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PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

EU response to COVID-19: preparing for autumn and winter 2023

1. INTRODUCTION

The COVID-19 summer wave, driven by Omicron BA.4 and BA.5, reminded us very clearly that the pandemic is not yet over. Between the beginning of June and the middle of July¹, the EU/EEA saw a tripling of COVID-19 cases. Since then, case numbers have been falling again, but remain high among people aged 65 years and over, with consequent increases in hospitalisation rates and intensive care unit (ICU) admissions in this age group². Overall, more than 2 300 people still die every week in the EU/EEA of COVID-19.

These numbers are worrying not least since they are likely to be an underestimation of the real situation and they do not account for repercussions such as long-COVID, as well as the impact of the pandemic on mental health. In addition, all countries have lifted most restrictions and their populations are experiencing pandemic fatigue, which can lead to changes in behaviour. These factors make it easier for the virus to circulate rapidly in the EU and this opens the door to new variants emerging that could evade immunity, spread more easily or cause more severe disease. It is therefore possible that the costly gains made in response to the pandemic could be lost if the virus is not controlled and further infections are not prevented.

Since the end of April this year, the uptake of COVID-19 vaccines in the EU has barely changed. Among people aged 60 years and over, 7.5 % are still unvaccinated and 16.3 % have not received their first booster. Looking at the vaccination rates in adults, 14.1 % of people aged 18 and over are unvaccinated and 35.5 % have not received their first booster. Additionally, while protection from vaccines continues to be high against severe outcomes (severe diseases, hospitalisation and death), protection is also waning, as most people received their last shot several months ago. The widespread exposure to Omicron, the varying vaccination coverage across and within countries, and waning protection from both natural infection and vaccines presents a complex landscape of immunity in the population.

The past 2 years have shown that the EU could face another COVID-19 wave this autumn and winter. With people returning from holidays, schools reopening, and colder weather driving people indoors for social gatherings, infection rates could further spike. It is also likely that the EU will face a season with an active circulation of other respiratory viruses, including influenza, as usual in the winter season. This forecast presents challenge to the already overburdened national healthcare systems and their workforce across the EU.

This Communication, building on the set of actions proposed in April³, urges Member States to put the necessary integrated strategies and measures in place to help avoid a surge of COVID-19 this autumn and winter, and to put in place the necessary structures that allow us to respond to future outbreaks in a sustained manner. Moreover, the Commission calls on Member States for continued coordination of preparedness efforts across the EU, ahead of the next wave and further rollout of vaccination programmes. Finally, by continuing to act now, we can limit the expected pressure on our healthcare systems, the disruption of our economies and challenges for our society.

¹ By the end of week 22 of 2022, the 14-day COVID-19 case notification rate for the EU/EEA was 350 (country range: 8.1-3 303) per 100 000 population, which increased to 1 207 (country range: 43.0-4 945) per 100 000 by the end of week 28 of 2022.

² Hospital admission rates per 100 000 nearly doubled between early May and mid-July 2022, and current levels are at over 40% of the pandemic maximum. ICU admission and occupancy rates currently correspond to 16% and 18% (respectively) of the maximum rates reported since the start of the pandemic.

³ 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* (COM/2022/190 final).

2. COVID-19 VACCINE DEVELOPMENT AND AVAILABILITY FOR AUTUMN AND WINTER

The development of COVID-19 vaccines can be considered a scientific triumph, and it is estimated that their successful roll-out has saved around 20 million lives worldwide during their first year⁴. In the context of the current resurging pandemic, driven by Omicron BA.4 and BA.5, it is important to reinforce the message that the current COVID-19 vaccines (monovalent vaccines targeting the original SARS-CoV-2 virus) continue to offer high levels of protection against hospitalisation, severe disease and death. Vaccination continues to be the most reliable way of avoiding severe disease and therefore reducing mortality from COVID-19.

At the same time, vaccine manufacturers are developing **adapted mRNA vaccines to be used as boosters** targeting Omicron variants. Adapted versions of the Comirnaty and Spikevax vaccines, targeting the original SARS-CoV-2 virus as well as the BA.1 Omicron subvariant were approved by the European Medicines Agency (EMA) and authorised in the EU at the beginning of September, under an accelerated process provided for by the Commission in 2021⁵. The EMA has also started a rolling review for a version of Comirnaty adapted to the original SARS-CoV-2 virus and to its Omicron subvariants BA.4 and BA.5, for a potential accelerated authorisation in the autumn. The adapted mRNA vaccines are expected to offer increased, broader protection against current and future variants of concern.

A second category of **protein-based vaccines, awaited in the coming weeks**, are expected to protect against SARS-CoV-2 variants and complement our broad vaccine portfolio and choice for vaccination strategies⁶. The Nuvaxovid and VLA2001 vaccines, currently available in the EU, use safe and effective conventional vaccine platforms that have the potential to increase COVID-19 vaccination acceptability. In addition, the Vidprevtyn and PHH-1V vaccines, targeting other strains of COVID-19 variants of concern, will offer effective alternatives for heterologous boosters. The EU vaccines contracts ensure that Member States have access to these latest vaccines in quantities needed as soon as they become available. In August this year, the first Joint Procurement framework contract was signed for a COVID-19 vaccine with the company HIPRA.

It is impossible to predict what variants will be predominant during the autumn and winter period, but the Union will continue to ensure access to a broad and flexible vaccines portfolio providing a very good level of immunity against SARS-CoV-2.

Thanks to the EU's Vaccines Strategy⁷, Member States are equipped to plan and launch their vaccination campaigns including adapted vaccines ahead of autumn, offering an additional booster as needed, according to the characteristics of such vaccines and national recommendations. The Commission continues its work with manufacturers to ensure that Member States will receive more adapted vaccines as a priority as they become available. In addition, the Commission continues to be in close contact with the suppliers of critical components that are needed throughout the production process. Furthermore, the EU-US joint COVID-19 manufacturing and supply chain task force⁸ has agreed on a list of critical materials necessary for the production of COVID-19 vaccines that are

⁴ The Economist, *Covid-19 vaccines saved an estimated 20 m lives during their first year*, 7 July 2022, <https://www.economist.com/graphic-detail/2022/07/07/covid-19-vaccines-saved-an-estimated-20m-lives-during-their-first-year?frsc=dg%7Ce>.

⁵ 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).

⁶ In addition to the existing contracts with Sanofi and Novavax, the EU has recently put in place a contract via the Joint Procurement Agreement to ensure Member States' access to the HIPRA vaccine.

⁷ https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en.

⁸ https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_4847.

considered worth monitoring⁹. Such monitoring will serve as an early warning scheme and will help to identify possible bottlenecks in the supply chain at an early stage.

Planning for the medium-term, the Commission is engaging with international partners and developers of potential pan-coronavirus, or combination vaccines that elicit broader, stronger, and longer-lasting immune responses. Moreover, the Commission is closely following the development of vaccines with intranasal, intramuscular and intradermal delivery systems. These vaccines are expected to be easier to administer, more accessible and may increase vaccination acceptance. In addition, the EU vaccines contracts also ensure that companies keep Member States closely informed on the progress made in the development of these vaccines.

Overall, funding for research and development, adapted regulatory pathways, and development of manufacturing and infrastructure capacities will be key to ensure access to safe and effective next-generation vaccines.

3. ROLLING OUT THE NEXT COVID-19 VACCINATION STRATEGIES

As different vaccines will be made available at different times in the coming weeks and months, Member States should consider both the potential protection offered by adapted vaccines and the benefits of vaccinating people in particular risk groups at the right time. National vaccination strategies should be coordinated and consistent with each other to avoid any major differences across the EU/EEA and to provide clarity and coherent messages to the public. Moreover, they should be rolled out ahead of the next wave.

The priority of national vaccination campaigns should remain improving vaccine uptake of the primary vaccination course and first booster dose among eligible individuals. This is of particular importance for population groups at higher risk of severe outcomes and for countries with lower vaccination rates. Significant gaps and disparities across countries and the population remain, and these should be tackled to strengthen protection.

The following section puts forward suggestions for Member States regarding their national COVID-19 vaccination strategies, including priorities and factors to be considered when preparing and implementing them¹⁰.

SUGGESTED ACTIONS FOR COVID-19 VACCINATION STRATEGIES FOR AUTUMN AND WINTER 2022-2023

Overall objectives and priorities to implement at this stage of the pandemic

- **Continue national COVID-19 vaccination strategies using the currently available vaccines to reduce hospitalisations, severe disease and death.**
- **Close vaccination coverage gaps.** Improving vaccine uptake of the primary vaccination course and first booster dose among eligible individuals, including eligible children and adolescents according to national vaccination schedules, remains a priority. This is of particular importance for population groups at higher risk of severe outcomes and for countries with lower vaccination rates.
- **Maintain sufficient vaccination capacities,** either by reactivating vaccination centres or by using other resources, such as general practitioners.

⁹ The compiled list is primarily based on experience incurred during upscaling of the production of COVID-19 vaccines. The list covers a wide range of products groups (44 essential items), such as enzymes and single-use and chromatography materials.

¹⁰ These recommendations build on the joint statement from the ECDC and the European Medicines Agency (EMA) on the administration of a fourth dose of mRNA vaccines of 6 April 2022 as well as *Preliminary public health considerations for COVID-19 vaccination strategies in the second half of 2022*, published by the ECDC on 18 July 2022.

- **Prioritise the administration of an additional booster dose (second or subsequent) for specific population groups:** people aged 60 years and over and individuals of any age at risk of severe disease (e.g. individuals with underlying comorbidities, immunocompromised individuals and pregnant women). The boosting of healthcare workers and long-term care facility personnel should also be considered. **Subsequent boosters could be administered as early as 3 months after the previous one**, and priority should be given to people who received their last booster more than 6 months ago.
- Ensure **long-term care residents** receive the recommended booster doses.
- **Combine COVID-19 and influenza vaccination campaigns where possible**, particularly targeting vulnerable groups and relevant age groups.

Measures to take when adapted COVID-19 vaccines are available

- **Develop national vaccination programmes outlining which vaccines should be used for which population groups.** This will depend on the characteristics of the adapted vaccines compared to first-generation ones, the epidemiological situation, and the possible emergence of new variants. Such strategies should be discussed in the appropriate EU forums¹¹, to exchange on experiences and to ensure coordination among countries.
- **Identify which population groups should be prioritised for** the adapted vaccines, in particular if these vaccines show greater effectiveness against variants circulating during autumn and winter.
- **Ensure there is sufficient capacity to administer the vaccines** when adapted vaccines are delivered, so vaccination campaigns can start immediately.
- **Closely monitor the effectiveness and safety** of the [new and] adapted vaccines once widespread rollout commences. If needed, national vaccination strategies should be adapted when more evidence on the performance of these vaccines becomes available.

Communication strategies related to the autumn and winter vaccination strategies

- **Implement and, if possible, coordinate effective communication initiatives and strategies to promote uptake of additional vaccine doses, and promote completion of the primary series by those who have not yet done so.** Clear information should be provided around the rationale for recommendations, and the benefits of the primary course and boosters for different population groups, including for those who already had the disease.
- Ensure that capacity is in place to **regularly update** public communication strategy, based on epidemiological developments, changes in the public's perceptions and attitudes of the ongoing pandemic and COVID-19 vaccination, including the capacity to monitor and swiftly respond to false or misleading information.
- **Increase vaccine confidence** by monitoring and addressing the public's questions and concerns, explaining the science behind the recommendations and debunking mis- and disinformation in the mainstream media and on social media. **Clear, consistent, and evidence-based messaging demonstrating the continued safety and effectiveness of COVID-19 vaccines is key.** **Target hard-to-reach population groups** through tailored communication and draw on health professionals and community leaders as trusted sources of information.
- **Ensure pro-active communication once new and adapted vaccines will become available.** Ahead of the deliveries of adapted vaccines, Member States should communicate clearly to the public to avoid confusion about how boosters will be given in the coming months, when and why it will happen, and who will have access to them.
- **Address the political dimension of vaccine hesitancy and disinformation campaigns linked to anti-Western and anti-EU narratives.** Particular challenges include channels where disinformation is circulating in relation to other crises, especially the Russian military aggression against Ukraine.

¹¹ Such as the Health Security Committee.

4. ESSENTIAL AREAS FOR INCREASED EFFORTS

Surveillance of respiratory viruses

The current testing strategies and reduced sequencing efforts in some countries are creating a dangerous blind spot in our knowledge of how the virus is spreading and evolving. There is an urgent need to develop and sustain resilient population-based **integrated surveillance systems**. Such systems would monitor different diseases like **influenza, COVID-19, and other respiratory virus infections**¹² in the EU in an integrated way. Data from such surveillance systems will enable countries to closely monitor the spread and intensity of circulating respiratory viruses and to detect changes in trends and the emergence of new variants of concern. This will, in turn, guide control measures and mitigate the impact of new variants. These systems will be a key element at this stage of the pandemic and for possible future cross-border health threats.

Strategic prioritisation and sustained financing are required to further expand and develop ‘**sentinel systems**’ to make them fit for purpose. Sentinel systems have been commonly used for the surveillance of respiratory infections (e.g. influenza). Instead of testing the whole population, a sentinel surveillance system takes samples from a number of representative cases from specific sites, such as general practices or hospitals, which are evenly spread across the country or region. A sentinel system with sufficient sites that are producing sufficient volumes of testing and that are geographically and demographically representative of the whole population of a country, is an efficient and effective way to monitor the spread of a (respiratory) infection.

Member States should aim to boost the number of sentinel sites, ensure that these sites represent the geographic and demographic distribution of their population, and increase the number of tests performed in sentinel surveillance sites. They should also plan to upscale their testing capacity, particularly if required to respond to the emergence of a new variant of concern or influenza variant. A sufficient **sequencing volume** also needs to be maintained to monitor circulating viruses and detect new virus variants promptly.

On 18 July 2022, the ECDC and the World Health Organization Regional Office for Europe published guidance¹³ with practical advice for countries on setting up effective surveillance systems and ensuring continuity of national surveillance in the 2022-2023 winter season and beyond. The guidance sets out the many advantages offered by population-based integrated surveillance systems, and Member States are strongly encouraged to study and follow up on its recommendations. Following the guidance will improve comparability between Member States and produce more robust epidemiological data; analysing this data will enable more effective and timely responses, ultimately improving the EU’s pandemic preparedness. Member States are invited to periodically share information with the ECDC about the status of their surveillance systems for respiratory viruses, for example by responding to short surveys when circulated.

Wastewater-based surveillance has emerged during the COVID-19 pandemic as a complementary tool to gather information on large population groups. It has been included more systematically in national surveillance strategies for detecting SARS-CoV-2 and its variants, and different EU measures have been implemented to support countries in these efforts. For example, 26 Member States have received direct action grants to support wastewater surveillance and related activities¹⁴.

¹² Such as respiratory syncytial virus (RSV) infections or new viral diseases of public health concern.

¹³ 18 July 2022, ECDC, *Operational considerations for respiratory virus surveillance in Europe*, <https://www.ecdc.europa.eu/en/publications-data/operational-considerations-respiratory-virus-surveillance-europe>.

¹⁴ https://environment.ec.europa.eu/news/coronavirus-response-monitoring-wastewater-contributes-tracking-coronavirus-and-variants-across-all-2022-03-17_en.

The forthcoming revision of the Urban Wastewater Treatment Directive¹⁵, planned to be adopted this autumn, will introduce wastewater surveillance, with the monitoring of public health relevant parameters including the virus and its variants in urban wastewaters. Member States are encouraged to continue their efforts to systematically monitor SARS-CoV-2 in wastewater surveillance and to apply the actions set out in the related Commission recommendation¹⁶.

Non-pharmaceutical interventions

Vaccines are a crucial part of the response to COVID-19. However, our experience with this pandemic has shown that our efforts need to include non-pharmaceutical interventions to limit the virus' spread, protect vulnerable groups and reduce the pressure on healthcare systems. Examples of highly effective non-pharmaceutical interventions include wearing masks and more restrictive measures like limiting the size of gatherings. Particularly if such interventions are implemented ahead of or at the beginning of a next wave, their impact will be greatest. It is therefore possible that any of the non-pharmaceutical interventions will need to be reintroduced in the coming months.

At this stage of the pandemic, the epidemiological situation varies between Member States. As such, the best and most efficient public health response may also differ. Countries will need to assess their particular epidemiological situation in terms of impact on public health, healthcare capacity, and the social acceptance of such public health measures, and make decisions accordingly. However, coordination of national approaches in the Council's integrated political crisis response (IPCR)¹⁷ arrangements and the Health Security Committee¹⁸ was essential in the previous waves to encourage a coherent approach in the EU and single market. It is essential that this continues.

The key indicators to assess when deciding on reintroducing non-pharmaceutical measures are set out below.

Data and thresholds to assess for reintroducing non-pharmaceutical measures

- Severity indicators to be used: incidence of **severe acute respiratory illness (SARI) due to COVID-19 or influenza by age; mortality attributed to COVID-19 or influenza by age.**
- Alternatively, **specific COVID-19 or influenza hospital and ICU admissions and/or hospital and ICU occupancy rates** can be used. These should ideally be broken down by age.
- Severity indicators must be combined with data on **healthcare capacity and health systems performance** to be able to assess the epidemic impact. Such impact assessments should be carried out regularly and be triggered by increasing trends in severity indicators.
- Data from previous years will help determine country-specific **thresholds of epidemic severity**, taking into account the different levels of severe disease and available healthcare capacity.

In many Member States, the mandatory use of **face masks** in healthcare settings and long-term care facilities is still in place. Their use in closed public spaces, including public transport, can be a first option to limit community transmission. Recent evidence shows that FFP2 face masks, which are readily available in the EU/EEA, have a stronger protective effect than medical masks or cloth masks in the community. Member States are therefore strongly encouraged to consider their use in specific settings. Ensuring adequate **ventilation** indoors is a key measure for reducing the risk of transmission

¹⁵ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (91/271/EEC).

¹⁶ Commission Recommendation of 17.3.2021 on a common approach to establish a systematic surveillance of SARS-CoV-2 and its variants in wastewaters in the EU, C/2021/1925, (OJ L 98, 19.3.2021, p. 3–8).

¹⁷ <https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/>.

¹⁸ https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response/health-security-committee-hsc_en.

of SARS-CoV-2 and other respiratory viruses¹⁹. More efforts are needed to improve ventilation across the EU/EEA. Other measures such as **working from home** or **limiting the size of mass gatherings** have proved effective to limit transmission of the virus. When implemented ahead of increases in cases, these measures can avoid the need for more disruptive ones such as lock downs, closing businesses and schools, stay-at-home recommendations and travel restrictions. **Political commitment and community engagement** are key for the success and the effectiveness of non-pharmaceutical measures.

Reopening of schools

As children return to school after the summer break, it is crucial to maintain safe school environments and minimise student and staff absences by preventing the transmission of SARS-CoV-2 alongside other respiratory viruses²⁰. Children of all ages are susceptible to and can transmit SARS-CoV-2. Children are often asymptomatic or present with mild symptoms of infection, but severe cases do occur, particularly among children with risk factors for severe outcomes. Post-COVID condition (or long COVID) has also been reported among children.

Important measures such as promoting the vaccination of pupils and staff against COVID-19, encouraging good respiratory and hand hygiene, establishing improved ventilation systems in school premises, and issuing frequent reminders to stay home when experiencing respiratory symptoms, are vital tools to reduce virus transmission. The implementation of in-school mitigation measures should be adapted to the educational setting and age group of the students. In addition, such measures should take into account the need to provide children with an optimal learning and social environment. The guidance published by the ECDC in July 2021²¹ and the recommendations from this document remain valid in this regard.

The COVID-19 pandemic has disrupted the lives of children and adolescents affecting their everyday routines, education, health, development and overall well-being. It is therefore important to keep in mind the negative impacts of school disruptions on the health and development of children. The implementation of measures at schools should be aimed to be kept at a minimum and the further loss of learning should be prevented.

Strengthening healthcare systems and capacity

The COVID-19 crisis has tested the resilience and agility of European health systems in an unprecedented way. In the summer of 2022, EU health systems continue to face challenges due to an increase in COVID-related hospital admissions and the need to clear the pandemic-induced backlog of non-COVID care. This pressure on healthcare systems is exerted against the backdrop of other longstanding challenges, such as the persistent shortages of health workers, which the COVID-19 pandemic has aggravated. According to a survey by the ECDC, many Member States are reporting issues in retaining and recruiting a sufficient number of healthcare staff with the right competencies²². Healthcare systems risk having insufficient capacity for the winter of 2022 if healthcare funding and human resources are not increased. Furthermore, other respiratory viruses (e.g. influenza) might pose an additional burden on healthcare systems. The pandemic has shown that it is imperative to have a strong, resilient and well-staffed healthcare system.

¹⁹ If adequate ventilation is not possible, the use of air-cleaning devices, such as those equipped with either HEPA (high-efficiency particulate absorbing) filters or filters with comparable effectiveness and ultraviolet germicidal irradiation (UVGI) can be considered.

²⁰ Such as influenza, respiratory syncytial virus (RSV) and norovirus.

²¹ 8 July 2021, ECDC, *COVID-19 in children and the role of school settings in transmission - second update*, <https://www.ecdc.europa.eu/en/publications-data/children-and-school-settings-covid-19-transmission>.

²² 3 August 2022, ECDC, *Assessment of workforce capacity and training needs for the prevention and control of communicable diseases - report on 2021 survey*, <https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-Assessment-Capacity-Training-Needs-EUEEA-2021.pdf>.

Investments under the Recovery and Resilience Facility to strengthen health systems are now in full swing. More than EUR 42 billion in investments are earmarked for fostering better healthcare under adopted recovery and resilience plans, and almost one third of this amount is dedicated to investment and reforms to drive the digitalisation of health systems. Specific investment also aims to strengthen the public health capacity of national health systems. Continuous effort will be needed to bolster the resilience of health systems, from the short-term to the long-term. In addition, the latest country-specific recommendations – adopted in July 2022 as part of the **European Semester** – addressed healthcare systems in eight Member States and stressed the need for better prevention and primary healthcare, as well as tackling workforce shortages.

The next edition of the biannual report *Health at a Glance: Europe* will be published by the end of 2022. It will in particular assess the disruption of health services for non-COVID patients during the pandemic and look at strategies to overcome backlogs in healthcare. It will also examine the impact of the COVID-19 pandemic on child and youth health, notably mental health.

Looking further ahead, health systems' preparedness for infectious disease outbreaks and other types of shocks must be improved. Running resilience tests will enable Member States to regularly review health crisis preparedness and check their health systems' resilience against specific high-pressure scenarios and long-term structural challenges. Resilience should also include resilience and efficiency of public procurement practices by hospitals and other purchasing bodies²³. Given the burden of the pandemic on mental health, particularly of the health workforce, Member States should strengthen measures to support good mental health of healthcare workers and of the overall population. Furthermore, strengthening the health workforce will make health systems more resilient. The Commission supports training for health professionals through the EU4Health programme²⁴, ESF+ and the EU Pact for Skills²⁵. Several projects are ongoing to support countries in addressing retention of staff, task-shifting and personnel shortages in 'medical deserts' (areas with limited access to healthcare). Moreover, the Commission intends to launch a joint action on improved health workforce planning and forecasting later this year. In addition, the Commission supports the availability of medical emergency teams, as well as of necessary personal protective equipment, medical items and therapeutics at national and EU level (e.g. via the Union Civil Protection Mechanism).

Use of COVID-19 therapeutics

The EU Strategy on COVID-19 therapeutics²⁶ aims to build a broad portfolio of safe and effective therapeutics. In particular, antivirals and antiviral monoclonal antibodies play an important part in treating COVID-19 patients. To date, eight COVID-19 therapeutics of different categories have been authorised, including six antivirals, addressing different stages and severity of the disease. Between October 2020 and July 2022, four Joint Procurement Framework Contracts, including extensions, were concluded to ensure the availability of antiviral medicines in a number of Member States²⁷.

The Commission will continue to work with Member States to identify priorities for further joint procurements for therapeutics and strengthen the integration with established national and EU

²³ In September the following HERA call will be published: Call for proposals to support structured dialogue at national or regional level on public procurement in the health sector.

²⁴ EU4 Health Programme, *Call for proposals to provide training for health workforce, including digital skills*, <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/eu4h-2022-pj-06>.

²⁵ Erasmus+ project, EHMA, *Blueprint Alliance for a Future Health Workforce Strategy on Digital And Green Skills: BeWell project kicked-off*, <https://ehma.org/2022/07/22/blueprint-alliance-for-a-future-health-workforce-strategy-on-digital-and-green-skills-bewell-project-kicked-off/>.

²⁶ Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions, *EU Strategy on COVID-19 therapeutics* (COM/2021/355 final/2).

²⁷ These cover the following therapeutics: remdesivir, bamlanivimab and etesevimab, casirivimab and imdevimab, and xevudy/sotrovimab.

processes. Increased cooperation and joint procurement strengthen solidarity by ensuring equitable access and the availability of therapeutics in participating Member States. As outlined in the 2014 Joint Procurement Agreement signed by 37 countries, procuring jointly also strengthens purchasing power, especially for smaller Member States, allowing for better contractual terms and economies of scale.

The need for multi-country clinical trials

As of January 2022, with the entry into application of the Clinical Trials Regulation²⁸, the assessment and supervision of clinical trials throughout the EU have been harmonised, notably via a Clinical Trials Information System (CTIS). The Clinical Trials Regulation allow swifter authorisation of clinical trials across Member States, thus improving the efficiency of clinical research as a whole. At the same time, the high quality and safety standards already set for such trials will be upheld.

With the Regulation and the CTIS, commercial and non-commercial sponsors can now apply for clinical trial authorisations in up to 30 EU/EEA countries at the same time. The new regulatory system and the platform improve information-sharing and collective decision-making on clinical trials. CTIS, whose use will be mandatory for the submission of the clinical trial applications by 31 January 2023, provides also a public searchable database for healthcare professionals, patients and the general public. On 31 January 2025, the Regulation will be fully applicable and all clinical trials will need to be compliant with the rules.

Over the coming years, this new European regulatory environment for clinical trials will facilitate, streamline, speed up and increase transparency for multinational clinical trials also for possible new COVID-19 therapeutics and vaccines. Moreover, it will ensure that the EU offers an attractive and favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants.

The Emergency Task Force, established as part of the EMA's revised mandate²⁹, provides advice on clinical trial protocols, including joint clinical trials, to developers of clinical trials that are carried out in the Union. Ultimately, the advice will facilitate the timely development and authorisation of medical products such as vaccines and treatments and improve overall clinical trial coordination in Europe. This scientific advice by the Emergency Task Force should be taken into account by Member States when authorising a clinical trial application.

Finally, two EU clinical trial networks have been established under Horizon 2020: one focusing on COVID-19 therapeutics and one for COVID-19 vaccines. The therapeutic trials network includes large-scale adaptive platform trials carried out in intensive care populations, hospitalised patients and primary care patients³⁰. In addition, the joint access advisory mechanism (JAAM) 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, the general adult population and children³¹.

²⁸ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

²⁹ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1–37).

³⁰ REMAP-CAP trial, EU SolidAct trial and ECRAID-Prime trial.

³¹ EU-COVAT-1 AGED, EU-COVAT-2 BOOSTAVAC and EU-COVPT-1 CoVacc.

Focusing on addressing post-COVID condition (“long-COVID”)

Emerging evidence suggests that as many as 1 in 8 people who recover from COVID-19 will experience debilitating symptoms lasting much longer than expected, leading to an impaired quality of life³².

Although the risk of developing post-COVID condition appears to be greater among older individuals with pre-existing conditions who were admitted to hospital because of COVID-19, studies have shown how it is also prevalent among previously healthy, young people who experienced mild to no symptoms when they first contracted the virus³³. People with post-COVID condition can experience a wide range of symptoms, including respiratory, cardiovascular, gastrointestinal, cognitive, musculoskeletal, and neurological symptoms. These symptoms can be intermittent, affect several of the body’s systems and range from mild to incapacitating, frequently impairing people’s ability to return to work. Against the backdrop of this long list of symptoms, to date there are no validated therapies to treat this condition.

This novel class of patients will require specific care, often from different medical specialisations. This is expected to add a substantial burden on European healthcare systems and can exacerbate the large backlog of non-COVID-related care accumulated throughout the pandemic. These considerations highlight the urgency of stepping up research efforts aimed at understanding the biological basis of post-COVID condition. Achieving a better understanding of the pathology underlying post-COVID condition will enable researchers to identify candidate therapies and ultimately develop large-scale clinical trials to verify their benefit.

In this context, the EU’s Horizon Europe work programme 2021- 2022 has provided funding for six research projects focused on post-COVID condition. These projects aim at better characterising post-COVID condition, as well as investigating risk factors for its development across different SARS-CoV-2 variants and population groups, with a view to identify potential biomarkers and inform treatment options.

The EU Strategy on COVID-19 therapeutics³⁴ refers to post-COVID condition in its framework of research, development and innovation actions. The strategy acknowledges that post-COVID condition requires a different therapeutic approach to acute COVID-19. Equally, and in keeping with the emerging hypothesis that persistent viral reservoirs may be one cause of post-COVID condition³⁵, therapeutics used to treat COVID-19 (such as antivirals) could also be tested as a potential treatment for post-COVID condition.

To provide expert guidance on how healthcare systems should design and develop appropriate health services for patients affected by post-COVID condition, the Commission has tasked the Expert Panel on effective ways of investing in health³⁶ to provide an opinion, due at the end of 2022, on the impact of post-COVID condition on health systems. Moreover, the European Agency for Safety and Health (EU-OSHA) has published a report on the impact of post-COVID condition on workers and

³² The Lancet, volume 400, issue 10350, P452-461, 6 August 2022, A.V. Ballering et.al., *Persistence of somatic symptoms after COVID-19 in the Netherlands: an observational cohort study*, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01214-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01214-4/fulltext).

³³ Daugherty, Sarah E., et al. "Risk of clinical sequelae after the acute phase of SARS-CoV-2 infection: retrospective cohort study." *BMJ* 373 (2021).

³⁴ Commission Communication, *EU Strategy on COVID-19 therapeutics* (COM/2021/355 final/2), [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355R\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355R(01)).

³⁵ Brodin, P., Casari, G., Townsend, L. et al., *Studying severe long COVID to understand post-infectious disorders beyond COVID-19*, *Nat Med* 28, 879–882 (2022), <https://www.nature.com/articles/s41591-022-01766-7>.

³⁶ Expert Panel on effective ways of investing in health, https://health.ec.europa.eu/expert-panel-effective-ways-investing-health_en.

workplaces³⁷ and has issued related guidance for workers³⁸ and managers³⁹. Member States are encouraged to join forces to gather up-to-date evidence on post-COVID condition and to increase training of health workforce in the recognition and management of post-COVID condition, especially in primary care. It should be recalled that the best way to prevent the post-COVID condition is to avoid being infected with SARS-CoV-2 in the first place.

Transport, mobility, travel

Since August 2022, all measures affecting free movement of persons in the EU have been lifted, including the requirement for travellers to hold an EU Digital COVID Certificate.

Continued efforts to facilitate **free movement in the EU** during the COVID-19 pandemic remain crucial, both for people and goods. It remains our shared goal to enjoy unrestricted free movement, if the epidemiological situation allows so. To respond to the specific challenges affecting the transport sector and disruption of the supply chain, the Commission and EU Member States should rely on the tools already developed so far, in particular Green Lanes⁴⁰, Contingency Plan for Transport⁴¹, and appropriate health protocols.

Travel restrictions should only be introduced or reintroduced where they are absolutely necessary and proportionate for the protection of public health. For example, certain non-pharmaceutical interventions, such as mask-wearing, should be considered before introducing or reintroducing any travel restrictions. Any new measures should be communicated to key stakeholders, such as transport operators, so they can prepare and avoid any negative potential impacts. Should Member States wish to activate contact tracing of cross-border passengers, common tools, such as the EU Passenger Locator Form, are available to exchange passenger data to enhance their contact tracing capabilities while limiting burdens on passengers and transport operators.

Member States can make use of the EU Digital COVID Certificate in case the epidemiological situation this autumn and winter makes it necessary for countries to temporarily reintroduce travel restrictions. The EU Digital COVID Certificate Regulation, which has been extended until June 2023⁴², provides the necessary framework to manage the impact of restrictions on free movement and to facilitate travel. It ensures that citizens can benefit from interoperable and mutually accepted certificates of COVID-19 vaccination, test and recovery. In principle, holders of valid EU Digital COVID Certificates should not be subject to any additional restrictions when travelling within the EU.

The EU Digital COVID Certificate has been a major success in providing the public with a tool that is accepted and trusted across the EU (and in several third countries) and in avoiding fragmentation of multiple national systems. As of 1 August 2022, 75 countries and territories from across 5 continents are connected to the EU Digital Certificate system (30 EU/EEA Member States and 45 non-EU countries and territories), and several more countries have expressed interest in joining the

³⁷ EU-OSHA, 20 May 2022, *Impact of Long Covid on workers and workplaces and the role of OSH*, <https://osha.europa.eu/en/publications/impact-long-covid-workers-and-workplaces-and-role-osh>.

³⁸ EU-OSHA, 6 July 2021, *COVID-19 infection and long COVID – guide for workers*, <https://osha.europa.eu/en/publications/covid-19-infection-and-long-covid-guide-workers>.

³⁹ EU-OSHA, 6 July 2021, *COVID-19 infection and long COVID – guide for managers*, <https://osha.europa.eu/en/publications/covid-19-infection-and-long-covid-guide-managers>.

⁴⁰ Communication from the Commission on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services 2020/C 96 I/01 (C(2020) 1897)

⁴¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A contingency plan for transport (COM(2022) 211)

⁴² Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022 amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 173, 30.6.2022, p. 37).

gateway or are already engaged in technical discussions with the Commission. This makes the EU Digital COVID Certificate a global standard.

The EU Digital COVID Certificate system is sufficiently flexible to adapt to the evolution of the COVID-19 response. Possible adaptations to the validity period of certificates issued for the first booster may become necessary in light of further scientific evidence and the evolution of the pandemic.

If the use of the EU Digital COVID Certificate were to be reintroduced, it remains important to ensure that everyone can obtain a valid EU Digital COVID Certificate. This means that **Member States should continue to ensure that sufficient testing and vaccination capacity is available and easily accessible. Member States should also inform citizens who underwent a SARS-CoV-2 infection of their right to receive a recovery certificate if they have done a PCR or antigen test.**

In addition, Member States should do their utmost to ensure that passengers are well-informed about possible travel restrictions they may face when entering another EU/EEA Member State. The Re-Open EU web platform⁴³ remains a key point of reference for anyone travelling in the EU. The Commission reiterates the continued importance of timely updates⁴⁴ by Member States on possible travel restrictions, public health and safety measures, so that European citizens can continue to rely on the platform to plan their travel with confidence.

The emergency brake procedure agreed in that Council Recommendation 2022/107⁴⁵ continues to ensure a coordinated approach among Member States in response to the emergence of potential new variants of concern.

The current ECDC colour-coded country categorisation has been discontinued in light of the evolving approaches and decreasing trends in testing volumes in Member States, which in turn did not allow the ECDC to draw up an adequate depiction of the epidemiological situation.

Furthermore, in the context of travel from third countries, in June 2020, the Council adopted a coordinated approach to travel to the EU+ area, which has since then been amended three times⁴⁶. The Commission intends to propose a revision of the Recommendation shortly, in order to take account of the changed epidemiological situation and the developments of the practices in the Member States, notably concerning the list of countries in Annex 1 to Council Recommendation (EU) 2020/912 that no longer reflect the current situation. Such a revision, that will be consulted with Member States, aims to provide a common framework for the coming months, ensuring a coordinated approach.

5. THE GLOBAL DIMENSION

In order to control and end the pandemic, world-wide efforts and support for fighting COVID-19 globally are essential. This is why, since the onset of the COVID-19 crisis, the EU, as Team Europe⁴⁷, has played a central role in the multilateral response for the rapid development, scale-up and equitable distribution of **COVID-19 vaccines worldwide**. The EU remains the biggest donor of COVID-19 vaccines globally, considering doses shared by Member States via COVAX (COVID-19 Vaccines Global Access) and as bilateral donations. In total, Team Europe has now shared almost 482 million

⁴³ <https://reopen.europa.eu/>.

⁴⁴ To ensure that the Re-Open EU web platform provides up to date information, Member States should inform the Commission about possible updates before introducing possible restrictions and measures.

⁴⁵ 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)

⁴⁶ Council Recommendation (EU) 2020/912 of 30 June 2020 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction (OJ L 208I 1.7.2020, p. 1).

⁴⁷ <https://europa.eu/capacity4dev/wbt-team-europe>.

doses with countries in need and remains committed to donation and exportation efforts in the upcoming months, should there be an increased interest for original formulations and adapted vaccines. Even though the global COVID-19 vaccines supply has stabilised, many countries, especially in Africa, are still very far from achieving sufficient vaccination rates. The lack of primary vaccination also creates a risk of missing out on the benefits of boosters, including boosters with adapted vaccines.

The current situation is marked by more supply of vaccines relative to demand: the global availability of vaccines has not been matched by a corresponding increase in vaccine uptake in some countries. The challenge has clearly shifted to ‘getting shots into arms’ or administering the vaccines received. This is why, for instance, the EU has put forward a Vaccine Support Package for its African partners, which covers supply, ancillary material, and delivery support. The EU has announced additional EUR 375 million support to countries with the lowest vaccination rates through the COVID-19 Delivery Support mechanism of the COVAX Facility⁴⁸. This funding supports national governments in service delivery, health workforce, demand generation, vaccination campaigns, supply chain systems, cold chain and rapid UCC capacity following a country needs-based approach. The funding also supports countries to sustain equitable access, reach marginalized populations, integrated COVID-19 vaccination and routine immunisation and strengthen immunisation systems.

The capacity of local healthcare systems needs to be further developed to ensure communities get vaccinated; local vaccine development and production should also be strengthened. The Commission supports strengthening of national healthcare systems in Africa, for example by engaging at the regional level to improve health security through a One Health approach, digitalisation of health systems and by supporting public health institutes.

The EU will also continue working through the Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (MAV+)⁴⁹. This initiative began in 2021 and is contributing to increase local and regional manufacturing capacity, diversify African pharmaceutical supply chains and to address bottlenecks in the international supply chain. Team Europe has mobilised so far more than EUR 900 million to support building capacities in South Africa, Senegal, Rwanda and Ghana and at regional level for regulatory strengthening and the African Medicines Agency (AMA), the African Union Development Agency (AUDA-NEPAD) and the Partnership for African Vaccine Manufacturing. Within the framework of matchmaking events, the EU has been enhancing collaboration between African and European companies concerning the value chains of the pharma and medical technology industry. The EU has also launched a new initiative on local manufacturing of vaccines and medicines to support efforts in Latin-America and the Caribbean.

The EU also pledged EUR 150 million to the Global Fund’s COVID-19 Response Mechanism (C19RM)⁵⁰ for ensuring access to medical countermeasures in partner countries (including diagnostics, tests, oxygen and personal protective equipment).

Moreover, the EU is actively contributing, alongside the US and other global partners, to the successful implementation of the **Global Action Plan** to beat the pandemic. The objective is to help coordinate actions and mobilise resources in six priority areas in relation to the global COVID-19 response. COVID-19 has taught us that only a united and multilateral response can effectively tackle a global pandemic.

⁴⁸ As well as the EUR 100 million of support from the humanitarian budget to roll out vaccines that has been implemented since 2021.

⁴⁹ The first support packages for Senegal, Rwanda, South Africa and Ghana have been mobilised.

⁵⁰ <https://www.theglobalfund.org/en/covid-19/response-mechanism/#:~:text=The%20COVID%2D19%20Response%20Mechanism,formal%20and%20community%20health%20systems>.

The fight against anti-vaccination mis- and disinformation should be continuously addressed globally. Tackling foreign information manipulation and interference requires a specific response. The European External Action Service (EEAS), in close cooperation with the Commission and Member States, has been developing the EU's toolbox to tackle foreign information manipulation and interference (**FIMI Toolbox**).

Lastly, the EU believes it is vitally important to build on the lessons learned from the COVID-19 pandemic and to strengthen the global health architecture – with a reinforced WHO at its centre. **The EU is determined to be a driving force in the negotiations on a new, legally binding, international agreement on pandemic prevention, preparedness and response and on targeted amendments to strengthen the International Health Regulations 2005.** These complementary processes are a priority for the EU and provide a historic opportunity to find multilateral solutions to common challenges, based on the principles of collective solidarity, equity, fairness, inclusiveness and enhanced transparency. Moreover, the new **Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and Response**⁵¹, to which Team Europe has already pledged at least⁵² EUR 588 million, will provide funding to support pandemic prevention, preparedness and response, including the implementation of the amended International Health Regulations and the new international agreement on pandemic prevention, preparedness and response.

COVID-19 has demonstrated that the international aspect of EU health policy has become more important than ever. We are learning these lessons and taking coordinated steps to protect and promote health globally and to strengthen the EU's leadership in, and contribution to, global health. The forthcoming **EU global health strategy** will provide the political framework with priorities, governance and tools, enabling the EU to speak with one influential voice and making the most of Team Europe's capacity to protect and promote health globally.

6. CONCLUSION

While the evolution of the pandemic is unpredictable, the EU needs to prepare itself – for the third time in a row – for a challenging autumn and winter. But the future of the pandemic does not only depend on new variants that may emerge and outcompete older strains. It is also greatly determined by human behaviour and how much immunity can be built up in the population. Minimising the number of new cases also decreases the chances of new variants appearing. These are factors that can be influenced, and Member States' healthcare systems and society must continue to adapt their collective response to this virus until the threat of COVID-19 is no longer acute.

As we have seen during the peaks of the COVID-19 pandemic, working together is essential. Now that a political agreement has been reached on the new EU regulation on serious cross-border threats to health, which is the final legislative piece of the European Health Union Package⁵³, **the Union will soon have a new set of tools to finish the revision of the EU health security framework and to strengthen the required infrastructure and processes for implementing COVID-19 preparedness and response measures.**

The pandemic has reminded us very clearly of the importance of collaboration. Through working together, we can make a real difference and strengthen the EU's capacity to prevent, prepare and respond to health crises – in the upcoming months as well as in the future. We are stronger, more resilient and more effective when we work together on a sustained management of the pandemic.

⁵¹ <https://unfoundation.org/blog/post/inside-the-new-fund-to-bolster-global-pandemic-prevention-preparedness-and-response/#:~:text=This%20new%20fund%2C%20which%20is,before%20the%20next%20pandemic%20occurs.>

⁵² More EU Member States are considering to contribute or are preparing their pledge.

⁵³ https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en.