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DELIVERING THE PEOPLE'S VACCINE: CHALLENGES AND PROPOSALS FOR THE BIOPHARMACEUTICAL INNOVATION SYSTEM

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Introduction

In the early weeks of 2020, the world was alerted to the emergence of a new deadly infectious respiratory disease, COVID-19, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). First reported in China, it rapidly spread across the globe. Until effective treatments or vaccines become widely available, the response to the pandemic largely relies on infection control measures such as hand hygiene, personal protective equipment including masks, physical distancing and restrictions on movement which have included variable periods of lockdown of cities, countries or regions. By January 2021, over 2 million people had died from COVID-19, among over 95 million people diagnosed. But hope is on the horizon — nine vaccines have been developed and approved in record time, are being rolled out in different parts of the world, including three particularly promising candidates from Pfizer/BioNtech, Moderna/NIH, and AstraZeneca/Oxford University.

It is clear that we are only as healthy as our neighbours — locally, nationally and internationally. Strong health systems, adequate testing capacity, and an effective, universally available vaccine will be key to protecting societies from COVID-19. Given the enormous health, social and economic impact of the continued spread of COVID-19, which is nowhere near being under control, it is no surprise that a lot of hope is set on finding a vaccine, and ensuring that no one is left behind.

This requires not just unprecedented collective investment, but also a very different approach to biomedical innovation and access. Underpinned by the rationale to create a symbiotic relationship between public and private actors with the purpose of tackling the COVID-19 pandemic globally, 140 public figures, including 50 former world leaders, have led the call for a 'People's Vaccine' — a "global guarantee which ensures that, when a safe and



effective vaccine (and other technologies for COVID-19) is developed, it is produced rapidly at scale and made available for all people, in all countries, free of charge" (UNAIDS 2020).



Source: Oxfam | See https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19

Realising this aim will require rigorous governance of the world's vaccine development and manufacturing efforts to ensure it squarely focusses on the public interest. With unprecedented financial support from governments, in particular the US, the UK and other European countries, as well as China and Russia, researchers and companies have engaged in what soon became a frantic race to create vaccines against COVID-19, resulting in over 50 vaccine candidates in clinical trials and many more in the pipeline. The first phase III efficacy data for several frontrunner candidates look encouraging. And while the arrival of a safe and effective vaccine would represent the beginning of the end of the COVID-19 pandemic, a closer look at the reality shows that we are far away of achieving a People's Vaccine.

The key deficiencies in the biopharmaceutical innovation system have been described and analysed, and in the times of COVID-19, the same fundamental flaws and additional problems become further exposed (Torreele, 2020a). While the private sector has a crucial role to play in bringing cutting-edge medicines to the market, the current pandemic exposes the inadequacy of existing health innovation systems, which are characterised by entrenched short-termism and striking misalignment with public interest (UCL Institute for Innovation and Public Purpose, 2018). Firstly, companies prioritise research and development (R&D) that is likely to deliver 'blockbuster drugs' at the expense of commercially unappealing medicines that are hugely important to public health (Moon, Bermudez and 't Hoen, 2012). Secondly, the pricing of these medicines does not take into account the contribution by other actors, including public institutions (Mazzucato and Roy, 2019). Thirdly, patents are often abused — being too upstream, wide, and strong — leading to extensive monopolies, high

prices and lack of knowledge sharing and collaboration (Mazzoleni and Nelson, 1998). Fourthly, high prices are driven by — and in turn fuel — the financialisation of parts of the industry, where share buybacks are outpacing R&D (Lazonick and Mazzucato 2013; Collington, 2020).

The state should therefore govern the drug innovation process to more effectively shape the market for public health purpose — steering innovation towards optimal public health interventions, getting fair prices, ensuring that patents and competition work as intended while stimulating collaborative research and knowledge sharing, collective intelligence, and governing medicine supply for equitable access. At a global level, this will require joint efforts from states to impose firm rules regarding intellectual property (IP), knowledge sharing, pricing, manufacturing, and supply — designed and enforced in ways that prioritise improving health outcomes globally, and foster international collaboration and solidarity rather than competition between countries and companies.

However, challenges associated with the development and the governance of a People's Vaccine abound. In this policy brief, we review these challenges, and look towards ways forward. Taken together, the unprecedented public investments in COVID-19 vaccines — including R&D and manufacturing capacities, the advance purchase commitments and liability transfers — all directly benefit companies that 'own' these technologies. They have come with little or no strings attached, de facto privatising all those public investments and the control over potentially hugely important public health interventions, which essentially should have been global health commons.

Directionality towards public health

Vaccine development and optimal use as public health intervention depends on continuous data-driven assessment of benefits and risks in the context of the evolving pandemic, with the view of maximising the public health impact of vaccination strategies (Torreele 2020b; Mazzucato, Torreele and Li, 2020). Aligning the direction of development with public health needs faces challenges in clinical, economic and political aspects, which are especially intense during a public health emergency like COVID-19 (Avorn and Kesselheim, 2020).

Alignment with clinical profiles:

Obtaining approvals from regulators is the most critical step to the vaccines gaining market access, and it is a company's primary goal to clear the lowest bar by designing trials in ways that gives the fastest and easiest way to success. This does not necessarily coincide with asking the most relevant clinical questions. For example, the first COVID-19 vaccines developed by Moderna, Pfizer, and AstraZeneca, were authorised based on trial data showing a reduction in the number of symptomatic

COVID-19 cases, without information on their capacity to protect against infection, nor about the duration of protection. WHO's Target Product Profiles lay out safety and efficacy targets and other preferred features such as dosage and scalability, but they are only aspirational and vaccine developers are under no obligation to comply with such criteria and ensure the products they are developing will be adequate as a public health intervention.

Alignment with economic and political incentives:

As soon as SARS-CoV-2 emerged, public and non-profit funding sources mobilised substantial funds to apply existing vaccine technologies to COVID-19, piggybacking on earlier investments in other diseases including cancer, Zika, Ebola, MERS-CoV, and "disease-X" (emerging infection of a so far unknown pathogen), thus quickly moving several candidates into clinical trials. However, this process also enables wealthy countries and powerful actors like pharmaceutical corporations to place their bets, allotting large amounts of money to propel a chosen candidate forward towards authorisation (Knaus, 2020). Financial and industrial backing such as through Operation Warp Speed, more than desirable product characteristics, is determining the early winners of this race, for which the primary finish line is obtaining first marketing approvals. The criteria used by regulators to allow a vaccine on the market are not necessarily responding to the critical question at hand: which vaccine has the potential to significantly impact global public health outcomes for COVID-19? The way in which the commercial and geopolitical 'race' for a vaccine is playing out, however, risks side-lining these critical public health objectives in an R&D process that hinges on the privatisation and commercialisation of knowledge, and is focussed on being first to get a vaccine to market (Torreele, 2020c). There currently is no mechanism to ensure that the best possible vaccines are being developed and deployed.

Collective intelligence over siloed research

Traditionally, the business case for vaccines — where profit is derived from the delivery of high volumes of items and low unit price per item — is not considered amongst the most attractive. The increasingly financialised pharmaceutical corporations will not invest in R&D for products that do not constitute guaranteed and profitable business opportunities. Few (10–15) existing players remain in vaccines, leading to market concentration with just four companies controlling 80% of the market. The classic approach to vaccine development is that private companies invest in R&D based on their own proprietary platform technologies (vectors, delivery systems, adjuvants), in which they integrate a specific antigen to adapt to the target disease.

Taking advantage of the massive public subsidies that started flowing towards COVID-19 R&D, both small biotechs and major pharmaceutical companies jumped on the opportunity to adapt or reorient their proprietary vaccine technology platforms towards COVID-19, allowing to fast-track what otherwise would require many years of research. For instance, Moderna/NIH's and BioNTech/ Pfizer's leading mRNA vaccine candidates built on 30 years of public and private research into the potential of RNA and DNA vaccines (yet none of them were made into a vaccine approved for human use) (Akpan, 2020). Similarly, Oxford University (who later partnered with AstraZeneca), J&J, CanSino and Gamaleya have rapidly repurposed their adenovirus-based vaccine platforms for COVID-19, which had been explored for many years and a variety of diseases including most recently MERS-CoV, Zika and Ebola.

With a pipeline of nearly 200 vaccine R&D projects, the 'race' to get a vaccine to market fastest unfortunately does not incentivise the best science for public health interest. Instead, it favours fragmentation and secretive competition, and precludes the free exchange of knowledge and learning from each other's successes and failures in real time, or a public health-driven and collaborative portfolio approach. None of the individual elements of each proprietary platform is necessarily the best suited for a COVID-19 vaccine, but each company will only research within the boundaries of its proprietary technology (covered by patents), hands tied from using other and possibly better fit elements that are owned by competitors.

This is despite each of these R&D efforts building on a wealth of earlier research by the global vaccine research community, much of which is traditionally done and funded by the public sector. The basis of our commercial R&D model is that universities and companies are allowed to appropriate such technology platforms as their own. Governed by the World Trade Organization's 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement that obliged countries to grant and enforce patents on pharmaceutical 'inventions', medical knowledge and technologies have largely been privatised, owned and traded as commodities, even when of critical public health importance. As a result, vaccine candidates essentially move through the pipeline as speculative commercial assets, whose market valuation can be followed through the share price of the companies owning them.

This is antithetical to a collective intelligence effort that would allow scientists all over the world to creatively combine the best elements of our medical knowledge and technological advances into a diverse and innovative portfolio of vaccine candidates with the best chance to achieve our common public health goal (Torreele, 2020d). Failing moreover to compare the performance of the different candidates directly, the current process

is bound to create a portfolio of suboptimal candidates that are neither the best in their class, nor diverse or complementary. In our supply-driven innovation system (in which the market is considered the ultimate arbiter), there is no public health mechanism to demand or impose that companies develop products according to pre-set and public health-driven performance criteria. As a result, less than optimal candidates can move through the pipeline, if sufficient resources are poured into it.

Manufacturing capacity

Realising that providing global access to an eventual COVID-19 vaccine would require manufacturing at unprecedented scale, governments also provided upfront investments in the companies' manufacturing capacity and infrastructure. Not only have they agreed to massively finance the expansion of private vaccine manufacturing infrastructure, with seemingly little or no strings attached, they also agreed to pay for the actual manufacturing of large volumes of selected vaccines before their safety and efficacy is proven — and committed to buy large volumes once they were approved (at undisclosed prices) through so-called advance purchase commitments (APCs). On top of this, companies have negotiated confidential liability transfers to governments, in case the vaccines would exhibit side effects that were not observed in the accelerated R&D process (Halabi et al., 2020).

In contrast to generic drug manufacturing, there is relatively little vaccine manufacturing capacity able to produce at large scale outside of the major (Western) vaccine corporations, with the notable exception of the Serum Institute of India, which has taken many years to build its meanwhile state-of-the-art capability. While strictly speaking there is no such thing as generic vaccines, vaccine manufacturing is technologically much more complex than small chemicals, and setting up the production of an existing vaccine typically requires lengthy technology transfer, including know-how sharing, for a newcomer to become operational. The massive investments of governments into scaling up manufacturing capacity for the COVID-19 candidates seem to have all gone into private companies under license from the 'originator' companies, which is a missed opportunity for the global health community to have invested in expanding the global technological capacity to produce vaccines as commons, and start challenging the oligopoly that now exists among major vaccine producers.

Conditionalities for access

An unprecedented amount of public funds has been poured into vaccine R&D and manufacturing at risk, estimated at over US\$12 billion for the six leading candidates including AstraZeneca/Oxford University (over \$1.7 billion), Johnson&Johnson/BiologicalE (\$1.5

billion), Pfizer/BioNTech (\$2.5 billion), GlaxoSmithKline/Sanofi Pasteur (\$2.1 billion), Novavax/Serum Institute of India (nearly \$2 billion), and Moderna/NIH/Lonza (\$2.48 billion) (Médecins Sans Frontières 2020). Additionally, front-running vaccine candidates are further derisked by advance market commitments (APCs), which is the main strategy used by government to ensure access (and often in combination with significant investments in R&D and even manufacturing).

While it is a formidable achievement that we already have a first generation of vaccines being rolled out just one year after the emergence of SARS-CoV-2 and the ensuring pandemic, we also have a global access failure — bordering a 'catastrophic moral failure' — unfolding before us: more than 39 million doses of vaccine have now been administered in at least 49 higher-income countries, but just 25 doses have been given in one lowest-income country (World Health Organization, 2021).

It is clear that the historic public investment into vaccine innovation is not translating into guarantees for equitable access globally. On one level, it is unclear whether the financing agreements for vaccine innovation are structured to recognise the nature of public and private co-investment, and ensure there will be commensurate sharing of the resulting outcomes in terms of access and pricing (the agreements have remained confidential). What is clear is that companies are set to profit hugely from the crisis (Gross, 2020).

On another level, national interests — especially those of developed countries — remain the dominant factor in vaccine rollout. While the international purchase and distribution platform COVAX represents a momentous step forward, its impact is being offset by massive bilateral advance-purchase agreements by rich countries that can afford to bet on multiple vaccines.

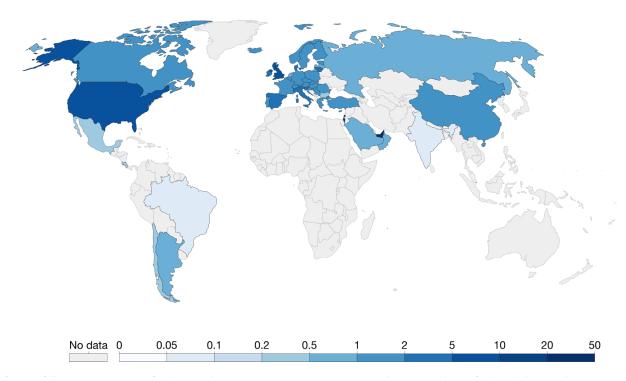
COVAX has its own limitations. It has been met with mixed success so far — lots of verbal support but so far limited concrete financial commitments. It is also being criticised for lack of transparency and representation from the countries for whom COVAX is supposed to deliver solutions. What is more, it shifts the power imbalance between governments and vaccines companies, who successfully turned the COVID-19 crisis to their advantage and positioned themselves as key to the solutions — while largely dictating the terms of engagement, not only for availability and access to vaccines in wealth countries but also globally.

Despite so, COVAX presents an important option for achieving global solidarity over equitable access to Covid vaccines. However, governments are using APCs to get into good positions in the queue, undermining the principles behind COVAX. Initially designed as a market-fixing pull mechanism to incentivise companies to do R&D

COVID-19 vaccine doses administered per 100 people, Jan 22, 2021



Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).



Source: Official data collected by Our World in Data. See https://ourworldindata.org/grapher/covid-vaccination-doses-per-capita

in directions they would not otherwise commit to, bilateral APCs have been perverted by governments to guarantee supply and buy up the first in line positions for once the vaccines become available.

For example, high-income countries have already bought close to 80% of the Pfizer/BioNtech and Moderna/NIH vaccine doses that will be available within the first year through bilateral deals (Global Justice Now, 2020a, 2020b). Rich countries have laid claim to 3.4 billion doses from different vaccine makers, compared to 3.1 billion (which includes around 700 million doses for COVAX) for the rest of the world combined (Launch and Scale Speedometer, 2020). In other words, high-income countries have pre-ordered enough doses to cover their populations several times over, leaving the rest of the world with potentially too few to cover even their most at-risk communities.

Proposals for the future

The COVID-19 crisis is a perfect test of whether a more public health-oriented approach to innovation and production will prevail in the years ahead. Fundamentally, achieving the mission of delivering a People's Vaccine, and

governing the innovation, production and distribution of health technologies for the common good require a very different type of public-private partnership in the innovation ecosystem (Mazzucato and Torreele, 2020).

First, collective steering of future R&D of vaccines and health technologies will be vital in selecting and pursuing promising potential products based on public health considerations globally. Otherwise, marketing authorisation will go to the best-resourced candidate from high-income countries rather than the most suitable one, as we are seeing already for the Pfizer/BioNTech mRNA vaccine that needs a cold chain at -70 degrees Celsius. Necessity and speed must not compromise robust data transparency, or worse, become an excuse for irresponsible communication practices such as prioritising press releases over publication in peer-reviewed journals — that enable companies to move the financial market to their gains during the crisis (Whitfill, 2020). In addition, strong steps need to be taken to ensure that critical technologies and data — especially those generated with public investments — are shared publicly in full, with rigorous scientific assessment.

On the positive side, COVID-19 has demonstrated that mission-oriented innovation agencies can enhance the role of the state in coordinating public and private sectors. For example, the US Defense Advanced Research Projects Agency (DARPA) and the US Biomedical Advanced Research and Development Authority (BARDA) have seeded and directed new technological trajectories in DNA and mRNA vaccine technologies, which has proven to be an important novel platform for vaccines against COVID-19 (Pardi, Hogan, Porter and Weissman, 2018; Hodgson, 2020). While there is increasing interest in some countries in increasing R&D investment and setting up or broadening the scope of ARPA-type programmes as part of a postpandemic recovery plan, it is critical that these programmes are designed to meet the public health purpose. This will require substantial changes in the governance of the healthcare and innovation systems to place much stronger emphasis on public health needs, broaden access to technology, lower pricing, enhance knowledge transfer and connect procurement at an international level, rather than simply focussing on competitive advantages that reflect narrow economic and industrial interests.

Second, to maximise the impact on public health, the innovation ecosystem must be better set up for using collective intelligence to accelerate advances. Science and medical innovation thrive and progress when

Science and medical innovation thrive and progress when researchers exchange and share knowledge openly, enabling them to build upon one another's successes and failures in real time. The COVID-10 technology access pool (C-TAP) — a voluntary pool for health technology-related knowledge, intellectual property and data proposed by Costa Rica and adopted and launched by the WHO — has offered a pragmatic solution with game-changing significance (Nature Editorials, 2020; World Health Organization, 2020).

And it can go further — ultimately, today's proprietary biopharmaceutical innovation model promotes secretive competition, prioritises regulatory approval in wealthy countries over wide availability and global public-health impact, and erects barriers to technological diffusion. Long-term solutions must look beyond voluntary patentpools and address the control that private, for-profit companies have over-critical technologies and data — even when these were generated with public investments. More generally for biopharmaceutical innovation, where the purpose must be improving health outcomes, patents must be seen through a knowledge governance perspective, not an innovation incentive perspective, so that the monopoly profit given to a company during the patent term should be governed to make sure that the patent produces productive entrepreneurship (Burlamaqui, Castro and Kattel, 2011), and global access to the innovation as needed. In tackling COVID-19, countries are increasingly aware of the potential of compulsory licensing, and policymakers should consider using it to allow countries to make the best use of the available tools and technologies. For example, Israel issued

compulsory licensing to enable the import of generic alternatives to lopinavir/ritonavir due to concerns over their supply (rather than their pricing, which is a more common rationale for invoking compulsory licensing) (Wong, 2020). Several other countries, including Chile, Ecuador, Canada and Germany, have also initiated legal and legislative steps to create a national framework for the use of compulsory licensing to facilitate access to health products and other technologies for managing COVID-19 (Wong, 2020; Bassi and Hwenda, 2020). Countries, especially highincome countries, should support the recent proposal from South Africa and India to the WTO for a COVID-19 Waiver on certain provisions of the TRIPS Agreement can be a constructive and realistic step towards a People's Vaccine (Silverman, 2020), even if it must be recognised that major efforts in technology transfer, and capacity and infrastructure building are needed to enable countries to become more resilient around their own manufacturing capability for essential public health technologies. In addition, compulsory licensing is an important, yet cumbersome, remedy for abusive monopoly power; more sustainable solutions for knowledge governance for public health purposes are needed.

Third, countries must take the lead in building and buttressing manufacturing capabilities, particularly in the developing world. While effective COVID-19 vaccines are now available, their rollout is limited by manufacturing capacity. In the future, a concerted and persistent effort is needed to establish the public and private capacity and infrastructure needed to rapidly scale the production of billions of doses of vaccines as necessary background preparation for global health emergencies, well before any new crisis emerges. Moving away from the concentration of capacity in centralised locales towards decentralisation with partners in multiple countries would be vital for distributing systemic risks, building systematic resilience in the manufacturing and supply of essential pharmaceuticals from local levels, and strengthening global health commons. As with this time, because it is not possible to know in advance which vaccine will prove most effective, we may need to invest in a range of assets and technologies. This poses a technological and financial risk that can be overcome only with the help of entrepreneurial states (Mazzucato, 2013) backed by collective, public-interest-driven financing. National and regional development banks, the World Bank, and philanthropic foundations are highly important actors in this space, and they will need to learn from the crisis to become much more proactive and long-termist in financing global health commons.

The measures in these areas are far-reaching and will require deep restructuring of the relationships between finance, productive activities and labour not just in vaccines, but in the biopharmaceutical sector in general. In terms of manufacturing, states are driven by current needs and, alerted by the fragilities in the global supply chain,

are finally paying long-overdue attention to strengthening local capacities (UCL Institute for Innovation and Public Purpose, 2020). There is a strong case for a public option in biopharmaceuticals - government-provided, qualityassured medicines and vaccines that are universally available at a reasonable and fixed price, which coexist with products from the private sector (Mazzucato and Li, 2020). This can range from the creation of a new business model dedicated to creating a functional, competitive market that responds to health needs and deliver affordable products, to states becoming directly involved in — and taking a substantial stake in — coordinating and executing the full range of activities in pharmaceutical innovation and manufacturing in order to retain a sufficient level of control that can ensure supply and availability (Singer, Kirchhelle and Roberts, 2019), as well as the direction of innovation, i.e. that optimal products are developed according the health system needs. As persistent market failures, and a lack of political and economic imagination in finding solutions beyond creating and aligning incentives for the private sector to address the gaps in innovation and pharmaceutical supply in a financialised market, become a repeated phenomenon, the drive to marry innovation, manufacturing and social policies may well provide new impetus for public-sector solutions.

Fourth, conditionalities must be put into place to ensure global, equitable, and affordable access to any innovations that have benefitted from public investment from the start of any future vaccine **development programme.** Given the substantial public investments in vaccines, firm commitments on a vaccine available to all — beyond statements of principle and generic pledges - will be necessary, as are concrete conditions that enable vaccines to be free at the point of use. This would allow public investments to be structured less like a handout or simple market-fixer, and more like a proactive market-shaper, driven by public objectives. Pricing of COVID-19 treatments and vaccines should reflect both the substantial public contribution to their development and the urgency and magnitude of the global health crisis (Mazzucato and Momenghalibaf, 2020; Moon et al., 2020).

Even though the arguments for conditionalities are strong, their substantive relevance remains finely in the balance in the complex political economy of biopharmaceutical innovation. It remains to be seen whether any of the current high-profile public-private partnerships at global and national levels will make firm and specific commitments that enable vaccines to be universally available according to need and free at the point of use, beyond commonplace statements of principle and generic pledges. At the same time, it is essential that these partnerships be more transparent about negotiations on pricing, procurement and potential conflict of interests. Mismanagement of issues around these areas will damage public trust and public health. Nevertheless, increased willingness for state investment to translate into partial public ownership

of companies and/or their public-funded innovations — partly driven by nationalistic concerns — may open up new policy opportunities for the state to shape the pricing, manufacturing and distribution of vaccines.

Conclusion

The COVID-19 pandemic has presented a critical window and created significant momentum for states to move away from market-fixing approaches to biopharmaceutical innovation towards market-shaping approaches. At a global level, states will need to make joint efforts to steer vaccine development for public health, setting up and making use of collective intelligence, building manufacturing capabilities, and putting in place conditionalities for global access. Delivering a People's Vaccine is only a first test; the public sector must finally rise to the challenge to reset its relationship with the private sector and prepare societies for even greater challenges.

Summary of proposals

Proposal 1: Future vaccine development, including the design of mission-oriented innovation programmes, needs to be steered towards delivering optimal health technologies for public health and global access, beyond narrow economic and industrial interests.

Proposals 2: To maximise the impact on public health, the innovation ecosystem must govern knowledge for the public interest and use collective intelligence to accelerate advances, making wider use of open science — or as needed, patent pools and compulsory licencing — to ensure equitable access.

Proposal 3: Countries, especially the developing world, must build and buttress manufacturing capabilities in the intervening time, rather than wait until waves of pandemics strike.

Proposal 4: Conditionalities must be put into place to ensure global, equitable, and affordable access to critical public health innovations, in particular where they have benefitted from public investment from the start of any future development programme for vaccines and treatments.

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