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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

COVID-19 - Sustaining EU Preparedness and Response: Looking ahead

1. INTRODUCTION

The global COVID-19 pandemic is not over. Vigilance and preparedness remain essential.

While varying case numbers are observed across Europe, increases are not leading to severe disease or death as often as before. The currently dominant Omicron variant is less severe than previous variants. Population immunity against the virus, whether natural or through vaccination, has also significantly improved.

The past two years have shown that the summer months are likely to see lower incidence rates. The pressure from the pandemic is thus likely to fall in the coming months. This creates a much-needed window to prepare for possible future pandemic surges. We need to act fast and together to fully use this opportunity to prepare for this autumn and winter and beyond.

Infections are still in the millions worldwide. Many people around the world are in lockdowns. Many are still suffering or dying from COVID-19. Waning immunity against infection, and possible winter seasonality all increase the likeliness that new variants of SARS-CoV-2 – the virus that causes COVID-19 – will emerge and spread.

With this in mind, several Member States have started to implement new approaches to manage the on-going COVID-19 pandemic towards a sustainable and resilient recovery.

While Member States are implementing new approaches towards managing the ongoing pandemic, fragmented preparedness and response strategies are likely to undermine the benefits that EU-wide coordination of health security measures has brought so far. The EU Vaccines Strategy has ensured access to enough safe and effective vaccines for all. The WHO and the European Centre for Disease Prevention and Control (ECDC) estimated that COVID-19 vaccines have saved nearly half a million lives across Europe¹ and substantially prevented serious illness.

By working together, the EU has also kept its single market operational, minimised travel restrictions and mobilised manufacturing capacity of critical products when supply chains were disrupted – thanks to the relentless work of people at the frontline. In this new phase of the pandemic, coordination will be, once more, essential.

This Communication puts forward an approach for the management the pandemic in the coming months, moving from emergency to a more sustainable mode. It invites Member States to take actions before the autumn, building on the successful EU-wide coordination for health preparedness and response. The common aim should be to protect public health while keeping society and economy open and resilient.

2. THE CURRENT CONTEXT AND CHALLENGES

When it comes to vaccination, two elements give rise to concerns ahead of autumn: plateauing and/or suboptimal vaccination coverage in several EU Member States; and lower vaccine effectiveness among individuals who have not yet received a booster dose. Over 90 million eligible people in the EU/EEA² are still unvaccinated, including approximately 9 million aged 60 and above, thereby increasing the risk of mortality and emergence of new variants. In addition, there are large differences in vaccination coverage rates across EU/EEA Member States. In some, almost 85 % of the total population has received a full primary vaccination course; in others, the figure is

¹ <https://www.ecdc.europa.eu/en/news-events/who-ecdc-nearly-half-million-lives-saved-covid-19-vaccination>.

² This number includes all individuals eligible for vaccination, excluding children younger than 5 years.

less than 50 %. Secondly, the percentage of adults over 18 in the EU/EEA who have received a booster has started to plateau, currently at around 64%³.

While the pandemic's future course is difficult to predict, one thing is certain: COVID-19 is here to stay. The virus will continue to evolve and the emergence of new variants is highly likely. Our response must be to maintain high levels of readiness for COVID-19 outbreaks and the emergence of new virus variants, and to step up vaccination coverage, with targeted efforts to reach those who are still unvaccinated.

Countries have been adapting their testing strategies, e.g. by focusing testing on severe cases and on people with risk factors for severe disease. With these changes, their coverage of tested people is likely to decrease in Member States. This will also make interpreting epidemiological data more challenging. It is therefore essential that new testing strategies are designed so that they ensure representativeness and therefore provide useful indications on the epidemiological trend.

These efforts have wider importance as health and economic prosperity are intertwined. The global economic loss due to the pandemic has been estimated at EUR 12.25 trillion by the International Monetary Fund⁴. Unprecedented economic and budgetary measures were able to substantially cushion the economic and social impact. Health security preparedness and resilient health and social protection systems are an investment in growth, stability and economic resilience, as has become evident once again in recent weeks, with China experiencing dramatic case increases and reintroducing stringent measures reminiscent of the very early days of the pandemic. Tens of millions of people in China were placed under strict lockdowns in early April 2022. Early evidence shows an impact on logistics and warehousing, as well as some key suppliers pausing production, for example in the electronics sector. Situations like the current one in China, could heighten the risk of adverse impacts on the global economy and global value chains – and the supply of strategic products from China on which the EU depends⁵. Therefore, supply chain resilience must remain a priority.

Over the past two years, we have witnessed the crucial role of resilient supply chains in our response to the pandemic. By monitoring the supply chains of critical input materials for vaccines, supporting the expansion of EU production capacity and working closely with international partners, the Commission's Task Force for industrial scale-up of vaccine production has addressed supply chain bottlenecks and supported the unprecedented ramp-up of production capacity. As bottlenecks can continue to appear, continuing this work remains crucial.

Public health and joint, coordinated preparedness and response capacity must remain at the top of the EU agenda if we are to future proof our economic growth path in the age of pandemics. In addition, the quality and resilience of healthcare systems must be improved, in particular in least developed regions, where the mortality due to COVID 19 has been higher than in more developed regions, as indicated in the 8th Cohesion report⁶. Cohesion funds are available to national authorities for that purpose. Over the 2014-2020 period, a significant part of ESF financing went to

³ ECDC, COVID-19 vaccine tracker, <https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#age-group-tab>.

⁴ <https://www.imf.org/en/Publications/WEO/Issues/2022/01/25/world-economic-outlook-update-january-2022>.

⁵ E.g. active pharmaceutical ingredients (APIs), IT components, critical raw materials and personal protective equipment.

⁶ Commission Communication on the 8th Cohesion Report: Cohesion in Europe towards 2050, COM(2022) 34 final.

support health and social services and the healthcare facilities constructed or improved so far with the support of the ERDF provided an improved service for 53.3 million people.

Russia's military aggression against Ukraine will put additional pressures on Member States' health systems over the coming months. Many of the millions forced to flee Ukraine are vulnerable and in need of emergency care, in particular of mental health support, treatment of chronic diseases and routine healthcare such as childhood vaccination. Refugees and displaced persons need access to healthcare, including vaccinations against COVID-19 as well as, mental health and psychosocial support.

The Emergency Response Coordination Centre has coordinated a wide array of actions in Ukraine and its neighbours to address the health emergencies resulting from the war⁷. For example, the Commission has set up a dedicated European solidarity mechanism through which Member States can request support to transfer patients in need of specialised hospital treatment and care. Operational recommendations from the ECDC⁸ also guide EU Member States and healthcare professionals in preventing and controlling infectious diseases in these situations, so that routine vaccination programmes for displaced persons, as well as vaccination against COVID-19 and other diseases can continue.

The Commission is also closely assessing possible future health threats and the availability and accessibility of medical countermeasures to address the specific health needs that the Russian invasion and on-going war in Ukraine has created. Increasing the number of vaccinated people, including among refugees, will help ease pressure on our healthcare systems. This, in turn, will free up space for helping injured, chronically ill or psychologically traumatised refugees fleeing the war.

3. REMAINING VIGILANT

In light of these ongoing challenges, the future course of the COVID-19 pandemic and its burden on society in the coming years will depend on the decisions we take now.

Member States should make use of this period to strengthen their surveillance, healthcare systems, and overall pandemic preparedness. Meanwhile, researchers and vaccine manufacturers should prioritise the development of universal, variant-proof vaccines that offer longer term protection against infection. Also, the development of COVID-19 therapeutics, particularly targeted for immunocompromised patients who are over-represented in intensive care units, and the continued need for improving access to COVID-19 vaccines and therapeutics globally are areas that require our attention.

(i) Increasing the uptake of COVID-19 vaccines

Vaccination strategies

The EU Vaccines Strategy has secured a wide portfolio of COVID-19 vaccines and access to vaccines for all. Currently, in the context of the Omicron variant, the focus should be on increasing the roll out of booster doses, especially for the most vulnerable groups. We still see large differences in vaccination coverage rates across Member States: while some have reached high

⁷ Commission Communication: Welcoming those fleeing war in Ukraine: Readyng Europe to meet the needs, COM(2022) 131 final.

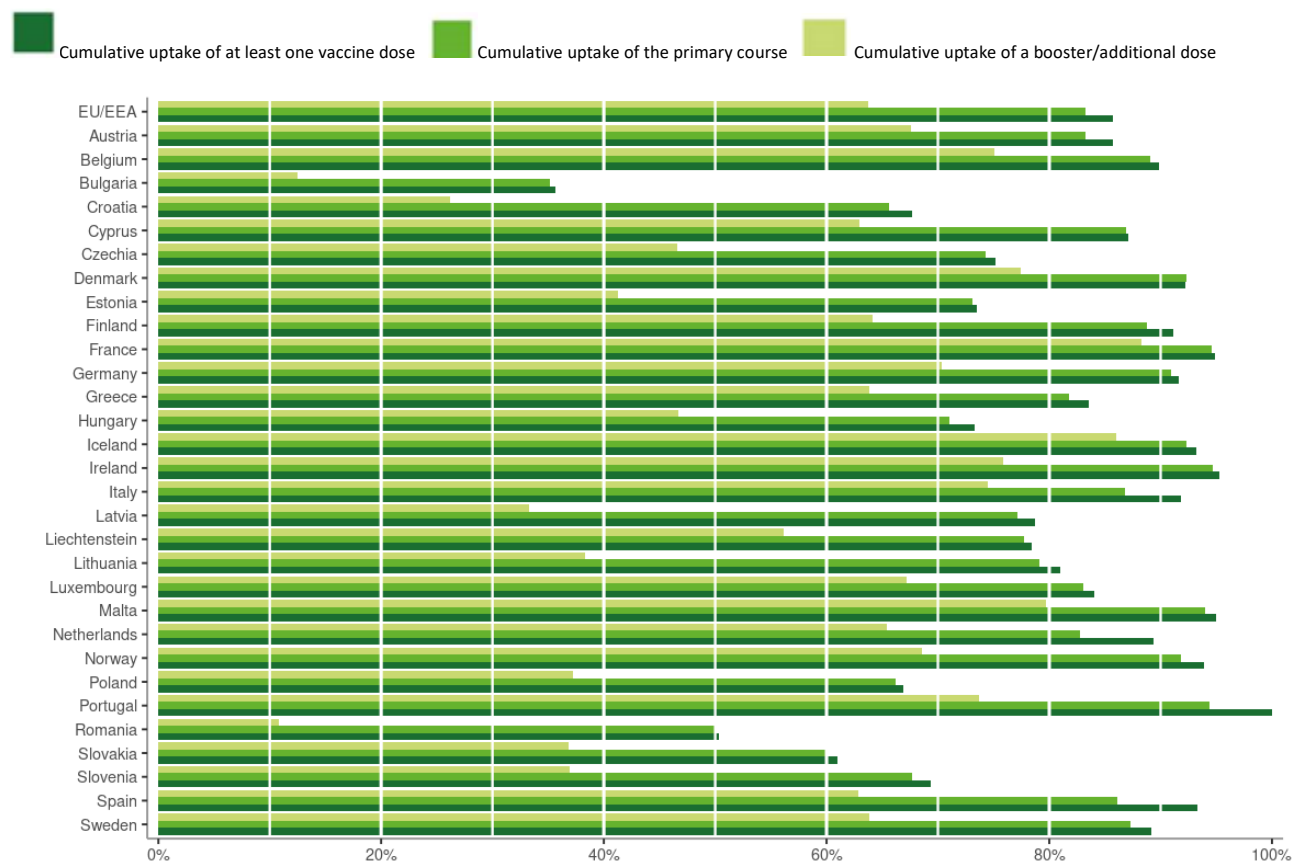
⁸ <https://www.ecdc.europa.eu/sites/default/files/documents/prevention-control-infectious-diseases-russia-aggression.pdf>.

rates, others are significantly lagging behind⁹. Closing vaccination gaps among adults, both within and between Member States, should remain the priority.

Cumulative vaccine uptake among people aged 18+ years, week 13 2022

EU/EEA values based on pooled data from 30 countries reporting

At least one dose administered and with available population data for the target group



In a joint statement published by the ECDC and the European Medicines Agency (EMA) on 6 April¹⁰, the EU agencies state that, based on the latest evidence available, a fourth dose of mRNA vaccines to immunocompromised individuals continues to be recommended. Due to the fragility of the very elderly (adults above 80 years of age), their lower immune response to vaccination and the higher risk of severe COVID-19, a second booster dose could also be administered to this group at least 4 months after the last jab and taking into account the local epidemiological situation.

Concerning children and youth, there are now several COVID-19 vaccines approved at EU level for use in adolescents (12-17 years old) and children (5-11 years old). Overall, vaccination uptake in adolescents in the European Union is high (e.g. more than 71 % of the 15-17 years old have received a full primary vaccination course), but is stagnating at low levels among younger children (e.g. less than 15 % of the 5 to 9 years old have received a full primary vaccination course). While closing vaccination gaps among adults remains the priority, EU Member States should consider strengthening their efforts to increase vaccination coverage rates among younger children.

⁹ ECDC, country overview report, vaccination, <https://covid19-country-overviews.ecdc.europa.eu/vaccination.html>.

¹⁰ <https://www.ecdc.europa.eu/en/news-events/ema-ecdc-statement-fourth-covid-vaccine-dose>.

Our current vaccine portfolio¹¹, and the access it offers to adapted vaccines where necessary in the future, offers Member States a range of possible options when it comes to future vaccination strategies. Member States should be ready to roll out additional doses of vaccines ahead of the upcoming autumn/winter season. This will need to take into account emerging evidence of waning protection conferred from vaccines and natural infection, the epidemiological situation and the emergence of new variants, as well as the development of new vaccines and their effect on infection and further transmission. Moreover, important public health questions will need to be answered, for example for determining the best vaccine combinations and how to best integrate the next generation vaccines in the vaccination schedules. The vaccination campaigns for the upcoming autumn and winter period also need to consider the co-circulation of COVID-19 and seasonal influenza.

KEY ACTIONS FOR MEMBER STATES

- Strengthen efforts to increase the uptake or completion of the primary course among the unvaccinated or partially vaccinated including by continuously monitoring and analysing vaccine hesitancy to overcome it.
- Increase efforts on the uptake of booster doses by all eligible adults, starting from three months after the primary course.
- Before the beginning of the 2022-2023 school year, consider strategies to increase vaccination coverage rates among younger children, e.g. by working with paediatricians and other health professionals who are trusted sources of information for many parents.
- Ensure a fourth dose for immunocompromised individuals and consider a second booster dose for individuals above 80 years of age, taking into account the local epidemiological situation.
- Prepare COVID-19 vaccination strategies for the upcoming autumn/winter season, and incorporate, as of 2023, COVID-19 vaccination into national vaccination programmes.
- Increase awareness of the annual seasonal influenza vaccination campaigns and ensure swift scaling-up of vaccination campaigns among the most vulnerable.

(ii) *Surveillance and intelligence gathering through testing and sequencing*

Integrated surveillance systems

The objective of surveillance should no longer be based on the identification and reporting of all cases, but rather on obtaining reliable estimates of the intensity of community transmission, of the impact of severe disease and on vaccine effectiveness.

The ECDC, along with the WHO, concur that there is a need to build on existing surveillance systems for seasonal influenza and other respiratory infections in order to achieve these goals. Member States should develop strategies for re-establishing sentinel primary care- and secondary care-based surveillance systems¹² for acute respiratory infections, taking advantage of the digitalisation of health information. This should be complemented with strengthening other monitoring systems such as wastewater surveillance of SARS-CoV-2 and beyond (e.g. poliovirus, influenza viruses or antimicrobial resistance).

¹¹ Currently, there are three different vaccine technologies available. With the Valneva vaccine, the EU will soon be able to offer its citizens a fourth vaccine technology.

¹² Sentinel surveillance is the "monitoring of rate of occurrence of specific diseases/conditions through a voluntary network of doctors, laboratories and public health departments with a view to assess the stability or change in health levels of a population.

There is also a continued need for ensuring that sufficient samples are collected for the monitoring of virus strains to detect new variants. The Commission will support such efforts through the EU4Health programme and its Health Emergency Preparedness and Response Authority (HERA) and in collaboration with the ECDC. These efforts should ensure that all sequences are shared through open access platforms, such as the European COVID-19 data portal¹³, to allow for a good understanding of the SARS-CoV-2 variants that circulate in Europe.

This will help identify high impact priority threats and potential gaps regarding the availability and accessibility of relevant medical countermeasures.

KEY ACTIONS FOR MEMBER STATES

- Put in place, as soon as possible, integrated year-round surveillance systems for acute respiratory illnesses (integrating surveillance of COVID-19, influenza and other respiratory viruses) that are sustainable, representative and based on common criteria for case identification and testing strategies in the EU as well as connect general practitioners, hospitals, laboratories
- Agree, with ECDC support, on common criteria for case identification and testing strategies in the EU.
- Continue to collect and share with the ECDC reliable and timely data from integrated surveillance systems¹⁴ as well as from population-based surveillance systems to monitor COVID-19 hospitalisations and deaths.
- Use of complementary surveillance systems, such as wastewater monitoring, to detect COVID-19 surges. Make full use of EU financial support to put in place or reinforce SARS-CoV-2 systematic surveillance in wastewaters.

EU INITIATIVES AND ACTIONS

- The ECDC will guide the transition from comprehensive EU/EEA COVID-19 emergency surveillance to routine integrated, sustainable, representative surveillance systems for acute respiratory illnesses and severe acute respiratory illnesses (integrating COVID-19, influenza and other respiratory viruses).
- The European expert group on SARS-CoV-2 variants will continue to provide advice on the development and potential use of vaccines adapted to new emerging variants.
- HERA will develop, during 2022-2023, a state-of-the-art IT system, generating actionable insights for decision-making in respect of medical countermeasures during both preparedness and crisis phase, complementing existing systems already in place.
- HERA, in collaboration with the ECDC, will strengthen the existing ECDC SARS-CoV-2 network of laboratories to conduct studies on the characterisation of emerging variants, and their impact on the effectiveness of vaccines and therapeutics.
- HERA, in collaboration with the ECDC and international partners, will identify high impact threats and address gaps regarding the availability and accessibility of relevant medical countermeasures
- The Commission will support Member States, with up to EUR 20 million, through the EU4Health programme in setting up integrated and coordinated surveillance systems under the One Health approach for cross-border pathogens¹⁵.

¹³ COVID-19 Data Portal: <https://www.covid19dataportal.org/>.

¹⁴ Such as from SARI (severe acute respiratory infections), ILI (influenza-like infections), or ARI (acute respiratory infections) integrated surveillance systems.

Testing and whole-genome sequencing

Targeted diagnostic testing should be put in place. Priority groups for targeted testing should include, for example, people in outbreak settings for containment or mitigation purposes, people at risk for developing severe COVID-19 and that need therapeutics, and people who are in regular contact with vulnerable populations, such as healthcare workers in acute and long-term care settings.

Rapid antigen tests are being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited PCR test capacities or where clinical needs require faster testing turnaround times. In this context, the EU Health Security Committee set up a dedicated technical working group to regularly review and update an EU common list of rapid antigen tests¹⁶ meeting specific performance criteria for SARS-CoV-2 detection.

KEY ACTIONS FOR MEMBER STATES

- Have sufficient testing and contact-tracing capacities in place, and plan for scaling up national testing strategies, when needed.
- Ensure readiness for rapid response in case of national or local outbreaks with barometer-type policy responses¹⁷.
- Continue capacity building for laboratory sequencing and virus characterisation services, including data reporting on open access platforms, and ensuring uninterrupted viral surveillance.
- Conduct periodical reviews of laboratory safety standards based on the lessons learnt from the COVID-19 experiences, informing necessary revision, and strengthening biosafety standards.
- Continue strategic testing linked to representative and targeted genomic sequencing (following the ECDC guidance¹⁸), to be able to monitor for the emergence and spread of variants.

(iii) Public health preparedness and response measures

Preparedness planning

Evidence shows that non-pharmaceutical interventions, such as mask-wearing, ventilation and physical distancing, are effective in slowing down the spread of COVID-19, if implemented early and comprehensively and accepted by society. Member States should have plans in place to swiftly and effectively reintroduce such interventions if the national or local epidemiological situation requires so, with the goal of protecting vulnerable groups and settings such as hospitals and long-term care facilities. Further synergies should be developed with occupational safety and health strategies to protect workers and ensure business continuity.¹⁹ Clear plans should also be in place

¹⁵ For example: "Direct grants to Member States' authorities: setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union" (CP-g-22-04.01); "Joint Action on Strengthened International Health Regulations and Preparedness in the EU (SHARP)": <https://sharpja.eu/>; and the Integrate Surveillance Joint Action.

¹⁶ Technical working group on COVID-19 diagnostic tests, https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en.

¹⁷ These are pre-defined, predictable policy responses implemented based on epidemiological thresholds, providing a framework for tuning COVID-19 response measures.

¹⁸ ECDC, Guidance for representative and targeted genomic SARS-CoV-2 monitoring, <https://www.ecdc.europa.eu/en/publications-data/guidance-representative-and-targeted-genomic-sars-cov-2-monitoring>.

¹⁹ Increasing preparedness for any potential future health crises is one of the three key cross-cutting objectives set up in the EU Strategic Framework for health and safety at work 2021-2027, COM(2021) 323 final.

managing educational settings should a new variant emerge, not only to limit further transmission among younger age groups and further transmission to vulnerable populations, but also to limit the closure of schools and their impact on the education and well-being of children.

Indoor ventilation is an area where further efforts are required. SARS-CoV-2 transmission principally occurs in indoor settings, especially when ventilation is poor. The use of devices equipped with high quality filters²⁰ should be considered by Member States, particularly in schools, high-risk and occupational settings.

KEY ACTIONS FOR MEMBER STATES

- Review, ahead of autumn 2022, the effectiveness, cost-effectiveness, and social acceptability of non-pharmaceutical interventions implemented to date and prepare to contingency plans to reintroduce public health measures if needed to limit the impact of new variants of SARS-CoV-2.
- Improve or maintain national healthcare system's capacity for coping with increasing numbers of cases of COVID-19 and/or seasonal influenza, including hospital/ICU capacity and adequate supplies of personal protective equipment, vaccines and therapeutics.
- Publish updated recommendations for the use of face masks in specific settings to protect people vulnerable to severe COVID-19, such as the older persons and people with underlying medical conditions.
- Quickly increase air quality indoors with appropriate ventilation, particularly in those spaces that many people visit, reside or work in, such as healthcare facilities and schools.
- Strengthen coordination between public health and occupational safety and health authorities, including drawing up preparedness plans for future health crises in national occupational safety and health strategies.
- Optimise and invest in infection prevention and control practices in both acute and long-term healthcare settings, e.g. by ensuring the availability of sufficient and appropriately trained human resources and of materials, such as personal protective equipment.

Intra-EU and international travel measures

The EU Digital COVID Certificate has been a success in providing citizens with a tool that is accepted and trusted across the EU. It has prevented the emergence of a fragmented system of multiple national certificates. The EU Digital COVID Certificate system is sufficiently flexible to be adapted, if necessary, to possible future developments and new scientific evidence.

Some Member States have also, based on national laws, used the EU Digital COVID Certificate at domestic level as a way to contain the spread of COVID-19, for example by requiring persons to hold a certificate to access cultural events, public transport and places of work. In addition, 37 non-EU countries and territories have joined the EU Digital COVID Certificate system and several more countries have signalled their interest or started the procedure to join, making it a global standard.

The EU Digital COVID Certificate system has proved to be key to the economic recovery, cultural and social exchange also beyond the EU borders.

²⁰ For example, standalone air-cleaning devices equipped with either HEPA (high-efficiency particulate absorbing) filters or filters with comparable efficacy and of ultraviolet germicidal irradiation (UVGI), devices in the ducts of heating, ventilation, and air conditioning systems or placed sufficiently high in rooms (upper-room UVGI).

As noted in Council Recommendation (EU) 2022/107²¹, any free movement restrictions put in place in response to the pandemic, should, in accordance with the principle of necessity and proportionality, be lifted as soon as the epidemiological situation allows. As a result, many Member States no longer require intra-EU travellers to present COVID-19 certificates or impose other travel restrictions. The Commission encourages other Member States, in particular those that lift similar domestic public health measures, to lift such travel restrictions where there is no public health necessity.

The EU Digital COVID Certificate was introduced as a temporary measure initially for one year. However, as it cannot be excluded that Member States consider it necessary to reintroduce it over the course of the coming year, the Commission adopted a proposal to extend the validity of the EU Digital COVID Certificate Regulation until 30 June 2023²². The proposal seeks to ensure that the well-established system remains available should the epidemiological situation require its use.

Furthermore, in the context of travel from third countries, in June 2020, the Council adopted a coordinated approach to travel to the EU²³, which has since then been amended three times. The last amendment, adopted on 22 February 2022, provides that Member States should lift temporary restriction on non-essential travel to the EU for persons vaccinated with an EU- or WHO-approved vaccine and for persons who have recovered from COVID-19 prior to travelling to the EU. The EU Digital COVID certificates and COVID-19 certificates issued by third countries which are deemed equivalent to EU Digital COVID certificates, should be used as the primary means of proving testing and vaccination, and as the only means to prove recovery, given that they can be securely verified.

Finally, efforts to strengthen Member States' contact tracing capabilities regarding cross-border passengers should be further strengthened, where necessary and proportionate. The results from the streamlining of digital Passenger Locator Forms, from promoting the uptake of the EU digital template and application and from enabling the effective exchange passenger data among Member States encourage further simplification and improvements.

KEY ACTIONS FOR MEMBER STATES AND EUROPEAN PARLIAMENT

- Lift the requirement for travellers to present EU Digital COVID Certificates as soon as the epidemiological situation allows, and in particular when lifting similar domestic measures.
- Ensure the adoption of the Commission proposal to extend the application of the EU Digital COVID Certificate Regulation.
- Lift the restrictions for travel within and into the EU, as soon as the epidemiological situation allows and, in particular, when lifting similar domestic measures.
- Join the Passenger Locator Form exchange platform, which will greatly facilitate work in case contact-tracing of cross-border passengers becomes a priority again should the epidemiological situation require its use. For this purpose, adopt digital versions, preferably the EU digital Passenger Locator Form template and application.

²¹ Council Recommendation (EU) 2022/107 of 25 January 2022 on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic and replacing Recommendation (EU) 2020/1475 (OJ L 18, 27.1.2022, p. 110).

²² https://ec.europa.eu/commission/presscorner/detail/en/ip_22_744.

²³ On the basis of Council Recommendation 2020/912 on the temporary restriction on non-essential travel to the EU and the possible lifting of such restriction.

(iv) COVID-19 vaccines, therapeutics and clinical trials

COVID-19 vaccines

A second generation of vaccines will become progressively available, offering additional and possible more effective options, including broader, more robust, and longer-lasting or better protection against infection or transmission. The Commission, working through HERA, and the European Medicines Agency, in conjunction with the EU's international partners, including the Coalition for Epidemic Preparedness Innovations, will continue working with vaccine developers to ensure a coordinated approach for second generation vaccines, meeting the needs of Member States. Moreover, at present, there are a number of vaccine developers working on combined vaccines against COVID-19 and seasonal influenza. If successful, such vaccines could prove a powerful tool for Member States.

Any regulatory flexibilities and simplifications needed for the next generation and universal vaccines against COVID-19, will be addressed by the Commission and EMA by building on the changes that were already made to the regulatory framework²⁴ as well as on existing guidance documents.²⁵

The success of the EU Strategy for COVID-19 vaccines has led to a stable and predictable supply of vaccines, which combined with plateauing vaccination rates, has accumulated unused doses. Therefore, the focus of the Commission and the Member States has now shifted towards working closely with manufacturers to align supply and demand in the most optimal way.

EU INITIATIVES AND ACTIONS

- Develop a strategy for the next generation COVID-19 vaccines encouraging coordination between public health actors, experts and researchers in this regard.
- Support projects on the development of the next generation of vaccines in the frame of Horizon Europe work programme 2022.²⁶
- Identify promising candidates for the next generation of COVID-19 vaccines and mobilise all available instruments to support their development.
- Promote research on new vaccine formulations and investment in world class infrastructures.
- Continue working with vaccine developers and international partners to address the accumulation of unused vaccine doses.

COVID-19 therapeutics

The EU Strategy on COVID-19 therapeutics²⁷ aims to build a broad portfolio of safe and effective COVID-19 therapeutics. It covers the full lifecycle of medicines from research, development, selection of promising candidates, fast regulatory approval, manufacturing and deployment to final use. To date, eight COVID-19 therapeutics of different categories have been authorised addressing different stages and severity of the disease, which are suitable for application either at home or in hospital.

²⁴ Commission Delegated Regulation (EU) 2021/756 of 24 March 2021 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, OJ L 162, 10.5.2021, p. 1–3.

²⁵ https://ec.europa.eu/health/system/files/2021-09/guidance_regulatory_covid19_en_0.pdf.

²⁶ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2022-disease-06-03-two-stage>.

²⁷ Commission Communication: EU Strategy on COVID-19 therapeutics, COM(2021) 355 final/2.

The Commission is supporting Member States to have access to therapeutics and has concluded four Framework Contracts that have ensured the availability of therapeutics in a number of Member States.

The Commission is also prioritising work on new therapeutics, including through the expert group on COVID-19 therapeutics, a subgroup of the European expert group on SARS-CoV-2 variants. It will continue its work on horizon-scanning for promising therapeutics, in close conjunction with Member States, to identify those that potentially offer the most benefits to patients.

New therapeutics should preferably be easier to store and administer. This could be particularly important for use in low-income countries and thus bring benefits to addressing COVID-19 at the global level. In parallel to work on new therapeutics, surveillance of viral resistance (e.g. to monoclonal antibodies or antiviral drugs) is necessary to choose appropriate therapies and to monitor the spread of resistant virus in the population. Surveillance of the potential emergence of antiviral resistance is thus critical during the COVID-19 pandemic.

EU INITIATIVES AND ACTIONS

- Work with Member States to identify priorities for further Joint Procurements for therapeutics and strengthen the integration with established national and EU processes.
- Further enable the coordinated assessment of new therapeutic compounds in large-scale European adaptive platform trials, through the joint access advisory mechanism.
- Foster research and development for COVID-19 therapeutics. HERA will explore possibilities to support projects targeting the development of antivirals.

Clinical trials

Due to the increasing need of developing new vaccines and therapeutics, clinical trials have become more important than ever. Large, multi-national clinical trials are regarded as the best approach to generate adequate clinical evidence in the shortest time for regulatory decisions. The COVID-19 pandemic has shown that there is a need for a faster and more robust procedure for a coordinated approval of multi-national clinical trials by Member States to avoid fragmentation, when small, mono-national trials are competing for the same resources and patient populations.

To enable large-scale multi-national trials for COVID-19 in Europe, addressing the specific public health needs of our continent, two European clinical trial networks have been established under Horizon 2020: one for therapeutics and one for vaccines. In addition, the joint access advisory mechanism supports an efficient use of resources between the trials and avoids duplication of efforts. The vaccine trial network includes public health focused vaccine trials in the elderly, in the general adult population and in children²⁸. Moreover, in January 2022, the European Commission, EMA, and the Heads of Medicines Agency launched ACT EU bringing together clinical research stakeholders to enable bigger, faster and better clinical trials²⁹.

The swift approval of large-scale clinical trials in the EU is also part of the EU Strategy on COVID-19 therapeutics, and a joint action³⁰ was launched to implement the fast-tracked assessment and approval of multinational trials for COVID-19 therapeutics. Moreover, the competence of the EMA

²⁸ EU-COVAT-1 AGED, EU-COVAT-2 BOOSTAVAC and EU-COVPT-1 CoVacc

²⁹ https://ec.europa.eu/health/system/files/2022-01/medicinal_accelerating-clinical-trials-eu_en.pdf.

³⁰ Kick off meeting, 3 February 2022: https://ec.europa.eu/health/events/joint-action-support-coordinated-and-expedited-assessment-clinical-trials-covid-19-therapeutics_en.

emergency task force was extended to include support for cooperation between sponsors to enable large-scale platform trials in public health emergencies.

As global actors, European regulators are contributors to the ongoing revision of the guideline on Good Clinical Practice of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and support the work within the International Coalition of Medicines Regulatory Authorities to facilitate the international acceptability of large-scale platform trials to address health emergencies³¹.

EU INITIATIVES AND ACTIONS

- Strengthen the national capacity in EU/EEA countries to undertake research and contribute to multi-country clinical trials during a crisis; priority should be given to the timely implementation of European multi-state trials.
- Monitor the full and timely implementation of the Clinical Trials Regulation with the development and regular publication of Key Performance Indicators.
- Support the coordinated and harmonised conduct and regulatory oversight of the EU-funded COVID-19 therapeutic platform trials under the Clinical Trials Regulation.
- Implement the ACT-EU initiative strengthening clinical trials that deliver evidence for decision-making, including on vaccines and therapeutics for public health crises and pandemics.
- Implement the EU4Health Joint Action for fast-tracked approval of COVID-19 therapeutic trials and the development of a harmonised procedure for expedited and coordinated assessment of clinical trial applications between Member States in case of future emergencies.

(v) *Resilient supply chains throughout the pandemic*

While vaccine production capacity currently meets demand, vigilance remains needed for supply chain bottlenecks, not only for vaccines, but also for other medical countermeasures and their input materials. Collaboration with global partners continues, such as through the Joint EU-U.S. Taskforce on COVID Manufacturing and Supply Chains.

Moreover, in order to maintain a part of the newly created production capacity in the EU for future health emergencies, the Commission has announced today the launch of EU FAB, a network of ever-warm production capacity for vaccines.³² The Commission is launching the procurement procedure to ensure that sufficient and agile manufacturing capacities for different vaccine types are kept operational and can be readily activated in times of crisis.

Beyond the health industrial ecosystem, further vigilance is also needed on the impact of the next phases of the pandemic on supply challenges in other industrial ecosystems, for instance due to the impact of local lockdowns or staff shortages on logistics. Close collaboration with stakeholders across industrial ecosystems remains important.

The COVID-19 pandemic has also highlighted broader challenges for the Single Market in case of unforeseen demand or supply shocks. Enhanced information-sharing and better communication channels could have made for better management of the emergency response in specific sectors of strategic importance. These aspects, amongst others, will be further assessed in the impact assessment of the Commission's forthcoming proposal on the Single Market Emergency Instrument.

³¹ [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00061-5/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00061-5/fulltext).

³² See the prior information notice published on 17 September 2021: <https://ted.europa.eu/udl?uri=TED:NOTICE:467537-2021:TEXT:EN:HTML&src=0>.

EU INITIATIVES AND ACTIONS

- Continued industry outreach on the impact of pandemic measures around the world on the availability of critical materials.
- Launch EU FAB, a network of ever-warm single and/or multi-technology production facilities in Europe for the production of vaccines.
- Continue supply chain monitoring for critical medical countermeasures and their input materials, notably in collaboration with global partners, including through the Joint EU-U.S. Taskforce on COVID Manufacturing and Supply Chains.

(vi) Addressing mis- and disinformation

The pandemic has been exploited by foreign actors to feed off and deepen insecurities, fears and genuine concerns of citizens for their own advantage. Such information manipulation and interference, including disinformation, has threatened the effective response to the pandemic and undermined public trust in the institutions dealing with the COVID-19 pandemic. For more than two years, the Commission and the High Representative have been supporting Member States to promote trust-worthy content, identify and respond to information gaps, engage in countering information manipulation and interference activities, and attempts by state and non-state actors to exploit the crisis and put citizens' lives at risk.

In response to the massive spread of false and/or misleading information in an unintentional manner, the EU and Member States have stepped up their communications efforts to provide timely and factual information about the pandemic and the measures taken. The EU has increased its cooperation, both within the EU Institutions and in particular with EU Member States, stakeholders from civil society and industry through the Rapid Alert System (RAS), to share information, analysis and best-practices on how to strategically communicate and raise resilience against pandemic-related information manipulation as well as cooperate in the framework of the EU's Code of Practice. The European Union has also published a Joint Communication on COVID-19 Disinformation³³. Due to the global scale and impact of information manipulation and interference in the context of the pandemic, the EU has also closely worked together with international partners, in particular the G7 Rapid Response Mechanism, to share insights into such activity and exchange on response options.

KEY ACTIONS FOR MEMBER STATES

- Ensure a continued, consistent and repeated messaging to reduce mis- and disinformation surrounding COVID-19, supported in particular by a monitoring of the information environment and trends to react and share accordingly.
- Prepare clear messages on balanced non-pharmaceutical interventions, the need for vaccination, and the possible re-introduction of measures based on the best available science.
- Put in place specific community engagement arrangements, for better understanding concerns and risk perception. Consider behavioural insight studies, especially for understanding the acceptance of vaccines – against COVID-19 as well as influenza – to be able to optimise their uptake.
- Prepare communication strategies for possible up-coming needs of additional doses of COVID-19 vaccines with new or modified vaccines.
- Keep sharing analysis and assessments of foreign information manipulation and interference related to the pandemic via the EU's Rapid Alert System.

³³

Joint Communication: Tackling COVID-19 disinformation - Getting the facts right, JOIN/2020/8 final.

EU INITIATIVES AND ACTIONS

- The Commission and the High Representative will continue to build on the actions listed in the Joint Communication on COVID-19 disinformation and the European Democracy Action Plan³⁴ to increase resilience to mis- and disinformation in the longer term. This includes facilitating the exchange of coronavirus-related communication materials between EU institutions and Member States³⁵, as well as monitoring, analysing and swiftly reacting to threats to public health.
- Through the strengthened Code of Practice on Disinformation³⁶ the Commission will enhance cooperation with online platforms and support European fact checkers.
- The Commission is supporting research for understanding how misinformation and information manipulation that may impact vaccine uptake. The need for further research will be assessed.

(vii) *Global dimension: solidarity and governance*

The EU, its Member States and financial institutions, acting as Team Europe, have been at the forefront of the global response to COVID-19 pooling resources and expertise.

The EU has led the way in global solidarity as the world's largest exporter of COVID-19 vaccines, with over 2.1 billion finished doses exported to 166 countries by March 2022, about two-thirds of its overall manufacturing to date, starting from the very early stages of the pandemic. An export authorisation mechanism, in the meantime replaced by a monitoring mechanism, has ensured transparency of vaccines exported and compliance by manufacturers with their obligations in the Purchase Agreements signed with the EU, which included commitments to make vaccines available internationally for ending the global pandemic.

Team Europe has committed close to EUR 6 billion to the ACT-A Accelerator, of which over EUR 4 billion to COVAX, the vaccine pillar, in grants and loans for vaccines purchase for low and lower middle-income countries. The COVAX Humanitarian Buffer that aims to enable vaccination in fragile contexts and difficult-to-reach areas has been supported with EUR 10 million so far. The EU has pledged at least 700 million doses of COVID-19 vaccines for donations to partner countries, of which over 474 million have already been shared. Moreover, it has made its EU Strategy on COVID-19 therapeutics is scalable for the benefit of COVID-19 patients globally. More generally, Team Europe has mobilised over EUR 46 billion to support partner countries in facing the health and socio-economic impact of the pandemic.

With a large supply of vaccines available, the challenge is shifting from providing high numbers of doses to administer these and help countries address their specific challenges in doing so. Team Europe has so far mobilised EUR 1 billion³⁷ to this end. The Vaccine Support Package presented at the African Union-European Union Summit (AU-EU Summit) in February 2022 covers supply, ancillary material, and delivery support. It will be adapted in response to countries' specific and changing needs. The EU calls for enhanced coordination of international efforts to strengthen

³⁴ Commission Communication on the European democracy action plan, COM/2020/790 final.

³⁵ Through the internal Network Against Disinformation and the Rapid Alert System (RAS).

³⁶ Commission Communication, European Commission Guidance on Strengthening the Code of Practice on Disinformation, COM/2021/262 final.

³⁷ https://ec.europa.eu/commission/presscorner/detail/en/fs_22_870.

countries' capacity for effective use and administration of vaccines, such as through the Global Action Plan and its Lines of Efforts.

In parallel, the EU is following up on the conclusions from the AU-EU Summit together with African partners, including on the implementation of the Team Europe initiatives to boost the manufacturing of vaccines, medicines and health technologies in Africa (MAV+) and to further strengthen health systems and regulatory frameworks. The Commission will further enhance collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC) and the African Medicines Agency (AMA), particularly aiming to further increase African health systems' resilience and promote regional cooperation, also in other regions of the world.

Work will continue across the Western Balkans and Eastern Partnership countries to strengthen the capacity of health systems to deal with local outbreaks of COVID-19 as well as other communicable diseases.

The experience with the COVID-19 pandemic has highlighted the need for reforms to the global health architecture and for the international community to respond to future pandemics collectively, effectively and immediately. Following the EU's advocacy, for a new legally binding international instrument on pandemic prevention, preparedness and response³⁸, negotiations have now started. Such an instrument should be a game changer for the global health framework by addressing the gaps exposed by the COVID-19 pandemic.

This goes hand in hand with the need to ensure better compliance and implementation of the International Health Regulations, and to strengthen the WHO including through sustainable and adequate financing to deliver on its mandate.

In continuing its leading role to improve the global health landscape, the EU will pursue multilateral efforts. The COVID-19 Summit convened on 12 May by the United States will be an occasion to enhance global cooperation. Furthermore, building on the Global Health Summit on May 2021, the Commission will convene the first Global Health Policy Forum with civil society organisations in the next months.

In addition, through the WTO, the EU is seeking to reinforce the resilience of global trade in essential products by encouraging its trade partners to undertake commitments to restrain from export restrictions of essential goods, ensure greater transparency of trade measures and facilitate trade in time of crisis. The EU is also actively working to reach an agreement on the role of intellectual property as part of a comprehensive trade and health approach by the 12th WTO Ministerial Conference.

EU INITIATIVES AND ACTIONS

- The EU will continue to pursue, in coordination with international partners, its leading role in the global response to COVID-19, adapting its efforts to the evolving context – notably by providing a further comprehensive vaccine support package to Africa based on supply, ancillary material and delivery support.
- Team Europe will continue to support access to adequate healthcare for all populations and stronger health systems in partner countries in all regions to detect, treat and prevent diseases, and respond to the current and future epidemics and pandemics, notably through strengthened local pharmaceutical production and through a One Health approach. The EU will invest over

³⁸ <https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>.

EUR 1 billion to strengthen health systems and at least EUR 1 billion to support local manufacturing of health products in Africa.

- The EU will continue supporting the Western Balkans and the Eastern Partnership and African countries in strengthening their health systems, including targeted service delivery, primary and secondary care, health workforce and health information systems, and a basic package of essential services to withstand shocks, to enable early warning of disease outbreaks and to prevent anti-microbial resistance.
- The EU will continue to encourage its partners in the Western Balkans to join the activities under the EU4Health programme, to be signatories to the EU Joint Procurement Agreement (which should also be opened to DCFTA countries 39 in the Eastern partnership), and, alongside Ukraine (and other DCFTA countries) to be able to participate in the Health Security Committee as observers.
- The EU will support and drive multilateral efforts to learn the lessons from the current pandemic by improving global health strategies, the global health architecture and the International Health Regulations.
- The EU will engage with trade partners in the run-up to the 12th Ministerial Conference of the World Trade Organisation to ensure the continuing availability of necessary materials through open supply chains and trade and to actively support work in the WTO on the response to the pandemic, including on intellectual property aspects.

4. MEASURES TO BE TAKEN IN THE MEDIUM AND LONG TERM

COVID-19 has created long-term challenges that the EU needs to address in order to be better equipped to sustainably address health threats posed by infectious diseases. Building on the shorter-term actions set out in the previous chapter, opportunities exist to further enhance, by taking a One Health approach, pandemic preparedness and strengthen coordination in responses between Member States as well as at the global level.

Furthermore, the Commission will continue supporting additional preparedness measures under the Union Civil Protection Mechanism further developing its rescEU strategic reserve of medical equipment.

It is important to ensure an alignment between COVID-19 recovery measures and long-term climate, environmental and social goals, to build back better.

Looking ahead, the ECDC has provided an analysis on qualitative long-term scenarios that demonstrate a wide range of possible outcomes, as shown below. In mid-April 2022, the recent resurgence observed in Europe appeared to be slowing down. This, combined with signs that the sustained transmission recently observed among older populations may not translate into rates of severe disease as significant as those seen earlier, results in a current situation that lies between ‘a diminished threat’, and ‘regular reinfections’ scenarios. It will have to be seen which scenario will hold in the long-term.

Five possible phases: Long-term scenarios for the development of the COVID-19 pandemic

A diminished threat	Regular reinfections	Barely manageable winters	Unmanageable winters	A new pandemic
<ul style="list-style-type: none"> • COVID-19 hospitalisations and mortality has become and 	<ul style="list-style-type: none"> • New immune-evading variants continue to emerge, driving frequent 	<ul style="list-style-type: none"> • The virus outpaces vaccines and our immune system's protection against 	<ul style="list-style-type: none"> • There is sufficient waning of immunity and viral evolution to regularly lead to 	<ul style="list-style-type: none"> • Under this scenario, the persistent threat of emergence of novel pandemic

³⁹ The Deep and Comprehensive Free Trade Areas (DCFTA) are three free trade areas established between the European Union, and Georgia, Moldova, and Ukraine respectively.

<p>remains very low.</p> <ul style="list-style-type: none"> • COVID-19 is deemed across the EU/EEA to be routinely manageable. 	<p>reinfections.</p> <ul style="list-style-type: none"> • Although COVID-19 mortality remains relatively low, waning immunity is apparent and there are non-negligible rates of hospitalisations and mortality among at-risk populations. 	<p>infection and onward transmission.</p> <ul style="list-style-type: none"> • SARS-CoV-2 variants emerge with higher intrinsic severity, combined with waning immunity. • A declining willingness among the population to take additional vaccine doses also contributes to significant winter-time strains on healthcare systems. 	<p>hospitalisation rates among the general population that exceed healthcare system capacities.</p> <ul style="list-style-type: none"> • Such circumstances would require stricter population-level NPIs, but these are highly unpopular and poorly adhered to, and thus mandatory measures have been effectively abandoned. • General vaccination fatigue. 	<p>strains is eventually realised.</p> <ul style="list-style-type: none"> • Return to 'flattening the curve' approaches for buying time to introduce revised vaccine. • The (re)imposition of stringent restrictions in an already pandemic-fatigued population would require careful assessment.
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Tackling wider health impacts of the pandemic, including “long COVID”

The complex, direct and indirect health impacts of the COVID-19 pandemic are so far only partly understood. Reaching a full understanding of such health impacts will require further data collection and analysis in the coming years. Moreover, the magnitude of the public health, economic and social issues related to people suffering from post-COVID-19 condition, also referred to as “long-COVID”, needs to be understood.

It will be important to increase the focus on healthcare system resilience adaptability in terms of financial and human resources, as well as allocated goods for healthcare delivery. Additionally, to better enable planning of healthcare need, we must improve our understanding of excess mortality and morbidity levels observed during the pandemic, which will also relate to backlogs in non-COVID care. Similarly, more efforts should be made at all levels to tackle conditions that have shown to increase the risk of severe outcomes from COVID-19 such as obesity and diabetes.

In parallel, the burden of the pandemic on mental health has increased, as reflected in a significant rise of reported anxiety and depressive disorders in most European countries. Available data suggest that the impact of the COVID-19 pandemic on people’s mental health has been especially marked in children⁴⁰ and young people, women, and vulnerable groups such as older people, and people with underlying health conditions or disabilities⁴¹.

The Commission launched in February 2022 a call for proposals for projects to support the mental health of vulnerable children and young people⁴², each to be funded with a EUR 4 million grant, and also contributing to the European Year of Youth. On 4 May, the 2021 EU Health Award will reward community-based initiatives alleviating the mental health impact of COVID-19. Up to EUR 750 000 is available to help roll out two practices tackling mental health challenges during COVID-19.

Speeding up digitalisation in health

The COVID-19 pandemic has clearly demonstrated the importance of digital services and has triggered a huge acceleration in the uptake of digital tools, including for public health and in

⁴⁰ UNICEF’s 2021 report on ‘The State of the World’s Children’ was dedicated to mental health. It warned that children and young people may feel the negative impact of the pandemic on their mental health for many years to come: <https://www.unicef.org/media/108121/file/SOWC-2021-Europe-regional-brief.pdf>.

⁴¹ WHO, 2022, Mental health and COVID-19: early evidence of the pandemic’s impact: scientific brief, 2 March 2022. <https://apps.who.int/iris/handle/10665/352189>.

⁴² EU4H-2022-PJ-03: DP-g-22-07.01/03 Call for proposals on promoting mental health.

healthcare services⁴³. Making digitalised systems within and outside Europe interoperable will also be instrumental for linking inter-regional and global surveillance and response as well as enhancing their efficiency. The Commission's upcoming legislative proposal on a European Health Data Space will aim to harness the power and potential of health data and for the benefit of patients, to increase the resilience of health systems and their capacity to respond quickly to health threats.

5. CONCLUSION

The COVID-19 pandemic has had a multitude of wide-ranging impacts on public health, on our health systems, our economies, and our entire way of life. How we approach the next phase in the pandemic could prove to be a turning point.

The relaxation of non-pharmaceutical interventions offers great relief, in particular for citizens and health systems, but also for economic operators recovering from the devastating impacts of the pandemic. Yet continued efforts are pivotal. The pandemic is still with us and future surges are likely. Effective preparedness and response should be viewed as a continuous process, and should be accompanied by ongoing evaluations of policies, plans and procedures based on lessons learned in order to be as effective as possible.

We can and must do more to identify and act on those lessons, so that we improve our public health preparedness and response to future pandemics and health crises. To succeed, we need to jointly address the gaps in our public health and healthcare systems and make sure that they are resilient enough to face future health threats, while recognising the importance of the One Health approach and of coordination across sectors in making the EU better prepared for emergencies. If we invest in these areas now, we also invest in the future as we may be able to curb impact of future outbreaks or pandemics.

Vaccination, natural immunity and a coordinated EU approach offer us a window of opportunity to act to better prepare Europe for the different scenarios to come. The swift adoption of all European Health Union proposals will further strengthen the EU's capacity to prevent, prepare and respond to health crises. This vigilance can pave the way for stronger health security at European and global level. Let's seize that opportunity and act while the window is still open.

⁴³ Such as electronic health records, telehealth, e-prescriptions and digital health applications. Moreover, digital platforms and apps have been used for COVID-19 monitoring and surveillance, contact tracing, vaccination programmes, and for issuing and verifying COVID-19 certification.