



November 8, 2021

Mr. Patrick Wilcken
Deputy Programme Director
Head of Business, Security, and Human Rights International
Secretariat
Amnesty International
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Ref: Right to reply to upcoming Amnesty International Publication

Dear Mr. Wilcken,

Thank you for the opportunity to comment on the topics you shared in connection to Amnesty International's forthcoming publication. Continuing with our commitment to open communication, we would like to provide some clarification and additional information that we hope will be helpful.

As mentioned in our earlier exchanges, we strongly agree with you that companies have an important responsibility, alongside other stakeholders, in ensuring respect for human rights. Pfizer's commitment to the right to health is reflected in our purpose: breakthroughs that change patients' lives. We are proud of the contribution our science has made to the health of millions of people worldwide, particularly during this pandemic. We know, however, that there are people we still have to reach.

COVID-19 vaccine deliveries to LICs/LMICs

From day one of our vaccine development program, our outreach has been broad and inclusive to ensure equitable access. We approached all governments where Pfizer has a presence and global health organizations in parallel, including COVAX. We also responded to government and stakeholder inquiries from across the world.

It is true that the majority of our first doses were reserved by the high-income countries because early on middle- and low-income countries placed orders first with other vaccine makers, either because of the uncertainty of mRNA technology or because they were pursuing other options. Because of some of the challenges faced by other vaccine producers, many of these countries later came back to us and we worked to rapidly establish agreements and allocate doses to them. Our contractual obligations on vaccine allocations have been determined by this sequence of events. To date, we have supplied nearly 2 billion doses of the Pfizer-BioNTech COVID-19 vaccine to 152 countries in every region of the world.

We are a proud partner to COVAX, with an agreement to supply 40M doses in 2021 in alignment with their allocation strategy for the Pfizer-BioNTech vaccine. Last July we signed a milestone agreement with the US Government to provide 1 billion vaccine doses that they would subsequently donate to COVAX's AMC 92 and African Union Countries in 2021 and 2022. The first shipment from the USG

agreement reached Rwanda on August 18, 2021. As of October 31, 2021, more than 92 million doses have been delivered to 42 low-and-lower-middle income countries as part of this specific program¹.

Similarly, we are also supporting the European Commission and participating member states in their efforts to provide donations to countries in need through COVAX. Pfizer/BioNTech, the European Commission and COVAX have established a framework that enables EC member states to donate doses from its allocation to low- and lower-middle-income countries in need² through COVAX, with France acting as the coordinating member state for donations. The first donation under this framework, which occurred in late October, was the donation of doses from France to Rwanda.

Because of all these ongoing initiatives and our continued efforts to boost vaccine manufacturing, we have pledged to supply 2 billion doses to low-and middle-income countries through 2022 – one billion each year. Our current allocation to low- and middle-income countries from all supply pathways³ has already surpassed this pledge in 2021 with over 1.1 billion doses contracted, and as of October 31, 2021, Pfizer and BioNTech have delivered more than 634 million doses to 81 low- and middle-income countries towards this pledge. This includes more than 154 million doses that have reached 42 low- and lower-middle-income countries. Close to 10% of these doses have so far gone to low- income countries.

These numbers hopefully respond to your concern about doses delivered to low-income countries. It is simply not accurate to say that *no doses at all* have reached these countries as of today. We recognize and are concerned by the relative lower pace with which vaccines ended up reaching low-income countries, however, it is important to also acknowledge that approximately two thirds of the 1.3 billion people living in poverty are in the middle-income countries. Lower-middle-income and upper-middle-income countries are currently home to 75% of the world's population and 62% of the world's poor. Nonetheless, we anticipate that there will be a substantial increase in dose shipments through the end of the year with a particular focus on low- and lower-middle-income countries that are further from global targets.

Further efforts to achieve equitable access supporting country readiness

As you, we want to ensure that we reach low-income country populations faster and believe global vaccination targets can be achieved with support from all global health stakeholders, including vaccine manufacturers. In order to do so the global health community has been working to support country readiness and absorption of vaccines to reach their populations, but more has to be done.

Distributing these types of products rapidly and at national scale has no precedent in modern public health, and close coordination across all stakeholders is critical for ensuring the success of vaccination campaigns. This is why we continue to partner with the global health community, governments and private industry to address challenges in these economies with gaps in cold chain and service delivery, insufficient workforce capacity and issues with demand and vaccine confidence. Without cold chain support countries are not able to accept high volumes of vaccine that allow for robust vaccination campaigns. And without service delivery and sufficient workforce capacity, vaccines in country will not result in vaccinations. In short, we believe that to achieve equitable access, it is not just vaccines that will bring an end to the pandemic, but vaccinations.

¹ More information about status of vaccine deliveries can be accessed via [USAID's website](#).

² The agreement with the EC also includes donations to UMICs

³ Our current supply pathways include direct supply agreements with country governments, supply agreements with supranational organizations like COVAX and the European Union, partnerships with wealthy nations to donate doses to countries in need and humanitarian donations to vulnerable populations.

Country readiness is critical in ensuring that a country is able to effectively receive, transport and administer the vaccine doses that it receives. Specifically, this includes acceptance by the country's regulatory body, confirmation that the country can meet product handling requirements, the availability of sufficient ultra-cold-chain (UCC) and/or traditional cold chain capacity for both the vaccine and diluent, basic supplies such as syringes, and the development of a delivery strategy to reach target populations.

Greater investment in readiness efforts in many lower income countries will be necessary in order to ensure that vaccines shipped effectively reach the population. The COVAX Facility and its international health partners have taken a key role in support country's efforts to achieve readiness for vaccines, and Pfizer is committed to providing our expertise and resources to strengthen healthcare systems where greater support may be needed.

Specifically, we are partnering with global health stakeholders, including COVAX, to analyze supply chain capabilities in low-income countries in order to understand where the private sector can lend expertise and support the delivery of any COVID-19 vaccine - including dry ice supply, transportation and best practice sharing:

- Pfizer and the UPS Foundation are committed to accelerating the equitable distribution of COVID-19 vaccinations. The UPS Foundation is donating freezers to countries that need assistance with building out their ultra-cold chain capacity. Our partnership leverages innovation in the healthcare cold chain to truly move our world forward by safely, securely and quickly delivering highly sensitive, critically needed vaccines and therapeutics to areas where they are needed most.
- As part of a four-year partnership with Zipline, Pfizer is supporting an innovative pilot initiative in Ghana, focused on delivering vaccines requiring cold-chain storage to hard-to-reach areas using drones. The initial success of the project suggests that the program could be quickly expanded to deliver doses of COVID-19 vaccines to remote regions across the world.
- Pfizer has signed an MOU with Global Environment and Technology Foundation to collaborate with Project Last Mile. The partnership is focused on aligning the supply chain expertise and technical capabilities of Coca-Cola, a company whose supply chain is characterized as one of the widest reaching in the world, with technical expertise from Pfizer on vaccine handling, storage and administration in order to improve the availability of vaccines in developing countries, and, in particular, to those residing in and around the last mile of the medical supply chain in Africa.

IP, innovation, and manufacturing

We understand there are diverging views about the relationship between intellectual property (IP), access to vaccines, and human rights so we would like to provide further clarification of our views. We believe that the IP system is an essential facilitator of access to vaccines around the world and that IP protections support the right to health by encouraging investment in needed medical innovation.

The incentives provided by the IP system enable the creation of the expertise and infrastructure that's required to tackle the worst diseases of our time, including the COVID-19 pandemic. Due to the legal certainty provided by the IP system, the collaborations needed to ensure the early introduction of new vaccines across different markets becomes possible—our collaboration with BioNTech is one such example. New treatments and vaccines, such as Pfizer-BioNTech's COVID-19 vaccine, as well as improvements to existing medicines, are made possible because advancements in science are

incentivized, valued, and protected by way of intellectual property rights.

We are fully committed to efforts to promote access to medicines and vaccines throughout the world and will continue to carefully evaluate and consider all reasonable options and mechanisms to ensure that the COVID-19 vaccine and any potential therapies to help address the pandemic are accessible to those who need it.

As mentioned above, experience has demonstrated that the challenges to ensuring equitable distribution of the COVID-19 vaccine stem not from the IP system but rather from tight vaccine input supplies, export controls and other trade barriers on inputs and vaccines, and distribution infrastructure limitations that determine country readiness, among other factors. As such, we do not believe that waiving IP rights will get the world closer to equitable access.

To further explain our position, it's important to understand that vaccine manufacturing is a biological production. It is extraordinarily complex under any circumstances, and even more so during a pandemic. The steps involved in a tech transfer include – but are not limited to – on-site development, equipment installation, engineering and process qualification tests, and regulatory approvals. The timeline for technology transfers is dependent on the extent of work needed during the transfer. On an average a fill/finish technology transfer (where product is filled into vials/syringes and packaged for delivery) takes anywhere from 18 months to three years from project kickoff to the qualification tests in which the new facility demonstrates that it can consistently execute a well-controlled process and make quality product (also known as performance qualification (PPQ) execution).

Let us reiterate that we are fully aligned with the overarching imperative of increasing overall supply to achieve equitable access. Since the beginning of our vaccine development program, we have focused our efforts and resources in ways that maximize our supply so we can support the global need. Because of the urgent need to vaccinate more people, we are continuously exploring innovative ways to increase the number of doses we're able to supply – which includes expanding our existing facilities, adding more suppliers, and bringing on additional Pfizer/BioNTech sites and contract manufacturers around the world to produce the vaccine.

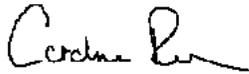
Pfizer and BioNTech's global COVID-19 vaccine supply chain and manufacturing network now spans four continents and include more than 20 manufacturing facilities, including contract manufacturing agreements that Pfizer has in place to further accelerate access around the world. Last July we announced a landmark agreement with The Biovac Institute in South Africa to manufacture the Pfizer-BioNTech COVID-19 vaccine exclusively for the 55 member states that make up the African Union, and in August, Pfizer and BioNTech also announced the signing of a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture our COVID-19 Vaccine for distribution within Latin America. Such efforts are made possible thanks to the IP framework that protects the innovation and allows for secure transfer of technical knowledge. We will continue to explore and pursue opportunities to bring new partners into our supply chain network to further accelerate access to the COVID vaccine.

To conclude, while we feel our Organizations' positions remain aligned around the overarching objective to achieve equitable access for all, we realize that our views on how we fulfill our human rights responsibilities and the complexities underlying our efforts to do so are still not fully understood. We will continue open to feedback from stakeholders as we continue evolving our COVID-19 response. Hopefully the information we clarified above will be taken into consideration in your report.

Similarly to our past exchanges, let me reiterate that we remain fully focused on getting high-quality, safe and effective vaccines to patients all over the world as quickly as possible to help end this deadly pandemic.

Pfizer's purpose, our core focus, is to bring breakthroughs that change patients' lives. Disease in its many forms continues to bring heartbreak and suffering to humankind and a burden to our societies, as the global COVID-19 pandemic has brought into sharp focus. With the people most in need always in mind, we will continue to work toward a future where disease doesn't win, but science does.

Your sincerely,

A handwritten signature in black ink, appearing to read "Caroline Roan". The signature is fluid and cursive, with a prominent initial "C" and a long, sweeping tail.

Caroline Roan
Chief Sustainability Officer, Pfizer Inc
President Pfizer Foundation