donations were pledged, they were largely slow, ill-timed, not delivered and inadequate to meet needs (Airfinity, 2022 and Gleeson, Tenni and Townsend, 2022). Moreover, charitable model initiatives such as this can just further perpetuate inequities as they do not address the essential problem of access, which is steady supply of affordable medicines (Gold, 2022).

COVAX governance also shut out meaningful inclusion and representation of both low-income governments and civil society (Médecins Sans Frontières (MSF), 2021). In general, the COVID response and the largely top-down governance structure meant low-income countries were not meaningfully engaged and did not have a sense of ownership of the initiative (WHO, 2022). Instead, wealthy governments and corporate partners dominated the global response, in part accounting for its failure.

Pharmaceutical companies also exercise power through making confidentiality clauses in health procurement contracts a condition of access to vaccines. A 2019 report by Transparency International found that only 7% of COVID contracts have been made publicly available and of those that have been released most of the crucial information has been redacted (Transparency International, 2019). These clauses prevent governments from releasing details of their COVID vaccine deals and have allowed pharmaceutical companies to embed inequitable terms in procurement contracts. This has fostered competition rather than cooperation between countries and proved to be a major barrier for equitable negotiation (Phalen et al, 2020).

The combination of monopolies on supply and price, the failure of COVAX and the lack of transparency of contracts contributed to substantial delays in access to vaccines for low and low-middle-income countries, leading to lower vaccination rates. In early 2022, for every dose of mRNA vaccine delivered to low-income countries, 56 were delivered to rich countries (Oxfam, 2022). Vaccination rates in low-income countries were less than 20% by January 2022, and were still only at 32% in August 2023. (Our World in Data, 2023). This has contributed to the estimated 17.7 million excess deaths due to COVID (Institute for Health Metrics and Evaluation), the majority of which are in low- and low-middle-income countries with low vaccination rates (Sachs et al, 2022). In early 2022, per capita deaths in low- and low-middle-income countries were 31% higher than in high-income countries (Oxfam, 2022).

These power asymmetries privileged high-income countries' vaccine access and amounted to a "tacit acceptance" of large-scale preventable deaths in the Global South (Gleeson et al, 2023: p.7). This led to what the WHO has described as a "catastrophic failure of the international community in showing solidarity and equity" (WHO, 2023: p.1).

Research shows the increasing likelihood of another global health emergency happening in our lifetime, meaning there is real urgency in the need to build architecture that supports international cooperation and builds more equitable systems for future international health emergencies (Marani et al, 2021).

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What issues do you think need to be prioritised to guide the world's future preparation for, and responses to, future pandemics and other international health emergencies?

1. Time-bound waivers of IP rights on pandemic response products to enable more equitable global access to such products

As detailed in answer to the previous question, the evidence from academic studies demonstrates that the failure to temporarily waive relevant aspects of the TRIPS agreement meant that a few companies controlled the quantity and prices for vaccines, and most vaccines were sold as a priority to rich countries at high prices. This resulted in much higher vaccination rates for high income countries, than for low- and low-middle-income countries, with even worse access to treatments when they became available. Preparation for future pandemics should ensure that intellectual property and technology for pandemic-related products is shared to enable equitable global production and distribution of such products at affordable prices.

Recommendations:

- *Support a legally binding commitment to time-bound waivers of IP rights on pandemic response products to accelerate and scale-up manufacturing of pandemic-related products which is automatically triggered when a Public Health Emergency of International Concern is declared.*
- *Update Australia's negotiating position on IP rules within pandemic instrument and IHR amendment negotiations to support appropriate temporary waivers of IP rules.*

2. Public funding for pandemic-related products should be conditional on sharing of intellectual property and technology.

Research and development of COVID vaccines was almost entirely publicly funded (Dolgin, 2021, Lalani, Avorn and Kesselheim, 2021), but as discussed in question 1, the pharmaceutical industry has leveraged public funding for massive private profit, at the expense of equitable health response.

Current international IP laws and voluntary mechanisms to waive intellectual property have failed to deliver equitable access to pandemic-related products. WHO proposals for a global plan for distribution of vaccines through sharing intellectual property and technology were not implemented (Gleeson, 2023).

IP rights have been linked to promoting innovation and research and development, including within the Australian Government negotiation priorities for a new pandemic instrument and amended IHRs (Australian Government, 2023). However, research shows IP was not a significant driver of innovation during COVID, but instead delayed global access to vaccines and drugs (Ning et al. 2022, Herder, Gold and Murthy, 2022 and Maxmen, 2022). While private companies played a critical role in development, this was largely financed from government procurement and early-stage funding rather than the prospect of IP (Gold, 2022).

Temporary timebound waivers do not threaten the global IP system. The Australian Government's priority to "uphold intellectual property rights" in the context of pandemics could undermine Australia's other outlined priorities, namely the promotion of "equitable and timely access to health emergency countermeasures" and efforts to "promote fairness… and uphold human rights". As detailed in answers to question 1, enforcement of IP rules without a temporary waiver during the COVID pandemic entrenched domestic and global disparities. The COVID pandemic demonstrated deeply inequitable, delayed access to pandemic-related products for low- and low-middle-income countries and the collective failure to protect the right to health. Prioritising IP rules during pandemics is not in line with Australia's efforts to improve and promote an effective response to international health emergencies.

Recommendation:

- *Make public funding for research and development of pandemic-related products conditional on open licensing and sharing of intellectual property, technology and know-how and include terms and conditions in contracts related to prices of products.*

3. Increased transparency requirements, particularly related to publicly funded research and development of pandemic-related products

Lack of transparency during the COVID pandemic has limited access to timely, critical information undermining accountability, equity and ultimately effective global responses to COVID (MSF, 2023).

The lack of transparency around vaccine prices and terms of contracts has allowed pharmaceutical companies to embed terms which enable inflated prices and inequitable terms. These terms include export restrictions, non-refundability and broad clauses protecting the pharmaceutical companies from liability. This had led to not only inequitable procurement terms, and significant price disparities, but has also proved to be a barrier to negotiating fair vaccine deals (Yamey et al, 2022).

The pharmaceutical industry has attempted to justify high prices of pandemic-related products through the costs incurred in research and development. Despite this, they remain untransparent about the actual costs, which are often largely publicly funded. This limits pharmaceutical industry accountability and undermines the assessment of fair pricing. Moreover, it weakens the ability of governments to negotiate prices based on true costs and so better align prices, product development, and public health to deliver more affordable and accessible products that respond to global health needs (MSF, 2021).

Recommendations:

- *Make disclosure of the publicly-funded spend on research and development a condition of funding.*
- *Support the restriction of confidentiality clauses in health procurement contracts during pandemics, particularly related to pricing, cost, manufacturing capacity, supply schedules, IP and technology licensing terms.*
- *Support the strengthening of transparency obligations in the Global Pandemic Agreement in line with the World Health Assembly 72 resolution on transparency.*

4. More equitable global development and manufacturing of pandemic-related products

Global production capacity is critical to capability to scale-up the supply of vaccines to meet global need. The integration of local production systems is important for strengthening the global health system and enabling access to affordable medicines (WHO, 2021). Global distribution, development and manufacturing is highly concentrated in the global north, which has shaped the unfair development and distribution of COVID health products and technologies (Kapczynski, 2022) and is largely responsible for the production bottleneck of COVID pandemic-related products (Crager, 2014). The WHO has recognised technology transfer as a significant barrier to equitable medicines access and created a resolution identifying priority actions to incentivise technology transfer (WHO, 2021).

Currently only a limited number of countries have the capacity to rapidly produce global health emergency vaccines (Crager, 2014). To effectively respond to international health emergencies, industrialised and at-scale technology transfer is needed. This includes sharing of know-how, operational and procedural knowledge and skilled human resources. But technology transfer projects face a range of barriers, including lack of political will (Fonseca, Shadlen and Achcar, 2023) and IP rules.

Incentivisation in the form of stable funding, removal of IP barriers and strong regulatory oversight is needed to ensure that production capacity does not remain siloed, preventing equitable access to pandemic-related products.

Recommendations:

- *incentivise technology transfer for manufacturing of pandemic-related products in low and middle-income countries.*
- *Take actions outlined in the WHO 2021 resolution 'Strengthening local production of medicines and other health technologies to improve access' to incentivise technology transfer (WHO, 2021).*

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