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Addressing together current and new COVID-19 challenges

ADDRESSING TOGETHER CURRENT AND NEW COVID-19 CHALLENGES

I INTRODUCTION

This autumn has seen a resurgence of COVID-19 in many Member States, with rapidly rising case numbers and renewed pressure on hospitals and health workers. Governments are again having to balance the need for restrictions to limit the spread of the virus with the cost to social and economic life. The return to a critical situation after a period of respite has sparked frustration and fatigue in many citizens. The new threat from the Omicron variant has accentuated concerns still further.

Urgent and determined action is required. The common efforts of the EU, Member States, and citizens mean that we are now much better equipped to act than at the start of the pandemic. We know far more about how to limit transmission of COVID-19 through hygiene measures and targeted restrictions. Therapeutics allowing COVID-19 to be treated are increasingly becoming available. Above all, vaccination is massively reducing the risks for most Europeans. It has allowed much of daily life to resume, economies to start their recovery and opened the door to initiatives to restore freedoms such as the EU Digital COVID Certificate. EU joint efforts to build up the production and supply of vaccines have substantially increased access to vaccination, and there is now no question about the availability of vaccines: a clear example of the added value of an EU-level approach. Vaccination means that responses to the pandemic can be more tailored to the situation of the individual.

Nevertheless, the renewed risk of new variants serves as a reminder that we must continue to be determined in action and swift in response. We now have a much wider range of tools and the experience to deploy them to best effect: but the success of vaccination has also meant that new measures to anticipate the current phase in the pandemic were not always taken in time. We are learning again that the more we delay in using these tools, the more drastic the action required.

This urgency also applies to global action. Only by working together we can tackle the pandemic effectively and progress towards long-term health security. The Omicron variant shows again the importance of real-time transparency and global coordination, as well as of sharing the tools needed to combat the pandemic. It also underlines that international efforts to support all countries in tackling the pandemic have not gone far enough. Accelerating this work must be a major priority.

The experience of the last 18 months shows that a coordinated EU response is the most effective and persuasive approach to the pandemic. It maximises the scale and impact of our actions, it ensures predictability for citizens and it provides a framework within which Member States can tailor their responses. It shows our citizens that policy continues to be driven by a strong scientific consensus. It is now urgent to draw on this approach once again. The EU needs to show its continued determination by taking swift, clear and coordinated steps to address the resurgence in the virus.

II THE NEW WAVE OF COVID-19 INFECTIONS

The EU today faces a double challenge. Member States are already in the midst of rapidly-rising cases serious enough to once again put health systems under the severest of challenge. To this is now added the threat of the Omicron variant: and although the detailed impact of this

variant is still under assessment, the rapidity of its spread and the extent of the mutation make it a clear variant of concern. The fact that it comes at a time when vaccination still falls short, when boosters are only now being deployed, and when health services have faced almost two years of intense pressure, means this demands urgent action.

The recent spread of the virus

COVID-19 cases have been rising steeply since October¹. This has led to week-by-week increases in serious illness, hospitalisations, and deaths, particularly in Member States with low vaccination rates. However, the rollout of vaccines also means that the proportion of people who are getting seriously ill or dying is significantly lower than in the initial waves.

One reason behind this resurgence is the dominance of the Delta variant, which is twice as transmissible as the original virus, even if the vaccines remain effective against the disease caused by this variant. In addition, immunity may have started to wane in those who received the vaccine first (in general, the most vulnerable and older age groups). The change in season caused much of social and economic life to move indoors, where the virus can be more easily transmitted. And the speed at which restrictions and precautions are relaxed or imposed by governments also has a clear impact on the ability of the virus to spread.

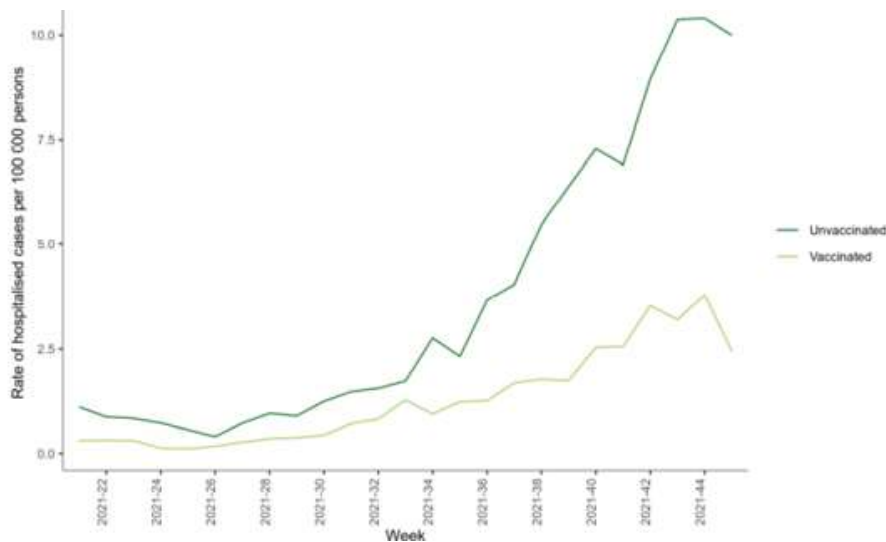
However, of critical importance to the current situation is that a substantial share of Europeans remains unvaccinated. Overall, 23.5% of adults across the EU are still not fully vaccinated,² and in some Member States this figure is as high as 70.8%. Perhaps most worryingly, in some Member States up to 65 % of people over 65 years are still not fully vaccinated.

It is clear that vaccination reduces the likelihood of infection, and is very effective in reducing severe disease and death. Vaccination does not offer a complete protection against infection and vaccinated people, if infected, can still transmit the disease. But infection in vaccinated people is far more likely to result in a relatively mild case of COVID-19. A first analysis of data from three Member States confirms that the hospitalisation rate is substantially higher in unvaccinated people compared to those vaccinated. In other words, vaccination very significantly reduces someone's chances of becoming seriously ill with COVID-19.

¹ The overall COVID-19 case notification rate in week 45 (08-14 November 2021) for the EU/EEA was 485.5 per 100 000 population from 8-14 November, and 612.2 from 15-21 November (ECDC 17th update of the rapid risk assessment).

² This equates to 34.3% of the total population.

Figure: Rate of hospitalisation for COVID-19 by vaccination in three Member States



While still offering solid protection, the effectiveness of vaccines naturally declines over time. On 24 November, the European Centre for Disease prevention and Control (ECDC) issued a rapid risk assessment indicating the need to urgently consider a booster dose for those 40 years and over, targeting first the most vulnerable and the elderly. ECDC also indicated that countries could consider a booster dose for all adults from six months after completing their primary vaccination³. All Member States have already started delivering booster doses to the most at-risk groups and a number of Member States are already offering population-wide booster campaigns.

In addition to adult vaccination, the approval of two vaccines for use in the 12+ age group has allowed Member States to extend vaccination still further. In addition to this, a vaccine has now been approved for use in the 5 to 11 age group..

The effectiveness of vaccination allowed much of social and economic life to resume over the summer. However, with the relaxation of constraints contributing to a renewed spread of the virus, basic hygiene measures such as mask-wearing were no longer enough. This left authorities with the challenge of identifying the most effective targeted measures to use as the number of cases started to increase.

The upsurge in cases of severe illness, especially among the unvaccinated, has resulted in an enormous strain on hospitals and healthcare staff already stretched by the events of the past 18 months. This overburdening of health care systems is also having a direct impact on the health of non-COVID patients, as once again access to healthcare for other conditions is put under pressure by the need to treat COVID-19 patients. The result is a burden on healthcare systems comparable to or higher than last winter. This is making the imposition of new measures inevitable, with governments faced with difficult decisions about when and what measures to apply.

Action to tackle the Omicron variant

The identification of the Omicron variant (B.1.1.529) by South Africa illustrates the importance of acting swiftly and decisively to reduce and slow down the transmission of the virus and to manage the risk of possible further mutations. South Africa’s work in carrying out analysis and

³ <https://www.ecdc.europa.eu/en/publications-data/rapid-risk-assessment-sars-cov-2-situation-november-2021>

its transparency in sharing the results has been indispensable in allowing a swift global response and is a model of how international cooperation should work.

As the World Health Organization⁴ concluded on 26 November 2021, a global effort is needed to ensure that variants are identified and tracked. This means:

- enhanced surveillance and rapidly expanded global genomic sequencing efforts;
- submitting complete genome sequences to a publicly available database;
- reporting initial cases and clusters associated with variants of concern infection to WHO and ECDC;
- performing field investigations and laboratory assessments to improve understanding of the potential impacts of the variants of concern.

As well as this global effort, the EU and Member States must act now. While urgent steps are taken to gather key data on the Omicron variant, precautionary measures are essential. Member States need to put contingency plans into action as soon as cases emerge. Increased vaccination, including the rapid rollout of booster campaigns, and the quick introduction of precautions and restrictions limiting social contacts should slow down the transmission of the Omicron, and any other, variant. Member States must take swift and decisive action whenever a cluster of cases is identified.

In this respect the EU can draw on key initiatives put in place over the past year. First, with the HERA Incubator, launched in February 2021, the Commission prepared for the detection of variants, the development, regulatory approval and production of adapted vaccines. The EU has made a major effort to strengthen its capacity to rapidly detect and characterise variants of concern. In February 2021, €200 million was made available to reinforce Member States' sequencing capacities. A whole genome sequencing service contract has helped 11 Member States and three Western Balkan countries to have more than 100,000 samples analysed. A new €77 million programme is building up long-term genome sequencing and testing infrastructure in 24 EU/EEA countries, with an extension proposed for 2022. This not only means a better response to the current pandemic, but also a permanent step up in capacity. The EU has also developed its capacity for the testing of wastewater to identify the location of new cases. As a result, the EU is now better prepared for variants: the investment in increased genetic sequencing capacity and effective data sharing will enable the real time identification of any further mutant strains, such that immediate responses can be put in place. Adapting vaccines to new strains when needed is now factored into contracts with vaccine manufacturers.

Second, with the launch of the EU Health Emergency Preparedness and Response Authority (HERA) in September 2021, the Commission has brought together both strategic direction and expertise at both national and EU level in the HERA Board and provides for joined up action. It is already deploying and networking modelling and foresight capabilities so that the right responses can be quickly identified and deployed. Its strong industrial dimension is leveraging industrial partnerships and expanding industrial capacity for vaccines and therapeutics.

Third, travel related restrictions can slow down further entry points of this variant from outside the EU. The common framework put in place to coordinate measures to restrict travel to the EU (see below) allowed an “emergency brake” to be applied within a matter of hours of the recognition of the Omicron variant by the WHO. The result was agreement on 26 November to apply targeted travel measures for those countries most affected by the Omicron variant. These arrangements also allow the situation to be constantly monitored to either expand the list

⁴ [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)

of affected third countries, to introduce possible measures within the EU or to lift precautionary measures as further scientific evidence becomes available.

The EU and Member States need to take immediate action:

- Member States need to have contingency plans in place to take rapid and decisive to control outbreaks of the variant wherever they are identified;
- Member States need to have booster campaigns immediately in place as an indispensable step towards increased protection against variants;
- Member States, supported by the Commission, should closely coordinate to apply real-time changes to border and travel measures in line with the Council Recommendations on travel to the EU and on free movement within the EU, including on testing and quarantine measures. Based on the latest available scientific evidence and in line with the precautionary principle, to answer to the current risk from the omicron variant, the requirement of a PCR test prior to arrival can be a suitable means for Member States to consider, in particular for travel to the EU, as well as for travel within the EU, as part of an emergency brake. Such steps should be for the shortest time necessary, proportionate, non-discriminatory and subject to constant review;
- Member States should increase genomic sequencing capacity and surveillance of the Omicron and any other variants of concern, including through widespread wastewater testing. The Commission will help to ensure that samples and results are shared swiftly;
- The Commission will support sampling for countries with low sequencing data as well as the rollout of antigen tests;
- Support should be provided at both EU and Member State level to countries in Southern Africa, and any other relevant countries, on gathering and studying clinical data associated with infections by this new variant;
- HERA will continue to use the potential it offers to tackle Omicron to the full:
 - The HERA expert group on variants acts as the focal point for situational analysis;
 - HERA works with vaccine manufacturers to ensure the swift adaptation of vaccines to the new variant if necessary and guarantee sufficient vaccine production capacity;
 - The HERA Board, also in coordination with the WHO, brings together the strategic direction of EU and national action.

III STAYING THE COURSE: COORDINATED ACTION TO COMBAT COVID-19

The virus has proved both durable and adaptable, with the Delta variant currently the dominant strain in the EU and with the new threat of the Omicron variant. Only sustained and determined action will allow the pandemic to be brought and maintained under control. This makes it particularly important that measures are taken not only in response to surges in infection and the arrival of new variants, but also when infection rates are low. This has been the guiding principle of EU action against the pandemic: to ensure the availability, supply and administration of vaccines; to improve the treatment of those infected; and to act together to ensure that restrictions are effective, but remain proportionate and fair.

One of the main lessons from the last eighteen months is the importance of agreeing on a common and coordinated EU approach and communicating that approach as clearly as possible. Discrepancies between national approaches to vaccination which are not clearly explained have undermined efforts to tackle vaccine hesitancy. Major differences in the public

health measures applied, which could not be explained by equally large differences in epidemiological situations, undermined public confidence.

Continuing to build effective vaccination

Vaccination efforts must be continued. **Supply** and production capacity is now assured through the EU Vaccines Strategy. By the end of this year, the EU will have an installed manufacturing capacity of over 300 million doses a month. The contracts put in place under the EU Vaccines Strategy give Member States access to as many doses of vaccines (including adapted vaccines if they prove necessary) as they need in 2022 and 2023. The EU will need to continue to invest in developing and producing better, more advanced vaccines against COVID-19 and its variants. HERA will allow the development of a powerful strategic capacity to perform exactly that function in order to combat both current and future threats through improving the development, manufacturing, procurement and distribution of vaccines. This will include identifying and addressing vulnerabilities in critical supplies and materials for the production of vaccines, building on the work of the Commission's Task Force for industrial scale-up. The existing Joint Procurement for syringes should be taken up by Member States to address potential shortages. Also key is improving access to vaccines, so that the administration of vaccines by health services can take place in local communities and with easy access for citizens.

A primary challenge today is to persuade those who are not yet vaccinated to get the vaccine. Member States are starting to use a greater variety of measures to reflect the reality that the unvaccinated pose more of a threat to the health of society at large and the sustainability of healthcare systems than the vaccinated. **Vaccine hesitancy** has a variety of causes. They often need tailor-made, local solutions with trust in local health professionals playing a key factor. Nevertheless, there are certain common elements which the EU and its Member States – as well as global partners such as NATO – could continue to work on together, not least the huge amount of misinformation and disinformation about vaccines which has been put into the public sphere. The Commission has set up a dedicated process to facilitate a swift response to disinformation. A Rapid Alert System allows for effective cooperation with Member States, with a dedicated COVID-19 Cooperation Space bringing together pandemic-related disinformation analysis and responses. The Commission has also offered direct bilateral support to those Member States with the lowest vaccine uptake rates, also reaching out to healthcare professionals in those countries⁵. This could now be expanded to mobilise other community leaders (such as business, trade union, religious, and sporting leaders). The Commission is also engaging with online platforms to motivate them to offer space for communication campaigns and promotion of expert views, as well as to monitor disinformation and to share data.

More data is now emerging about the rate at which immunity wanes. **Booster doses** are the key response to address this waning. They are also essential tools in protection against variants. At the moment, all EU Member States are offering boosters or additional doses to the most at-risk groups, such as the elderly, the immunocompromised and immunosuppressed, long-term care facility residents and healthcare workers. In view of the ECDC guidance above, all Member States need to ensure that the most vulnerable have a booster shot as a matter of priority, and to deploy the right equipment and resources for mass booster campaigns. The onset of the Omicron variant adds extra urgency to the need to roll out mass booster campaigns in all Member States.

⁵ The EU Coalition for Vaccination brings together European health professionals' and students' associations to advocate for vaccination in their daily work with patients and fellow health professionals.

Treating people with COVID-19

Better treatment of those who do contract COVID-19 has also been a key development in combatting the virus. This is one consequence of better diagnostics to understand the prevalence of the virus and how to address it. Member States will increasingly be able to use ***therapeutic medicines*** in the fight against COVID. The EU COVID-19 Therapeutics Strategy is now up and running with a portfolio of the ten most promising candidate therapeutics, with several joint procurements with Member States now concluded to ensure equitable access to such therapeutics. Three treatments have now been authorised. This will play a particularly important part in limiting the risks of COVID-19 for the most vulnerable, and could also help address the challenges of post-COVID complications for recovered patients. Communication will be key to explain the benefits of authorised treatments and the risks of misinformation. These therapeutics will help individuals to recover faster and mitigate the impact of the virus on individuals and on health systems: however, they are a complement to vaccination, not a replacement for it. This will also be an important part of the work of HERA in the medium and long term.

At the same time, the rise in cases in some Member States risks taking their health systems back into crisis mode. The ***Union Civil Protection Mechanism*** remains available to galvanise support from less affected Member States to those under most pressure. Since the beginning of October, the Emergency Response Coordination Centre has facilitated the delivery of immediate life-saving assistance from several Member States⁶ to Romania and Latvia.

Prevention measures

Daily behaviour is an essential component in combatting the virus and should remain the norm. This includes most obviously the use of mouth masks in closed and at risk settings, avoidance of high risk gatherings, social distancing, and proper ventilation of closed settings.

The reality is that with increased spread of the virus and the risk that this will extend still further with the Omicron variant, further ***preventive measures*** will also be needed to limit the risks of contact and infection. Vaccination is not enough to hold back the virus on its own. Experience since the start of the pandemic shows that such measures are an essential part of action to combat the spread of the virus. Success factors include decisive decision-making, good communication, and community engagement. As has been the case throughout the pandemic, authorities will need to find the right point of balance so that such restrictions are timely, effective but also proportionate: individuals should not have their liberties restricted if doing so does not make a significant contribution to reducing the impact of the virus. Lessons must also be learned from previous experiences in applying these restrictions – for example, the high impact of closing schools, universities and colleges on the mental health and educational performance of children and young people. But equally, waiting too long before applying essential steps means that that more radical measures are then needed. Measures such as improved hygiene or staying at home when showing symptoms may become norms for society over the longer term.

With a growing share of the population being vaccinated and now receiving boosters, restrictions are increasingly shifting away from measures for the whole population to measures that take into account both individual circumstances and the risk that a given individual could

⁶ 11 Member States (Austria, Czech Republic, Denmark, Finland, France, Germany, Italy, Lithuania, Poland, Slovakia and Sweden) as well as Serbia provided medicines, medical equipment, personal protection equipment and vaccines. Poland and Denmark sent medical teams to Romania. Support was provided from the EU-financed rescEU strategic reserve hosted by Hungary, the Netherlands and Sweden.

make the situation worse. Measures such as requiring those working in environments with vulnerable people to get vaccinated are a logical response to the current reality.

The toolbox to monitor and manage the situation

Alongside these requirements, Member States should continue to use the tools at their disposal to facilitate everyday life. Available and accessible **testing** will remain an indispensable tool to manage and control the pandemic and respond swiftly to outbreaks. Member States need to look ahead to ensure that sufficient testing will be available to manage surges in the virus. Testing strategies should be targeted, for example on settings with high-risk groups such as long-term care facilities and hospitals, as well as on areas of high transmission such as schools. This could also be combined with testing for other circulating viruses such as influenza. Work should also continue on ensuring the accuracy of testing, such as whether the effectiveness of tests is influenced by vaccination.

Contact tracing remains part of the toolbox to contain a resurgence of COVID-19 and Member States should maintain a sufficient capacity. By complementing existing manual contact tracing, contact and warning tracing apps can also continue to play an important role in breaking the chain of infections, nationally and across borders, thus contributing to saving lives. To date, 21 EU/EEA countries have a contact and warning tracing app, with 18 connected through the European Federated Gateway Service, allowing people to continue using their app even when cross borders: all Member States are encouraged to participate.

The **EU Digital COVID Certificate**, designed, adopted and implemented with unprecedented speed, is a key enabler of recovery and has proved an invaluable tool for Member States and citizens, enabling cross-border movement of EU citizens and helping social and economic activity to continue with the minimum of disruption. Member States have now issued over 650 million EU Digital Covid Certificates.⁷

The successful and widespread implementation of the EU Digital COVID Certificate also makes possible a revised approach to **free movement within the EU**. The Commission has therefore made a proposal for a new Council Recommendation on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic.⁸ This sets out a new approach based on the Certificate, so that travellers with a valid EU Digital Covid Certificate should in principle not be subject to additional restrictions to free movement, such as quarantine or tests. It also takes account of the situation where the virus is circulating at very high levels in some areas of the EU, where Member States should advise against all non-essential travel to and from such areas. Travellers without a vaccination or recovery certificate arriving from such high-risk areas should have a test prior to departure, as well as post-arrival quarantine/self-isolation. Finally, the proposal also adapts the methodology and factors vaccine uptake into the regional map prepared by the ECDC.

Requirements to control the virus such as testing and quarantine within the EU are foreseen under the emergency brake procedure of the Council Recommendation in the face of a high prevalence of a variant of concern such as omicron. Member States should consider applying measures as part of precautionary steps to limit the risks of spread whilst first analysis of

⁷ See Report from the Commission on the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates to facilitate free movement during the COVID-19 pandemic (COM(2021) 649).

⁸ Proposal for a Council Recommendations on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic (replacing Recommendation (EU) 2020/1475, COM (2021) 749) and on a coordinated approach to facilitate safe travel during the COVID-19 pandemic in the Schengen area (amending Recommendation 2020/1632, COM (2021) 755).

omicron is under way. Such steps should be proportionate, non-discriminatory, transparent and fully coordinated.

A key issue is to ensure the right length for the *validity of vaccination certificates* under the EU Digital COVID Certificate, recognising that in time, the reassurance provided by the certificates wanes alongside the effectiveness of the vaccine. The length of validity of certificates therefore needs to be compatible both with this waning effect, as well as with the need for a reasonable time to allow booster campaigns to be implemented, so that the constraint on free movement from validity coming to an end is fully proportionate. The Commission considers that, with effect from 10 January 2022, certificates which are more than nine months from the initial vaccination course should no longer be accepted by Member States. This is reflected in the Commission's proposal which takes into account the guidance of the ECDC regarding the administration of booster doses as of six months, and provides for an additional period of three months to ensure that national vaccination campaigns can adjust and citizens can have access to boosters. In addition, the Commission is considering whether to provide for such validity in a binding manner.⁹ Finally, the Regulation currently applies until 30 June 2022. As it appears unlikely that the pandemic will have ceased by then, the Commission is therefore preparing a legislative proposal to extend its applicability for a limited period of time..

The EU Digital COVID Certificate is the only large-scale COVID-19 certificate system in force, addressing the impact of COVID-19 on daily life and also facilitating the travel of non-EU residents to and from the EU. The linking of the Certificate to third country systems has already allowed connections to 51 countries, and will continue to be further extended, including to Africa.

The Commission has also proposed to amend the *rules for travel to the EU*, establishing a link with the EU Digital COVID Certificate and the third-country certificates deemed equivalent to it. This revision would, from 10 January until March 2022, allow for a fresh review of the list of eligible third countries from which non-essential travellers are allowed on the basis of the epidemiological situation. For most other countries, travel would be limited to essential travel, the vaccinated and the recovered,¹⁰ with Member States also able to apply quarantine and additional testing. Member States would accept not only COVID-19 vaccines authorised in the EU, but also those having completed the emergency listing procedure of the World Health Organisation (WHO), if travellers also have a valid proof of a negative PCR test before departure. From March 2022, the Commission proposes to shift from the current hybrid country/person-based to a purely person-based approach, privileging vaccinated and recovered travellers. A coordinated approach to travel restrictions from particularly high-risk areas will continue to be vital to slow or limit the arrival and transmission of new variants in the EU.

Member States and Schengen Associated Countries must follow this Recommendation and coordinate restrictions for all types of travel into the EU+. As set out above, the key need for this effective coordinated approach is now being demonstrated in the case of Omicron variant. The swift application of the *emergency brake procedure* rules showed that the EU framework for a coordinated approach works and will help to limit the spread of the new variant. A day-to-day assessment is needed in order to assess whether further countries should be added to the measures, as well as the nature of testing and quarantine for essential travellers still allowed to come to the EU. However, the reality is that the variant has already spread, and travellers may have contracted the variant before the final point of departure to the EU. It is therefore essential to have the 14-day travel history of all arrivals into the EU, as well as the ability to identify

⁹ Through a Delegated Act under the Digital COVID Certificate Regulation.

¹⁰ Persons who have recovered from COVID within 180 days before the travel, with a negative PCR test before travel.

those in close contact with an infected passenger on the trip, so that they can be effectively traced, including across borders. This underlines the need for all Member States to put in place effective *passenger locator forms*. Without clear information about the countries visited by all travellers in the 14 days before arrival in the EU, a deteriorating situation is more likely to require a complete travel ban from outside the EU for non-essential travellers, and more stringent quarantine requirements for essential travellers. The Commission will propose an EU legal framework for a coordinated approach to passenger locator forms to the extent necessary to stem the spread of COVID-19.¹¹ Transport operators can also play a key role helping to ensure this critical information is available.

Structural resilience and coordination

Close coordination between Member States will play a particularly important part in maximising the ability of the EU to harness its tools to address the current resurgence of the virus. This implies a high level of information flow on planned national measures, a constant monitoring and consistent use of the guidance from ECDC and EMA. Key fora such as the Health Security Committee and the Integrated Political Crisis Response (IPCR)¹² need to be used to the full.

A swift adoption of the full package of the European Health Union proposals and the emergency framework to allow the EU and its Member States to use the new possibilities offered by HERA to act decisively on future serious cross-border health threats is a necessity to tackle the challenges of the pandemic in 2022. In parallel, HERA should reach its goal of giving a full voice to all key stakeholders in defining an operational EU approach.

IV THE IMPERATIVE OF GLOBAL ACTION

The EU should continue to lead efforts to ensure that the whole world is protected against COVID-19. No one is safe until everyone is safe.

From the beginning, the EU has been leading the global response to the pandemic by supporting neighbours and partner countries in facing its health and socio-economic consequences. It has also been a driver of vaccine research, the world's biggest exporter of vaccines, and at the forefront of vaccine sharing. It has also been leading support to countries facing the combination of severe health impacts and economic slump. This work now needs to be further intensified.

Openness and fairness are Europe's trademark. Over 1 billion *vaccines produced in the EU have been shipped to more than 150 countries* on all continents. The EU has exported as much as it has delivered to its citizens. At least every second vaccine produced in Europe is and has been exported. A proposal for a new export transparency mechanism will ensure that the EU can continue to track exports of vaccines and active substances.

Ensuring *access to safe and affordable COVID-19 vaccines* around the world, notably for low and middle-income countries, is a priority for the EU. With only 2% of the population in low-income countries and 19% of the population of lower-middle income countries vaccinated, the priority must be to speed up global vaccination if the pandemic is to be effectively addressed.

¹¹ Existing platforms linking national systems provide valuable experience.

¹² Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response Arrangements.

Africa is a particular focus¹³ and a support package will be identified ahead of the EU-Africa summit in February 2022.

The Commission is constantly working with manufacturers to ensure a continued regular and predictable supply of vaccines. Member States can have confidence that they will have the doses to meet their vaccination needs, including for boosters or adapted vaccines. Member States should therefore also feel confident in continuing to redirect significant numbers of planned deliveries of vaccines to low and middle-income countries.

On top of exports, the EU is delivering on commitments made on *vaccine sharing*. 250 million doses will be shared by Team Europe before the end of 2021, with a total of 700 million to be shared by the middle of 2022, 200 million of these funded through the EU budget. Through an EU Vaccine Sharing Mechanism and supported by a task force set up by the Commission, Member States have already delivered over 100 million vaccine doses worldwide: donations and delivery of vaccine sharing can and must now be accelerated. This is work which will need to be maintained for the foreseeable future, and will be more effective the quicker it is delivered.

These commitments are in addition to Team Europe's existing and leading support to ACT-A and its vaccine pillar COVAX, including deliveries to humanitarian settings through its Humanitarian Buffer. The Commission will follow up on the commitment made by industrial partners at the *Global Health Summit* in Rome to make 1.5 billion vaccine doses available to low income countries at no profit, and to middle income countries at lower prices. Also key is to stimulate production worldwide: Team Europe is also investing €1 billion to ramp up mRNA production capacity in Africa.

However, dose supply is not enough. Member States, manufacturers and COVAX need to work together to ensure that vaccines can be distributed more predictably in the places of greatest need, and with the logistics in place to minimise the risk of wastage. The availability of equipment such as vials and syringes, as well as clear and effective logistical planning, is indispensable to effective delivery by donating countries and absorption of supplies by recipient countries. Also key is support to health services such as personal protective equipment, tests, treatments, and key supplies such as oxygen. The EU will work with partner countries and COVAX to ensure that this is in place.

Team Europe programmes are also under way to help set up vaccine manufacturing capacity and develop conducive regulatory frameworks in partner countries such as South Africa, Senegal and Rwanda, which can act as regional vaccine hubs. HERA will also provide an important new dimension to the EU's work.

By November 2021, 44 third countries had directly requested vaccines and ancillary material from the EU via the *Union Civil Protection Mechanism*. This led to support and co-financing for the delivery of almost 24 million doses to 37 countries, meeting 22 requests in full. More recently, the donations of vaccines has been accompanied with the syringes needed for their administration. The Commission will continue to support operationally and financially further needs in the future.

The EU is also actively pursuing agreements in the World Trade Organisation to ensure the continuing availability of necessary materials through open supply chains and trade, and existing flexibilities in the intellectual property system.

¹³ For example, the EU is currently supporting the vaccination rollout in seven Southern African countries with up to €13 million in support to national health systems and vaccination campaigns.

Cooperation with the US will be a driving force for global solidarity and health security. The EU - US *Agenda for Beating the Global Pandemic* in September included the goal of vaccinating 70% of the world population by mid-2022 and the establishment of a joint EU-US Covid-19 Manufacturing and Supply Chain Taskforce.¹⁴ The EU–US partnership is supporting the efforts at the World Health Organisation towards an improved global health architecture and instruments to improve preparedness for and response to future pandemics and to strengthen the International Health Regulations (IHR).

Enhancing global pandemic preparedness and response, and strengthening the *international framework for global health* is now more urgent than ever. The G20 Declaration adopted at the Global Health Summit in Rome provides a compass for developing multilateral cooperation, with principles emphasising the political commitment to act, using a One Health approach and underlining the need for sustainable financing. The EU should continue to take a leading role in turning these principles into action, identifying shortcomings and finding solutions, working in particular through the G7 and G20. It will work through the G20 Joint Finance-Health Task Force to develop coordination arrangements between Finance and Health Ministries, thus promoting collective action and effective stewardship of resources for pandemic preparedness and response. In doing so, it will follow up on the recommendations of independent panels to establish a global health and finance body and a financial intermediary fund.

At the 74th World Health Assembly, held in May 2021,¹ the EU advocated for the start of a WHO process towards a new Framework Convention on Pandemic Preparedness and Response.¹⁵ A few months later, at the Special Session of the World Health Assembly of 29 November-1 December 2021, WHO members agreed by consensus to start negotiations in 2022 on an international agreement or other international instrument on pandemic prevention, preparedness and response. This is of primary importance in emerging from the present crisis with a stronger global health architecture able to prevent, manage, and significantly reduce the impact of the next pandemic. The EU's participation in the negotiating process is essential. A key element in the work of this global intergovernmental process must be to strengthen transparency.

V CONCLUSION

The EU again faces a serious threat from COVID-19, with the combination of a rise in cases and the Omicron variant. This is again a global threat which needs global action. In tackling this threat, the lesson of the last two years is clear: that whatever the policy area, a coordinated approach by the EU and its Member States has worked better than an uncoordinated approach; and that delayed action comes with higher risk. A collective approach to vaccine production, development and procurement delivered safe and effective vaccines at the earliest possible opportunity and at the scale needed. It now means that there is no obstacle to a swift rollout of boosters, and is also now being applied to ensure timely and equal access to therapeutics. Adoption of the complete Health Union package and the full rollout of HERA will further consolidate this approach, reinforcing preparedness and structural resilience. A coordinated approach to the EU Digital COVID Certificate has delivered a key tool that helped Europe to re-open and is in constant use throughout the EU. Team Europe continues to take a lead in the global fight against the pandemic, as well as efforts to improve global security for the future.

¹⁴ Statement of 22 September 2021.

¹⁵ The Council adopted the position to be taken on the Union's behalf in the World Health Assembly on 20 May 2021 (OJ L 238, 6.7.2021, p. 79).

All these are steps which have made the EU increasingly capable to deal with the pandemic and to help build recovery, with EU action helping national health systems to cope with the huge pressures they face.

We now need to should fast to these principles as the EU tackles the twin challenge of rapidly rising cases and the risk of the Omicron variant. The EU and Member States need to show our readiness to react quickly need to put in place action to address the upsurge in the virus and to maintain the drive for a strong and sustainable long-term response to this threat. This calls for a determined and urgent response:

- The EU and Member States should commit to implementing a joined-up strategy to limit the spread of the Omicron variant, with a day-by-day review of essential travel restrictions and a readiness to impose all necessary controls;
- Member States should make a renewed campaign to target unvaccinated people in all eligible age groups, with targeted national strategies to address vaccine hesitancy;
- Member States should rapidly deploy booster doses to maintain a strong level of protection against the virus and the Omicron variant, starting with the more vulnerable;
- EU agencies should ensure that the necessary scientific guidance is rapidly available;
- The Commission will step up efforts to produce, authorise and jointly procure COVID-19 therapeutics;
- The European Parliament and the Council should adopt the full European Health Union package and the Council the HERA crisis regulation as a matter of urgency;
- Member States should put in place targeted and proportionate precautions and restrictions to limit the spread of the virus, saving lives and reducing the pressure on healthcare systems. Full EU coordination should be assured. The onset of the Omicron variant means that particular attention should be paid to applying and communicating specific measures on contacts during the end-of-year period;
- Member States should agree on and implement the revised approach for free movement with a standard 9-month validity period for vaccination under the EU Digital COVID certificate;
- The EU and Member States should accelerate Team Europe efforts on vaccine sharing to achieve the global vaccination target of 70% in 2022 agreed at the G20 summit in October 2021. Work to support capacity building for sequencing, testing, treatment and vaccination logistics must also be stepped up;
- The EU must be a driving force towards a renewed global health architecture which mobilises the resources needed to deliver stronger, more equitable and more transparent cooperation and solidarity.