

Response of the Government of the United Kingdom of Great Britain and Northern Ireland to OL GBR/10/2021 from the Working Group on the issue of human rights and transnational corporations and other businesses enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on extreme poverty and human rights.

Throughout the pandemic, our top priority has been to save lives. We firmly believe that the best way to do this is to support the world's leading scientists to continue developing innovative products to help contain, treat, and prevent COVID-19 and to ensure the dissemination of that innovation. No single country has all of the elements that will enable us to tackle it fully and the UK recognises the many challenges faced by all, in relation to this pandemic.

We continue to promote voluntary licensing and technology transfer partnerships, standing at an unprecedented number of over 300, which are contributing to the production and dissemination of vaccines and other health technologies across the world. These partnerships are making positive impacts on vaccine production, with monthly vaccine dose outputs standing at an estimated 1.5 billion. It is estimated that 24 billion vaccine doses will have been manufactured by June 2022. This is commendable and unprecedented. Alongside other factors, such as early investment into manufacturing, collaborative public-private partnerships driven by cooperation and trust can make real-world change. Focus must also be given to ensuring vaccines are distributed equitably and administered promptly, building vaccine confidence while also ensuring health systems can maintain essential services including routine immunisation.

- 1. We would like to inquire about the views of your Excellency's Government on the proposed temporary waiver of certain COVID-19 TRIPS protections to ensure that intellectual property rights on the vaccine do not become a barrier to the effective enjoyment of the fundamental rights.**

At the World Trade Organisation (WTO), the UK has and will continue to engage constructively in the debate around the proposed TRIPS waiver. The latest G7 Trade Ministers' communiqué outlines our commitment to an outcome on trade and health, including how IP can continue supporting the pandemic response. The role of the legal framework provided by the TRIPS Agreement during the pandemic cannot be overstated. It has and will continue to be crucial in supporting the rapid development and production of new and existing vaccines, including responding to emerging new variants and future crises. It must continue to do so by maintaining its ability to incentivise future research and development investment and provide innovators with the confidence to continue forming collaborative partnerships.

We share concerns about the lack of vaccines in many parts of the world and recognise the need to find more ways of ensuring that those vaccines can be delivered effectively. The UK's action to improve global vaccine equity is outlined in the following sections. However, the UK believes that we must focus on the real challenges to vaccine equity, instead of dismantling the intellectual property framework which has helped, and will continue to help, in developing products, contributing positively to the pandemic response. Those challenges include: improving regional manufacturing capabilities and supply constraints; resolving supply chain issues such as export restrictions, tariff measures, trade facilitation; regulatory issues; supporting health systems to get available vaccines in arms; and building vaccine confidence and uptake. We remain open to initiatives which help overcome these challenges, which waiving IP rights do not.

We look forward to further discussions on the TRIPS waiver, while continuing to take pragmatic action on voluntary licensing and technology transfer partnerships for COVID-19 goods.

2. Steps that your Excellency's Government has taken, or is considering to take, including policies, legislation, and regulations, to protect against any actual or potential human rights impacts related to pharmaceutical companies, such as Astra Zeneca within its territory and/or jurisdiction production or developing COVID-19 related vaccines.

We are proud that Oxford University and AstraZeneca agreed to scale up global manufacturing, initially providing the vaccine on an at cost basis and continuing to offer affordable and tiered pricing to ensure fair access to the vaccine. AstraZeneca has secured manufacturing agreements across the world for the production and supply of the vaccine. To date, 2.5 billion doses have been distributed to over 170 countries, two-thirds of which are low and middle-income countries that have needed vaccines most. Many of these doses have been delivered via COVAX, demonstrating why international partnerships are vital to help get vaccines to low- and middle-income countries. The UK is a strong champion of COVAX and supporter of CEPI (the Coalition for Epidemic Preparedness Innovations) and Gavi (the Vaccine Alliance).

All our supply agreements with manufacturers, including but not limited to AstraZeneca, specify that they shall use reasonable endeavours to ensure that employees, agents and/or subcontractors shall, at all times, act in a way which is compatible with the European Convention on Human Rights within the meaning of Section 1 of the Human Rights Act 1998.

3. Information about the relevant national policies, laws, and practices, including the use of compulsory licence orders under the TRIPS Agreement by your Excellency's Government to produce and distribute vaccines in the public interest, to scale up production of vaccines and

treatments against COVID-19 and to open up more opportunities for dissemination to a larger number of the population.

The UK is compliant with the flexibilities outlined in the TRIPS Agreement with regard to Use Without Authorization of the Right Holder. UK law (Patents Act 1977) contains provisions on compulsory licensing and Crown use and details the processes to invoke them. These provisions would enable the compulsory licensing or Crown use of a therapeutic drug or vaccine (including in health emergencies such as pandemics), if the government decided this was necessary.

The right to use of compulsory licensing is supported by the UK as a legitimate tool to access pharmaceutical products as per our commitment to the 2001 Doha Declaration on Public Health. Throughout this pandemic, the UK has continually encouraged WTO Members to use TRIPS flexibilities, where necessary, to achieve their public health policy objectives. At TRIPS Council we have frequently asked Members, who have noted challenges they experience using compulsory licensing, to share specific areas they think could be streamlined to facilitate use of TRIPS flexibilities. We remain committed to having such conversations.

While we support use of compulsory licensing, we believe that voluntary licences are a preferable approach to allow other manufacturers to produce a patented product. They are more likely to benefit from the knowledge exchange, create lasting beneficial relationships, and are more likely to achieve successful manufacturing of a product. The use of voluntary licences also incentivises the creation and commercialisation of new medicines, such as life-changing vaccines, to deal with future pandemics and other health emergencies. We have and continue to encourage industry to keep on with this type of collaborative approach and are working to facilitate more partnerships. Working with commercial partners within the existing international IP system is the most effective way to make use of global capacity to produce life-saving medicines at pace.

More generally, the COVID-19 crisis has taught us that resilient, robust, and diversified supply chains operating in a predictable trading environment are very important to effectively address public health emergencies. This global health crisis requires a coordinated global response, where trade policy has a big part to play.

We have supported previous statements, such as the G20 Trade and Investment Minister's statement in October 2021 and May 2020 which had commitments to facilitate international trade in light of the pandemic. We are pleased to see that others share our commitment to open and transparent trade. The UK used its G7 presidency to show leadership and build on international collaboration to date, including the work of the Ottawa Group.

The UK is a proud co-sponsor of the Ottawa Group's Trade and Health Initiative (TAHI). TAHI, which was fully endorsed by all members of the Ottawa Group on November 23, 2020, was first presented as a Communication on Trade and Health to the WTO General Council in December 2020. We welcome the broad sponsorship that the TAHI has now attracted, and support efforts to continue to build participation

from across the WTO as the world continues to grapple with the COVID-19 pandemic.

The Initiative calls on WTO Members to implement trade-facilitating measures for essential medical goods in the areas of customs, services, and technical regulations; limit the use of export restrictions; temporarily remove or reduce tariffs; and improve transparency. It also calls for further cooperation among all WTO Members, and between the WTO and other international organisations and the private sector to support the production and distribution of essential medical goods, including vaccines. The UK underpinned its support for TAHI by unilaterally announcing tariff suspensions on COVID-19 critical goods and additional disciplines on the use of export restrictions.

TAHI focuses on the current pandemic, but with the knowledge we now have on the importance of access to COVID-19 critical products and vaccines, we must also consider creating a proper home for the Trade and Health agenda at the WTO and as part of that are exploring what permanent measures we can take to support future pandemic preparedness.

4. The ways in which your Excellency's Government supports efforts for international economic and scientific cooperation and international solidarity to avoid vaccine hoarding and to ensure global vaccine procurement and distribution, to provide financial and technical assistance to governments of low- and middle-income countries to address the human rights consequences of the current crisis.

HM Government recognises the many challenges faced by all, in relation with the COVID-19 pandemic. It is vital that low-and-middle-income countries have access to vaccines because vaccines save lives and reduce the risk of serious illness. The UK is committed to help bring the acute phase of the pandemic to an end and is supporting vaccine access globally through the COVAX Facility. We are among the largest donors to COVAX's Advance Market Commitment, committing £548 million. This support has helped COVAX deliver over one billion doses globally, with more to come in 2022.

Under the UK's Presidency, G7 Leaders have committed to working together to vaccinate the world in 2022. This includes a commitment to share at least 870 million doses by June 2022. This includes 100 million doses from the UK of which 80% of UK vaccine donations will go through COVAX, enabling them to accelerate support to those countries identified as most in need of additional vaccines. The UK is working closely with international partners to deliver this ambitious goal. This includes efforts to increase vaccine supply, strengthen downstream delivery and develop more sustainable approaches to financing vaccines.

The UK has championed the 100 Days Mission to protect the world from future pandemics, through accelerating the time to develop and deploy diagnostics, therapeutics and vaccines. The Mission is an advisory report to the G7, and the G7

Chief Scientific Advisers (CSAs) recently published the first independent [Implementation Report](#), summarising progress to date and proposed implementation plans to achieve the Mission. A key priority for the G7 CSAs in 2022 is to apply innovations in ‘programmable’ vaccine and therapeutic platform technologies (e.g., mRNA, viral vector) to COVID-19 variants and to wider endemic diseases, including to support technology transfer and strengthen global manufacturing capacity, and equitable access is at the heart of the Mission.

We are working through the governing boards to ensure Gavi and World Bank funding available for in-country delivery is approved and disbursed in a timely manner. We are working with COVAX, technical partners (WHO, UNICEF), bilateral programmes and the FCDO diplomatic network to tackle bottlenecks that can be addressed through focused funding, equipment or technical assistance available through COVAX, the World Bank and others. COVID-19 vaccines donated through COVAX are administered by Gavi and their Alliance partners, who work with governments to ensure robust and transparent distribution and reporting plans are in place to ensure priority groups are reached. For UK bilateral donations, we have sought assurances from recipients that they have the capacity to roll-out doses in line with National Deployment and Vaccination Plans.

The UK is a responsible global customer, only procuring doses that we need. By design, the UK does not hold a stockpile of COVID-19 vaccines. The UK manages our vaccine supply so that all procured doses are either used rapidly by our domestic programme, allowing all those eligible the opportunity to be vaccinated as soon as possible, or shared internationally. We continue to ensure any vaccine that the UK does not need is reallocated to others wherever possible and as soon as possible. This enables the UK to better manage vaccine supply with our future need. This careful management of vaccine supply benefits both us and others.

In March 2022, CEPI hosted its Replenishment Conference in partnership with the UK Government. CEPI has been a vital organisation in the response to COVID-19, creating one of the world’s largest and most diverse portfolios of COVID-19 vaccines (including the Oxford/AstraZeneca, Moderna and Novavax vaccines), and co-creating COVAX. CEPI is aiming to raise \$3.5bn to support its new 5-year strategy (CEPI 2.0) to reduce the risk and impact of future epidemics and pandemics. Through CEPI we can strengthen the world’s defences against COVID-19 by urgently addressing the critical remaining COVID-19 vaccine R&D gaps, including the immediate threat of variants, and reduce the risk of future epidemics and pandemics, potentially preventing millions of deaths and trillions of dollars in economic damage. Participants at the Conference made political and financial commitments to support CEPI, galvanising action on pandemic preparedness, and raising a significant down-payment for CEPI’s new five-year plan. US\$1.535 billion was raised on the day, which met our internal HMG target. This will fund collaborative work to save millions of lives and prevent trillions of pounds in economic damage. Furthermore, at the Conference the UK, CEPI and Life Sciences Industry Associations issued a joint statement formalising our commitment to the 100

Days Mission. The statement includes commitments to invest in R&D to combat diseases most likely to cause epidemics and pandemics, reduce manufacturing complexity, and enable equitable access to vaccines during outbreaks. It recognises the critical role of public and private partnerships in reducing global health threats and secures meaningful commitment from the associations representing vaccine manufacturers, biotech and pharmaceutical industry.

The UK will continue to work towards our commitment to ensure COVID-19 vaccines are accessible for all those who need them.

5. Laws and policies of your Excellency's Government on full transparency in its contracts with pharmaceutical companies purchasing vaccines, including all elements of vaccine development, procurement, and provision to ensure that your Excellency's Government and companies domiciled on its territory comply with international law and that their related responsibilities can be effectively monitored and enforced, especially regarding the pricing policies and the human rights impact of indemnification clauses, as well as the partial or full built-in immunity clauses for the case of adverse side effects of the vaccines.

Transparency in contracting is embedded in HM Government policy. Under The Public Contracts Regulations 2015 (the PCR), European Publication requires the contracting authority to publish certain commercial information about the contract and procurement – see Regulation 50(2) of the PCR. This includes, for example, name of contractor, value of contract, description of services, details of procurement, etc. National Publication requires the contracting authority to publish the name of the contractor, the value of the contract and the date on which it was concluded – see Regulation 108(2) of the PCR.

Additionally, HM Government's policy obligates all central government bodies to publish contract documents on Contracts Finder (the "Contract Publication Objective"). While a contract may be redacted (in accordance with the principles of the Freedom of Information Act 2000 ("FOIA")) to avoid prejudicing the commercial interests of either party, that commercial prejudice, as with information withheld in relation to PCR Publication, must be duly substantiated.

6. Any additional information and/or comment(s) you may have on the issues raised.

The UK welcomes the decision made by the World Health Organization (WHO) to launch an intergovernmental negotiating body that will consider a convention, agreement or other international instrument on pandemic prevention and preparedness. We will continue to advocate strongly for a new legally binding instrument that will achieve real change in the way member states and international organisations prepare for and respond to pandemics and other health threats.

I hope this reassures you that the UK will continue to work towards our commitment to ensure COVID-19 vaccines are accessible for all those who need them.