BERLIN DECLARATION: KEY CLAIMS AND CRITIQUES

THE PEOPLE'S VACCINE

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BACKGROUND

On 19 July 2022 the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) published the *Berlin Declaration – Biopharmaceutical Industry Vision for Equitable Access in Pandemics* ("the Declaration").[1] This Declaration represents pharmaceutical companies' attempt to dictate the terms on which medical technologies should be developed, funded, priced, and distributed during future public health emergencies (PHEs). In doing so the Declaration ignores three basic facts: the COVID-19 pandemic is not over, global access to existing medical countermeasures has been grossly inequitable, and that public funding has an essential role in developing current technologies. The Declaration is a continuation of a consistent "third way" campaign[2] by the biopharmaceutical industry to maintain exclusive intellectual property (IP) protections and monopoly control over the medical technologies needed to defeat the pandemic. Any lessons learnt to address future pandemics must first acknowledge and redress the diagnostic, treatment, and vaccine apartheid that confronts us now.

The Declaration obfuscates the fact that public funding has been foundational in developing safe and effective COVID-19 vaccines and in bringing these to the market at the scale needed, but came with no strings attached. Despite receiving massive public subsidies, pharmaceutical corporations have systematically ignored or frustrated efforts to ensure equitable and affordable access to COVID-19 technologies. They have refused to share their IP, frustrated technology transfer initiatives, ignored pooled technology and IP facilities (e.g. CTAP) and pooled procurement efforts, and taken a leading role in multi-stakeholder initiatives like COVAX – thereby ensuring their influence trumps that of public institutions in shaping access responses to the pandemic. If governments ignore the problems with the current system, described in detail below, they will continue to perpetuate and further entrench a global health architecture that protects pharmaceutical corporations' profits, IP, unqualified access to public subsidies, and influence over procurement strategies. As a result, biopharmaceutical inequity will be normalised. This is unacceptable.

It is extremely concerning that this Declaration has been welcomed by institutions like GAVI,[3] and that it may shape policy decisions at G7 and G20 summits, revisions of the International Health Regulations (IHR), and the new pandemic treaty instrument being negotiated by the Intergovernmental Negotiating Body (INB). As we show below, the Declaration obscures a longstanding truth: the pharmaceutical industry has and continues to prioritise profits, not public health. A Declaration that obscures this truth is not an acceptable reference point for efforts to institutionalise a more just and democratic global health governance architecture.

FACT CHECK 1: PUBLIC FUNDING DRIVES INNOVATION

Claim 1: "The innovative biopharmaceutical industry" has "developed COVID-19 vaccines and treatments at record speed and in historic quantities" [4]

It is simply not true to argue that the pharmaceutical industry is solely responsible for producing safe and effective COVID-19 vaccines and treatments. Decades of publicly funded research serves as the scaffolding that allows pharmaceutical companies to reap massive profits. What's more, public investment has supported research into technologies like messenger ribonucleic acid (mRNA) even before their commercial success was clear. In contrast, pharmaceutical companies radically increased investment in mRNA vaccines once the prospects for accessing massive public subsidies and reaping massive profits transpired.

Public funding prioritises innovation for the public good, not innovation for profit

The Declaration draws no distinction between innovation driven by profit incentives, and innovation driven by public health needs. It emphasises the intentions of the "innovative biopharmaceutical industry" to protect the wellbeing of the poor and marginalised through various voluntary mechanisms, including via "donations, not-for-profit supply, voluntary licenses or equity-based tiered pricing".[5] This does nothing to address the longstanding critique that the existing research and development (R&D) system is market-driven and neglects investment in diseases that primarily affect poor people. According to Policy Cures' G-Finder report, just 12% of global funding for Neglected Tropical Diseases (NTDs) R&D came from the private sector in 2020.[6] Paradoxically, despite claiming credit for developing COVID-19 vaccines and treatments, industry still demands continued public "derisking mechanisms" to financially support R&D and manufacturing scale-up.

Profit-driven innovation strains public welfare

The European Commission, in its 2020 Pharmaceutical Strategy for Europe, acknowledges that the pharmaceutical industry's innovation strategy is profit-driven, i.e. it focuses on developing niche medicines and that this "poses a growing challenge for the majority of [EU] Member States. The business model has moved from selling blockbusters to marketing 'niche-busters'. Often, new products are priced even higher, with growing uncertainty as to their real-life effectiveness and related overall costs. This puts the budgetary sustainability of health systems at risk, and reduces the possibilities for patients to have access to these medicines."[7] The report further notes that "novel payment approaches, such as risk-sharing arrangements and deferred payment schemes, may have long-term implications, and thus affect affordability of new medicines."[8] The Commission's critique of the pharmaceutical industry's market-driven R&D practices is ironic, as it defended these practices as cornerstones of innovation during the TRIPS waiver negotiations.

Before the pandemic decades of public funding supported research on mRNA technologies

This pandemic provides solid evidence that public funding is a major engine for innovation. Globally, the public sector allocated at least €93bn to COVID-19 vaccines and therapeutics in 2020 (with about €88.3bn being allocated to vaccines).[9] Additionally, long-established vaccine technologies have scaffolded speedy vaccine development during the pandemic. Kiszewski et al estimate that a "robust body of published research on vaccine technologies was supported by 16,358 fiscal years of National Institutes of Health (NIH) funding totalling $17.2 billion from 2000–2019" demonstrating "the importance of sustained public sector funding for foundational technologies in the rapid response to emerging public health threats".[10] The truth is that pharmaceutical companies benefited from extensive public funding into research that led to the development of COVID-19 vaccines.

During this pandemic public funding speeded up the development of safe and effective mRNA vaccines

The mRNA technology used in Moderna and Pfizer-BioNTech vaccines draws on decades of publicly funded research conducted at universities in the USA and Europe.[11] Ironically, pharmaceutical companies could access "much of [this] foundational intellectual property" on mRNA because relevant patents had expired by the time the pandemic hit.[12] Pharmaceutical companies have nevertheless insisted on privatising knowledge on mRNA by securing new intellectual property rights (IPRs) on this technology. Their patent applications are sometimes so broadly written that they block other innovators' efforts to build on existing knowledge in order to address public health concerns. For example, the mRNA Vaccine Technology Transfer Hub ("the WHO Hub") in South Africa (SA) is aiming to build platforms that will not only make mRNA COVID-19 vaccines. Dr Petro Terblanche, managing director of Afrigen, who plays a leading role in the WHO Hub, has noted that "Covid [sic] is our demonstration project. We will have mRNA vaccines for HIV, TB, malaria, vaso [sickle cell disease], dengue fever, Ebola - because mRNA lends itself towards those kinds of vaccines."[13] However, the South African government has granted Moderna at least three patents, including wide-scope ones covering mRNA technologies, that may lead to litigation and political pressure that frustrate this innovative work.[14]

Public funding sped up development of safe and effective adenovirus-vectored vaccines

Research by Cross et al estimates that the Oxford-AstraZeneca COVID-19 vaccine "relies on two decades of research and development (R&D) into the chimpanzee adenovirus-vectored vaccine (ChAdOx) technology at the University of Oxford", and that "public and charitable financing accounted for 97%–99% of identifiable funding for the ChAdOx vaccine technology research at the University of Oxford underlying the Oxford–AstraZeneca vaccine until autumn 2020".[15] Both the UK government and "overseas government bodies" contributed funding to this research. During the early months of the pandemic (January and October 2020) the UK government contributed 95.5% of funding to support this research.[16] However, in the pre-pandemic period "overseas governments, including the EU" contributed 37.9% of funding for R&D on chimpanzee adenovirus-vectored vaccine technology (versus the UK government contribution of 8%).[17] Pre-clinical stage trials for the Oxford-AstraZeneca vaccine also utilized American taxpayer money, because the trials were partly run by the National Institutes of Health.[18]

Public funding supported expanded production capacity for COVID-19 vaccines

Pharmaceutical companies received public funding to scale up their manufacturing capabilities of COVID-19 vaccines at "record speed and in historic quantities".[19] Research by Public Citizen shows that Moderna most likely only developed the manufacturing scale up that would allow it to produce vaccines in larger volume after securing $483 million in funding from the US government.[2021] Writing about Operation Warp Speed (OWS) Bown and Bollyky argue that policymakers' interventions were important in ensuring specific vaccine makers could access the inputs they needed to produce COVID-19 vaccines.[22]

Advanced purchase commitments protected pharmaceutical companies from commercial losses

Advanced purchasing commitments financed by the public purse paid for many vaccines, and when vaccines failed, the costs fell on the public. For example, the US government concluded a $2.04 billion contract with Sanofi/GSK for 100 million doses of their vaccine, and invested $30.8 million in the development of their vaccine.[23] However, this vaccine has not yet been approved for use in the USA.

In other cases, advanced purchased commitments contributed to de-risking vaccine development, and facilitated ease of access to major consumer markets once vaccines were approved for use. This has allowed companies to make super profits. For example, Moderna took $10 billion in government funding (including vaccine pre-orders)[24] and had already produced $12 billion in vaccine profits by the end of 2021.[2526] While Pfizer says they did not accept public funding to develop their vaccine, they received nearly $2 billion in guaranteed pre-orders from the US government.[27]

Advanced purchasing commitments have contributed to Moderna and Pfizer making record profits: in November 2021, Pfizer/BioNTech and Moderna reportedly made "combined profits of $65,000 every minute" – a direct consequence of prioritising sales to high-income markets. As of October 2021 Pfizer and BioNTech had delivered less than 1% of their total vaccine supplies to low-income countries (LICs), and Moderna only 0.2%.[28]

FACT CHECK 2: INTELLECTUAL PROPERTY RIGHTS *DO* IMPEDE INNOVATION

Claim 2: "The innovative biopharmaceutical industry succeeded in developing and scaling up multiple high-quality, safe, and effective vaccines and innovative treatments against COVID-19 in historic record time, thanks to the intellectual property system ... Intellectual property rights should be respected since society depends on them to stimulate innovation and the scale up of supply".[29]

This has been the pharmaceutical industry's enduring claim, presenting IPRs as the only engine of innovation that must be protected and even enhanced through free trade agreements (FTAs) and bilateral trade agreements. As shown above, public funding and public scientists underpinned COVID-19 vaccine R&D – but the public contribution has been ignored in pharmaceutical corporations' rush to secure IPRs.

TRIPS has impeded innovation

Henry and Stiglitz have argued that the TRIPS regime has been disproportionately shaped by "special interests", that it is poorly designed, and that it can impede innovation (e.g. by allowing for overly broad patents to be granted).[30] Under the current system patents do a poor job of clearly and timeously disclosing information about new innovations. This impedes the ability of other inventors/developers to ground their future innovations on this knowledge.[31] Stiglitz described the consequences of these dynamics with respect to the TRIPS regime as follows,

> "When the trade ministers signed the TRIPS agreement in Marrakesh in the spring of 1994, they were in effect signing the death warrants on thousands of people in sub-Saharan Africa and elsewhere in the developing countries [living with HIV/AIDS]. This is one of the reasons that TRIPS has generated such immense concern"[32]

Patent litigation creates legal uncertainty that has a chilling effect on innovation

The patent landscape for the mRNA technologies used in COVID-19 vaccines is characterised by intricate webs of IP claims.[33][34][35] This has led to disputes centred on rival ownership claims, for example: Moderna's suit accusing Pfizer of copying aspects of the mRNA technology that it "pioneered".[36] Moderna also initially insisted that it should be the sole patent owner with respect to COVID-19 mRNA technologies, ignoring that the technology was developed in collaboration with US government employees and with US government funding.[37]

Such litigation has a chilling effect on efforts to decentralise and localise manufacturing of mRNA technologies in developing countries.[38] Significantly, several US manufacturers have been able to expand production of COVID-19 technologies without the fear of this kind of litigation, as they are protected by government authorisation to use patented inventions without patent-holders' permission, provided that this is for "use or manufacture for the United States".[39] Potential manufacturers in developing countries, where vaccine access remains extremely limited, did not have the benefit of this kind of legal certainty for much of the pandemic.

Patents block innovation through evergreening

The IFPMA Declaration never acknowledges the reality that IPRs are used to block innovation and competition. Patents have frequently been used for "recycling and repurposing" profitable older medicines, rather than to protect bona fide new inventions.[40] Between 2005 and 2015 "78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs"; "[a]dding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% had their protection extended at least once, with almost 50% having the protection cliff extended more than once."[41]

This use of patents, according to Feldman, is "pervasive and persistent, but it is also growing across time"[42] and harms innovation by preventing the entry of competing manufacturers.[43] Unless governments address this loophole in their IPRs systems, evergreening is likely to pose a problem for COVID-19 technologies and other technologies needed to respond to future PHEs.

FACT CHECK 3: VOLUNTARY INITIATIVES ARE INADEQUATE IN ENSURING EQUITABLE ACCESS TO MEDICINES

Claim 3: "We support collaborations, a geographically diverse sustainable manufacturing footprint and mechanisms for rapidly scaling-up supply in a future pandemic. We will build on existing manufacturing partnerships, business-to-business agreements set up in advance, ongoing capability development and voluntary licensing and/or early, voluntary technology transfer where this will facilitate rather than impede scale up and global supply."[44] [...] "Each company will take measures, in partnership with Governments, to help ensure that authorized pandemic vaccines and treatments are available and affordable in countries of all income levels, including via donations, not-for-profit supply, voluntary licenses or equity-based tiered pricing based on countries' needs and capabilities, or any other innovative mechanism as during COVID-19."[45]

In the context of this pandemic and previous pandemics – notably the HIV/AIDS pandemic – pharmaceutical companies have been slow to engage in voluntary mechanisms, particularly when they threaten their market share, profits and intellectual property rights. Historically pharmaceutical companies tend to revert to voluntary mechanisms under threat of compulsory licenses (CLs) and/or public pressure. Voluntary mechanisms like donations, tiered pricing and voluntary licenses (VLs) are typically used to protect pharmaceutical corporations' profits, market share, and IPRs – and to frustrate generic competition.

Pharmaceutical companies have not supported the work of the WHO mRNA Hub

The pharmaceutical industry has, in the past, used voluntary initiatives strategically to defend IPRs and market dominance. Most recently, when the World Health Organization (WHO) established the mRNA Hub in Cape Town, industry put pressure on South African officials to cease its operations.

The kENUP Foundation, "a consultancy hired by BioNTech, has claimed that WHO's hub, which is creating a COVID-19 mRNA vaccine that African companies can make, is unlikely to be successful and will infringe on patents".[46] As reported by the BMJ in February 2022, kENUP sent South African government officials a document in late 2021 demanding that:

> "The WHO Vaccine Technology Transfer Hub's project of copying the manufacturing process of Moderna's COVID-19 vaccine should be terminated immediately. This is to prevent damage to Afrigen, BioVac, and Moderna...Provided that the release from patent cover will be granted by Moderna only during the pandemic, the sustainability outlook for this project of the WHO Vaccine Technology Transfer Hub is not favourable."[47][48]

The pharmaceutical industry has ignored C-TAP

The pharmaceutical industry's claim to support collaboration and voluntary sharing of IP is contradicted by its lack of engagement with the WHO COVID-19 Technology Access Pool (C-TAP),[49] which the Pfizer CEO described as "nonsense, and also dangerous" in May 2020.[50] Unfortunately, universities have also been remiss in contributing to this mechanism, particularly in light of the public funding they have received for developing COVID-19 vaccines.[51]

Pharmaceutical companies neglected supplying COVAX and prioritised supplies to high-income markets

It seems like a pointed oversight that the Declaration is ignoring that for nearly 10 months at the height of the pandemic, African countries did not know which vaccine would arrive, when, and what number of doses. Therefore, it was very difficult to plan and prepare for delivery or to run vaccination campaigns to enhance vaccination uptake. COVAX, the flagship voluntary initiative of the COVID-19 pandemic, was supposed to prevent these problems.

COVAX's supply shortages resulted from vaccine manufacturers' reluctance to sell to it, contrasted with their enthusiasm to sell at higher prices to larger and more powerful countries. Pfizer, for example, only made a deal to sell 40 billion doses of its vaccine (or 2% of its projected output for 2021) to COVAX at the end of January 2021,[52] after WHO Director General Tedros warned rich countries and pharmaceutical companies earlier that month that vaccine hoarding by high-income countries (HICs) was contributing to a "catastrophic moral failure".[53]

By March 2021 an estimated 85% of Pfizer/BioNTech vaccines and 97% of Moderna vaccines had already been purchased by high-income countries for 2021.[54] In contrast, by November 2021 COVAX had only delivered 537 million doses out of the 2 billion it had targeted for 2021, partly due to the supply shortages created by pre-purchasing agreements.[55] At this point in the pandemic "more than 80% of the world's vaccines had gone to G20 countries, whereas LICs had received just 0.6% of all vaccines".[56]

In the words of African Union (AU) special envoy on COVID-19 Strive Masiyiwa, "[t]he people who bought the vaccines and the people who sold them the vaccines knew that there would be nothing for us [the African continent]". He critiqued COVAX as an empty promise; saying "[i]f ever there was an inquiry into how this was done, we even find COVAX culpable because we were misled. We were led down the garden path [...] We got to December [2020] believing that the whole world was coming together to purchase vaccines, not knowing that we had been corralled into a little corner while others [had] run off and secured the supplies."[57]

Voluntary Licensing (VL) is largely restricted to small molecule medicines and typically excludes many middle-income countries

Though pharmaceutical companies have issued VLs for essential medicines in the past, especially HIV antiretrovirals (ARVs), such licenses were often issued only after companies faced pressure to do so (e.g. through public protests or in response to avoid a CLs being issued).[58] This has remained true in the COVID-19 response where vaccine originators have largely eschewed VL and

technology transfer for COVID-19 vaccines except to their business partners and tightly controlled contract manufacturers. Companies have been slightly more willing to VL small-molecule COVID-19 therapeutics, both bilaterally (Gilead) and to the Medicines Patent Pool (MPP) in the case of Pfizer and Merck. Although these licenses have included most LICs and lower-middle-income-countries, their geographic scope excludes many, mostly upper-middle-income countries (UMICs) in Latin America, Asia, and Eastern Europe. For example, Merck and Pfizer's MPP licenses on outpatient COVID-19 antiviral therapies, now routinely available in high-income countries (HICs), exclude nearly 50% of the global population.

Companies also add conditionalities such as limitations on sourcing active pharmaceutical ingredients (APIs). In addition, bilateral VL initiatives don't necessarily translate into lower medicines prices, and may contribute to market segmentation.[59] However, some VL initiatives do lead to price reductions. For example, VLs for antivirals used to treat COVID-19 have been negotiated with the MPP and in May 2022 generic manufacturers of Pfizer's Paxlovid (nirmatrelvir/ ritonavir) agreed to prices below $25/course of treatment.[60]

Several other examples illustrate some of the failures and limitations of voluntary licensing during this pandemic:

- AstraZeneca's agreement with the Serum Institute of India (SII) and other producers emerged in response to Oxford University's (the vaccine's originator and an IP holder) conditionality to prioritise low- and middle-income countries (LMICs), sell at non-profit price and share IP with any developing country manufacturer able to produce it.[61] This case illustrates another problem with bilateral VLs: they are normally secretive arrangements, not open to public scrutiny. For example, it was not known that AstraZeneca's license to SII included prioritising AstraZeneca's requests over deals with developing countries. This was only apparent when at the height of the pandemic, SII shipped millions of doses to the UK and Canada (countries that had other deals) and left Africans uncertain of when they would receive their supplies.
- In South Africa, Johnson and Johnson's fill and finish agreement with Aspen Pharmaceuticals, and Pfizer and BioNTech's fill and finish agreement with Biovac,[62] emerged amidst sustained public pressure in support of the TRIPS Waiver Request. At the press conference announcing the deal with Biovac, Pfizer argued against the waiver and framed it as an impediment to voluntary arrangements, saying "Weakening IP rules will only discourage the type of unprecedented innovation which brought vaccines forward in record time and make it harder for companies to collaborate going forward".[63] Neither deal involves technology transfer and vaccine drug substances continue to be sourced from abroad.
- BioNTech have struck deals to establish pre-constructed "BioNTainer" production sites for mRNA vaccines in Rwanda and Senegal.[64] However, it is not clear when the role of local partners will extend beyond fill and finish functions.[65]

In sum, VLs at their best only go part way in addressing equitable access challenges, even though they can help ensure market aggregation and quicker access to more affordable generic products in the poorest countries.

Tiered pricing can undermine access in middle-income markets and discourage generic competition

Company-controlled tiered pricing arbitrarily segments markets and gives corporations a greater influence than public institutions in decisions about pricing and supply.[66] Although industry's so-called "equity-based" tiered pricing practices typically result in a lower cost, to LICs (and sometimes LMICs), tiered pricing typically result in a lower cost to LICs (and sometimes lower-middle income countries), tiered pricing typically results in substantially higher and often non-transparent pricing in many middle-income markets, especially upper-middle-income markets.

Historically tiered pricing promises don't always correspond to lower prices for LICs. For example, Médecins Sans Frontières (MSF) found instances of HICs paying lower prices than MICs for childhood vaccines in a 2015 report.[67] During this pandemic, Uganda reportedly paid "roughly triple"[68] and South Africa "more than double"[69] the price being paid by the EU for each dose of AstraZeneca vaccine it procured. Similarly, some COVID-19 vaccine manufacturers have indicated they plan to charge a premium in private markets in countries such as Brazil and India.[70]

In the therapeutics context, tiered pricing deals offered by Merck on molnupiravir and by Pfizer on Paxlovid (nirmatrelvir/ritonavir) have had mandatory non-disclosure provisions, though there are reports of very high prices to UMICs for Pfizer's COVID-19 antiviral – as high as $250 for a course of treatment. This is nearly 50% of the US price of $530 a course or treatment[71] and grossly disproportionate to the per capita income in UMICs compared to the US. It also greatly exceeds the less than $25 per course of treatment negotiated by the Clinton Health Access Initiative (CHAI) with several generic manufacturers.[72]

While tiered pricing may contribute to a temporary reduction of prices in some poorer markets during health emergencies, generic competition and price transparency remain important drivers of sustained lower medicines prices. Pharmaceutical companies do not acknowledge the importance of generics in sustainable price-lowering mechanisms anywhere in the Declaration.[73]

Voluntary donations are unsustainable, may be clinically inappropriate, and create logistical difficulties

Voluntary initiatives like the donations proposed in the Declaration have been described as "volatile, unsustainable strategies that can even complicate the healthcare system"[74] as they come with constraints that limit public health authorities' control over the donated product. These include: the type of medicines not being compatible with national treatment guidelines; uncertainties regarding delivery timelines; duration of donations and volume of doses to be received; lack of clarity about expiration dates; mismatches between medicines and the infrastructures available to store and use them (e.g. colds storage facilities); disposal problems relating to unusable supplies; and contributing to equivalent stocks, already paid for, expiring.[75]

Donations during future pandemics may well deepen these distortions in health systems, particularly in developing countries who are most vulnerable to donor-driven programmes.

It is also worth noting that, in the long term, pharmaceutical companies don't necessarily make a loss by donating their products.

- Donations are often tax-deductible at a rate above actual costs of production meaning that US taxpayers, for example, not the companies, end up subsidising donations.[76] That same taxpayer subsidy could instead be used to buy cheaper generic equivalents.
- Donations can also be used to secure market share by crowding out competitors' products, including generic competitors who may ultimately be forced out of the market, leading to monopolies after donations end.[77]
- Donations may also disrupt efforts to build local and regional manufacturing capacity because they "reduce the size of the residual market for a particular drug, create uncertainty about future market effects of donations of other drugs, change the risk–benefit ratio with respect to patent-related issues, registration barriers, and costs of negotiating a distribution system, and reduce the market-pull advantage of an identifiable, sizeable, and sustained source of secure financing".[78]

While the Declaration thus demands market-making interventions for the pharmaceutical industry (e.g. upfront procurement financing), its emphasis on donations for developing countries risks exposing infant industries and generic manufacturers to market-breaking dynamics.[79] This problem is compounded by the Declaration's emphasis on building on "existing manufacturing partnerships" since manufacturing capacity is currently concentrated in India, Europe, and North America.[80]

Donations also don't necessarily sit easily alongside the right to dignity, enshrined in the Universal Declaration of Human Rights.[81] As research on ARV adherence in Francophone West Africa shows, the combination of limited donations and massive need during the early years of the HIV/AIDS pandemic placed patients in the precarious position of having to participate in a "market for testimonials" that served as a triage mechanism determining who would access ARVs because "[n]o matter how many donations they [HIV/AIDS groups] received, demand always outstripped supply."[82]

FACT CHECK 4: THE PHARMACEUTICAL INDUSTRY'S PROMISE TO RESERVE AN ALLOCATION OF REAL-TIME PRODUCTION FOR DISTRIBUTION TO PRIORITY POPULATIONS IN LOWER-INCOME COUNTRIES IS UNDULY LIMITED AND FULLY CONDITIONAL ON STRONG, FULLY FUNDED INTERNATIONAL PROCUREMENT MECHANISMS

Claim 4: "Companies will reserve an allocation of real-time production for distribution to priority populations in lower-income countries, as determined by health authorities during pandemics."[83]

This supply allocation promise is quite limited and dependent on immediate and full payment for procurement and on no-fault compensation and liability protections.

This promise is much smaller than it would appear, and is conditioned on there being fully funded international procurement mechanisms to pay in advance for the allocated supplies and on no-fault compensation programs and liability protections being in place. Industry continues to blame the lack of advanced and adequate funding as the explanation for vaccine nationalism instead of acknowledging that it is profiteering and commercial control over distribution that put poorer countries at the back of the line.

It is important to notice that the supply allocations promised by the Declaration are only for priority populations and not for the general public. Similarly, it is important that the promise is limited to low- and lower-middle income countries, purposefully excluding UMICs where industry expects to exploit its monopolies.

The Declaration calls for "strong, fully funded international procurement mechanisms" and the ability to "sign advance purchase agreements" as mechanisms to ensure access to medicines for the general public. It thus seeks to normalise and institutionalise a system of full payment, up-front – even for medical products needed to mitigate PHEs. During this pandemic, COVAX was unable to deliver that, so pharmaceutical companies put COVAX at the end of the line. And there are few signs that funding for the proposed World Bank Pandemic Financial Intermediary Fund (FIF) will have anything close to the resources needed to fund advance purchase commitments for all needed biopharmaceutical products for future pandemics – especially given that companies will normally decide the price.

In addition to demanding full payment in advance, the pharmaceutical industry is also repeating its demands for no-fault compensation schemes and for liability protections. Although such schemes have become more routine with respect to vaccines only in HICs, they are far from routine in LMICs. Moreover, the liability protections demanded by the companies for COVID-19 vaccines have been unprecedented in their scope. Pharmaceutical companies have demanded excessive liability protections even with respect to their own potentially negligent or reckless behaviour. They have demanded forms of security for the liability protections that have also been unprecedented.[84] Not only has industry demanded derisking of R&D, clinical trials, and expanded manufacturing capacity, it demands derisking of its liabilities and fault as well.

FACT CHECK 5: THE PHARMACEUTICAL INDUSTRY SUPPORTS PRIORITISATION AND ALLOCATION FRAMEWORKS AIMED AT MAXIMISING PROFITS, NOT HEALTH EQUITY

Claim 5: "We support evidence-based prioritization and allocation frameworks when medical supplies are limited. For pandemic vaccines, priority groups identified by health authorities, such as health care workers and high-risk individuals, should be vaccinated first, regardless of the country they live in. For pandemic treatments, prioritization should be based on medical need and up to date clinical guidelines."[85]

Vaccine distribution during the pandemic led to a high over-supply of vaccines (and significant vaccine wastage) in HICs, while high-risk populations in LICs remain unvaccinated to this day. This pandemic has once again shown that the pharmaceutical industry's actual prioritisation and allocation frameworks are profit-driven, not needs-driven, resulting in unfair distribution of COVID-19 technologies.

Vaccine allocation has been driven by profit-maximisation, not need

There is little evidence to suggest that pharmaceutical companies have embraced evidence-based prioritisation and allocation frameworks in this pandemic or during previous health emergencies. Instead, allocation has and continues to be decided on the basis of maximising profit through prioritising countries with significant purchasing power.

For example, during the early years of the HIV/AIDS pandemic, impoverished and stigmatised communities in both developed and developing countries struggled to access expensive highly active antiretroviral therapy (HAART) regimes due to the high cost of medicines.[86] In fact the majority of HIV infections were in developing countries. Instead of prioritising need-based allocation, pharmaceutical companies actively campaigned against global governance reforms, including the Doha Declaration, aimed at enabling increased access to more HIV/AIDS medications in developing countries.[87] Post-Doha, countries with big pharmaceutical industries placed immense political and legal pressure on developing countries when they sought to use compulsory licensing to address public health concerns,[88] including during the COVID-19 pandemic.[89]

During the current pandemic evidence-based allocation would have suggested that COVID-19 vaccines would be distributed on a public health basis as stated in WHO Equitable Access Framework that defined at-risk groups that should be prioritised across all countries. This did not happen. Instead, market-based allocation mechanisms allowed pharmaceutical companies to divert vaccines produced in developing countries with low or no access to vaccines to developed countries with relatively high vaccination rates.[90]

Vaccine hoarding in developed countries has contributed to significant wastage. For example, the UK reportedly discarded 800,000 doses of AstraZeneca at the end of August 2021 after vaccine uptake declined.[91] Reports of vaccine wastage in the USA suggests that "up to 15 million doses" had to be thrown away between March and September 2021.[92]

FACT CHECK 6: DEVELOPING COUNTRIES CAN ENSURE VACCINE UPTAKE

Claim 6: "... whereas there is now broad acknowledgment that supplies of COVID-19 vaccines have outstripped global demand, lack of country readiness and absorption capacity leave highest risk populations in many countries vulnerable."[93]

During the HIV/AIDS pandemic and during this pandemic developing countries have shown that they can effectively implement complex and large-scale public health interventions – provided they have control over the terms on which medications are made available to their citizens. It is inaccurate to argue that vaccine hesitancy and vaccine wastage are largely problems of developing countries. Developed countries face these challenges too – and have struggled with addressing them.

The Declaration's statements about a lack of "country readiness" is reminiscent of the pharmaceutical industry's arguments, articulated during the early 2000s, that developing countries' broken health systems rather than the industry's excessive prices impeded access to ARVs to populations in need.[94] Indian generic companies changed this perception by introducing three ARVs in one affordable pill, to be taken in the morning and evening.

MSF research and actual clinical experience convincingly countered the pharmaceutical industry's claims that developing countries' health systems were too dysfunctional to implement HAART programmes.[95] Their research demonstrated that standardised ARV regimens could be implemented in resource-poor settings, and could achieve adherence and viral suppression rates comparable to those in developed countries.[96]

During this pandemic, research suggests that "lack of country readiness and absorption capacity" is not intrinsic to developing country health systems. It was difficult for governments of developing countries to run vaccination campaigns or prepare the health system when they did not know when they would receive vaccines, how many doses would be arriving, and of which vaccines. Some doses arrived near expiry date and had to be discarded. COVAX's unpredictable, uncoordinated and unaccountable (to national governments) vaccine allocation process, and the lack of operational support that accompanied donations, was a major driver of this confusion.[97] Nonetheless some developing countries, for example Somalia, consumed 90% of the vaccines it received through COVAX, despite short notification times.[98] In September 2021, GAVI reported that only 0.2% of COVID-19 vaccine doses (or a total 386,000) donated to LICs through COVAX expired before they could be administered.[99]

Significantly, community health workers (CHWs) have played a significant role in promoting uptake of COVID-19 vaccines in developing countries because they have the trust of their communities. Similarly, the 2014 Ebola outbreak demonstrated the integral role CHWs' expertise played in surveillance and response efforts.[100] This mostly female labour force has succeeded in boosting vaccine uptake despite poor working conditions, no or nominal remuneration, and limited recognition by their national governments.[101]

FACT CHECK 7: PATHOGEN SHARING AND BENEFIT SHARING ARE INTERDEPENDENT

Claim 7: "Governments should ensure robust surveillance world-wide and guarantee the immediate and unhindered sharing of emerging pathogens and their associated data to all researchers, as any delays will slow the delivery of pandemic products."[102]

Speedy sharing of the genomic sequence of the COVID-19 virus in January 2020 allowed for the development of tests, treatments, and vaccines. The aim of doing so was to contain an emerging global PHE. Instead, it has led to an apartheid situation in tests, vaccine and treatment. This violates the principle of benefit sharing and exposes everyone to the risk that new, more lethal and more infectious variants of COVID-19 may emerge that compromise the efficacy of existing COVID-19 technologies.

Previously Indonesia and other developing countries have had to fight to remedy the situation where developing countries donate the genetic material of viruses in order to support R&D into new medicines, but are then faced with pharmaceutical companies selling them the resulting products, e.g. vaccines, at high prices. This led to a WHO agreement on benefit sharing of flu viruses (despite heavy objections by the pharmaceutical industry).[103]

The IFPMA Declaration insists on pathogen sharing, but fails to elaborate measures for fair and equitable benefit sharing, in keeping with the Nagoya Protocol.[104] This is concerning in light of previous instances of the "misappropriation of biological resources in the public health sector"[105] using the IP system. For example, in 2003 a patent application filed by researchers in Canada, Hong Kong, and the USA was described by the WHO as "sufficiently broad to allow their holders to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the [2003 SARS] outbreak", thereby impeding innovations by non-patent holders and equitable access to medicines during that pandemic.[106]

FACT CHECK 8: MULTISTAKEHOLDER INITIATIVES ERODE PUBLIC AUTHORITY AND ACCOUNTABILITY, AND OFFER NO GUARANTEES OF COMBINING "EFFICIENCY" AND "EQUITY"

Claim 8: "Achieving equity requires actions from all relevant stakeholders, underpinned by sustained political support, as all countries must build the technical and health infrastructure, human resources and financial capacity to successfully vaccinate, test and care for their populations."[107]

The Declaration indicates that the pharmaceutical industry, through multistakeholder initiatives, wishes to continue playing a leading role in responding to pandemics. The current pandemic shows that multistakeholder mechanisms like COVAX[108] have boosted the pharmaceutical industry's influence in global health governance initiatives – even as developing country and WHO influence in these initiatives has been eroded.[109]

The Declaration's enthusiasm for stakeholder-led initiatives has implications for the pre-eminence of governments and intergovernmental organisations as the leading decision-makers in global health governance. Stakeholder-led initiatives increase the political influence of for-profit entities like the pharmaceutical industry, and marginalise the authority of developing countries in global governance institutions.[110]

Multistakeholder initiatives like COVAX contribute to a "diffusion of responsibility, obligation, and liability" amongst private sector, government and intergovernmental organisations. When these initiatives fail to deliver on their promises, citizens are left in the dark about "who is really accountable"[111] and their governments are left carrying the blame for decisions over which they had very little control.

FACT CHECK 9: STATES HAVE A BINDING LEGAL OBLIGATION TO PROTECT AND PROMOTE THE RIGHT TO HEALTH

Claim 9: "No-fault compensation programs and liability protections are pre-requisites for rapid pandemic [vaccines, treatments and diagnostics] VTD deployment under emergency conditions."[112] "Countries should avoid restrictive clauses in their procurement or contracting processes that could prevent biopharmaceutical companies from executing on equitable access priorities."[113]

The Declaration insists on expanding de-risking mechanisms to secure the pharmaceutical industry's willingness to use voluntary mechanisms to respond to public health emergencies.[114] The Declaration also demands liability waivers and investments by health authorities in increasing "clinical trial capability globally to support the rapid development of new treatments and vaccines."[115] In short, it foresees a future in which pharmaceutical companies benefit from guarantees of ever-expanding indemnities and subsidies, while governments rely on the pharmaceutical industry's willingness to engage in voluntary mechanisms aimed at ensuring equitable access.

During this pandemic companies have acquired indemnities that they did not have before. For example, governments accepted liability in order to facilitate emergency regulatory approval of COVID-19 vaccines.[116] Yielding to demands that governments implement "no-fault compensation programs and liability protections [as] pre-requisites for rapid [access to] pandemic" vaccines, treatments and diagnostics has exposed public institutions to financial risks historically borne by pharmaceutical companies. It also has slowed down procurement in countries like India, South Africa, Brazil, and Argentina.[117]

The Declaration emphasises what governments "should" do to "enable" the pharmaceutical industry's willingness to realise its "vision for equitable access in pandemics." However, it obscures what they must do when it comes to their citizens.

Under international law, governments have a binding obligation to protect and promote the right to health. This obligation is recognised in Articles 7 and 8 of the TRIPS agreement, in the Doha Declaration,[118] and in the International Covenant on Economic, Social and Cultural Rights (ICESCR).[119] In the context of the COVID-19, pandemic-specific rights obligations have been emphasised in statements released by the International Commission of Jurists,[120] the Committee on the Elimination of Racial Discrimination,[121] and the Committee on Economic, Social and Cultural Rights.[122]

Fulfilling the obligation to realise the right to health means governments may legitimately include actions that regulate the functioning of for-profit corporations. What the Berlin Declaration refers to as "restrictive clauses in [countries'] procurement or contracting processes" – presumably measures aimed at facilitating price transparency, robust ethical standards for clinical trials, access to post-trial benefits, liability requirements, and so forth – are perfectly legitimate in light of governments' legal obligations to promote the right to health.

FACT CHECK 10: TRANSPARENCY IS AN ESSENTIAL FEATURE OF ANY PANDEMIC RESPONSE

Claim 10: The terms transparency and accountability do not appear anywhere in the IFPMA Declaration

In the Declaration, the pharmaceutical industry makes no explicit commitment to transparency concerning its R&D and manufacturing costs, manufacturing capacity and contract manufacturing agreements, or its inventories, prices, or supply and distribution agreements.

An absence of transparency leads to an absence of accountability and capacity to plan and respond.

In response to COVID-19, the world has been left in the dark about nearly every bit of information that pharmaceutical companies control and treat as confidential. There is a lack of information on R&D expenditures, clinical trials costs, partnership and contract manufacturing agreements, IPRs filed and granted in countries; regulatory landscapes, prices being charged, actual costs of production, etc.

Instead of transparency, this pandemic has seen pharmaceutical companies impose contractual limitations on disclosure concerning even the most basic information such as the price paid by governments for particular medical technologies. Instead of promising transparency, the Declaration, by its silence, errs on the side of the status quo that leaves governments, normative entities like the WHO, global health institutions, and the general public in an information-free zone.

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