



Council of the
European Union

Brussels, 16 November 2020
(OR. en)

12974/20

SAN 410
PHARM 56
MI 496
COMPET 562
PROCIV 77
COVID-19 26

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	12 November 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2020) 724 final
Subject:	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats

Delegations will find attached document COM(2020) 724 final.

Encl.: COM(2020) 724 final



Brussels, 11.11.2020
COM(2020) 724 final

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

**Building a European Health Union: Reinforcing the EU's resilience for cross-border
health threats**

1. THE NEED FOR A STRONGER EU HEALTH SECURITY FRAMEWORK

Health is a precondition for our society and economy to function. The COVID-19 pandemic is causing immense human suffering, pushing health systems and healthcare workers to their limits. As of early-November 2020, over 50 million people worldwide had been infected with the coronavirus. More than 12 million, or 25% of those, were people living in Europe. In the EU/EEA and UK, nearly 250 000 people had lost their lives to COVID-19¹. The measures needed to contain the pandemic and save lives have a huge impact on people's livelihoods, their jobs and their freedoms.

During the early days of the COVID-19 outbreak in Europe, Member States took unilateral measures² to protect their own populations. However, these uncoordinated measures were not effective in overcoming the virus. Reintroduction of internal border controls, for example, disrupted mobility and the daily life of millions of people living and working in border regions. They disrupted vital supply chains and prevented the flow of essential goods and services across the internal market.

European citizens have been increasingly clear that they expect the EU to have a more active role in protecting their health, particularly in protecting them from health threats that transcend national borders³. Coordinating and where necessary pooling efforts at European level will deliver more effective responses to the expectations of European citizens in an area which is consistently among their top concerns. We need to heed this call now and in our discussions on the future of Europe. Attention needs to be given also to the risk of popular scepticism on health measures, that is partly triggered by an increase of mis- and disinformation on health issues. Health is a prerequisite for a dynamic economy stimulating growth, innovation and investment.

From the beginning of the pandemic, solidarity has been real and tangible. Healthcare workers were at the forefront, working day and night to care for COVID-19 patients, social workers continued to perform indispensable tasks to support the most vulnerable, including older persons and persons with disabilities. Often, these essential workers were operating while being confronted with staff shortages, limited information on preparedness and insufficient protective equipment, resulting in an overexposure to the virus.

Solidarity has also inspired the EU's response: as the pandemic progressed, EU Member States turned from unilateral measures, such as export restrictions or the reintroduction of internal border controls, to support each other, either by receiving COVID-19 patients from neighbouring countries or by sending healthcare professionals and key medical equipment to other regions in need⁴. Through the Coronavirus Response Investment Initiative (CRII), which enabled the mobilisation of unspent EU funds under Cohesion policy, so far EUR 5.9

¹ <https://www.ecdc.europa.eu/en/covid-19/situation-updates>

² Such as export restrictions on personal protective equipment and the reintroduction of internal border controls.

³ <https://europarl.europa.eu/at-your-service/en/be-heard/eurobarometer/public-opinion-in-the-eu-in-time-of-coronavirus-crisis-2>

⁴ Many border regions already have a history of and structures for cross-border cooperation, including in health. https://ec.europa.eu/info/sites/info/files/guidelines_on_eu_emergency_assistance_in_cross-bordercooperationin_healthcare_related_to_the_covid-19_crisis.pdf

billion euros have been reallocated since 1st February 2020 to support health systems and actions in EU Member States and regions⁵. In addition, the European Solidarity Fund's scope was extended to encompass major public health emergencies. Cooperation and coordination at EU level has increased and efforts across all sectors have been made. This is the only way to effectively address the different interlocking damage caused by the pandemic in the health, economic and social sectors.

The collective effort to fight the ongoing COVID-19 pandemic, as well as other future health emergencies, calls for strengthened coordination at EU level. Public health measures need to be consistent, coherent and coordinated to maximise their effect and minimise the damage for people and business alike. The health situation in one Member State is contingent on that of others. Fragmentation of effort in tackling cross-border health threats makes all Member States collectively more vulnerable.

In her 2020 State of the Union address, the President of the Commission called on Europe to draw lessons from the current crisis and **build a European Health Union**. As the experience of the current pandemic is showing, gathering the EU Member States' strengths helps overcome individual weaknesses. By working with the European Parliament and the Council towards a stronger Health Union, the EU can be equipped to prevent, prepare for and manage health crises both at the EU and global level, with all the societal and economic benefits that it would bring.

A strong European Health Union will protect our way of living, our economies and societies. If public health is in danger, the economy inevitably suffers. The close relationship between saving lives and saving livelihoods has never been so apparent. The proposals put forward today will also contribute to a more resilient EU internal market and a sustained economic recovery.

This agenda for a Health Union is presented in the midst of a widespread resurgence in COVID-19 cases across Europe and the world. The EU and its Member States will need to continue to take the necessary measures to contain and manage the pandemic on a day-to-day basis, for which coordinated EU-level action remain essential. At the same time, planning for future outbreak and increasing our capacity for preparedness and response becomes more pressing as recurrent outbreaks of communicable diseases are becoming more likely.⁶ Moreover, long-term trends such as antimicrobial resistance⁷, pressures on biodiversity⁸ and climate change, all associated with increasing communicable disease threats worldwide and in Europe, keep rising⁹. In addition, changing demographic structures in our population, in particular ageing, lead to changing health vulnerabilities and disease patterns. This requires a systemic, foresight-based approach recognising the interaction between human and animal

⁵ https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1864

⁶ <https://www.weforum.org/agenda/2020/03/coronavirus-global-epidemics-health-pandemic-covid-19/>

⁷ <https://atlas.ecdc.europa.eu/public/index.aspx?Dataset=27&HealthTopic=4>

⁸ <https://ipbes.net/pandemics>

⁹ <https://easac.eu/projects/details/climate-change-and-health/>

health and the environment to develop structural, future-proof solutions, coherent with a One-Health approach.

The European Health Union builds on the EU's joint effort to reconcile our relationship with the natural environment by engaging in different and more sustainable patterns of economic growth, as put forward by the European Green Deal. Fighting climate change and finding ways to adapt to it, preserving and restoring biodiversity, improving diets and lifestyles, reducing and removing pollution from the environment improves will have positive effects on citizens' health and the European Health Union will be able to better protect.

This Communication proposes first building blocks for a European Health Union. It implements the obligation to ensure high level of human health protection as defined in the Charter of Fundamental Rights of the European Union. It outlines the lessons learnt from the first stage of the pandemic, and advocates the strengthening of existing structures and mechanisms for better EU level protection, prevention, preparedness and response against human health hazards. It recommends a reinforced framework for cross-border cooperation against all health threats in order to better protect lives and the internal market as well as to maintain the highest standards in the protection of human rights and civil liberties. It also strengthens the EU role in international coordination and cooperation to prevent and control cross-border health threats and improve global health security.

These first proposals are envisaged within the current Treaty provisions, particularly in respect of Article 168 (5) of the TFEU. By upgrading the EU framework for cross-border health threats, these first building blocks of the European Health Union will bring greater overall impact while fully respecting the Member States' competence in the area of health.

Concretely, this Communication is accompanied by three legislative proposals: an upgrading of Decision 1082/2013/EU on serious cross-border health threats, a strengthening of the mandate of the European Centre for Disease Prevention and Control (ECDC), and an extension of the mandate of the European Medicines Agency (EMA)¹⁰. It links to the proposal for enhancing the Union Civil Protection Mechanism¹¹, proposed by the Commission in June 2020¹². Together, these proposals will put in place a robust and cost-effective framework to enable EU Member States to respond to future health crises as a Union.

Where the legislative proposals entail the processing of personal data, this will happen in full compliance with the applicable EU data protection rules. The principles and specific safeguards laid down by the EU data protection framework¹³ allow for an effective and comprehensive protection of personal data, including data concerning health.

¹⁰ To be added once available

¹¹ The Union Civil Protection Mechanism (UCPM) allows the Commission to support Member States in coordination of efforts to prevent and prepare for disasters as well as through its Emergency Response Coordination Centre (ERCC) in responding when their national capacities are overwhelmed by any kind of disaster, including ones such as COVID-19. Indeed, amidst the pandemic, EU Member States, UCPM Participating States as well as third countries resorted to the UCPM for support requesting for in-kind assistance in form of PPE, sanitation, but also for requesting for support of medical teams.

¹² COM(2020)220

¹³ Regulation (EU) 2016/679 (the General Data Protection Regulation (GDPR) and Regulation (EU) 2018/1725

2. EARLY LESSONS LEARNT FROM THE COVID-19 PANDEMIC AND PROPOSALS FOR THE WAY FORWARD

In 2013, the EU put in place a health security framework to protect its citizens, to promote coordination between Member States and with neighbouring countries, and to respond to the increasing threat of communicable diseases. The Decision on serious cross-border health threats¹⁴ was adopted, aiming to improve preparedness across Europe and to strengthen its capacity to rapidly detect, monitor and coordinate responses to health emergencies caused by communicable diseases, biological or chemical agents, or environmental and climate events, and threats of unknown origin.

The 2020 Annual Strategic Foresight Report showed that there is a need to better anticipate health risks and prevent the spread of new infectious diseases and associated disorders. Embedding foresight in health policies will therefore contribute to better preparedness and resilience.

The COVID-19 public health crisis has highlighted that the EU and Member States must do more regarding preparedness and response planning for epidemics and other serious cross-border health threats. While structures and mechanisms set up at EU level as part of the Decision on serious cross-border health threats facilitated the exchange of information on the evolution of the pandemic and supported specific national measures taken, they could do little to trigger a timely common EU level response and ensure coherent risk communication. This lack of coherence and coordination continues to be an obstacle to tackling the pandemic.

The crisis response from the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA)

ECDC's role in the EU's health security framework is crucial. However, there is a need to strengthen the Agency's capabilities to better protect citizens. For example, its surveillance system has to be reinforced so as to deliver its full potential as at present the ECDC has a limited mandate/capacity to provide analysed data that support early evidence-based decision making and real-time situational awareness. In a context such as the COVID-19 pandemic, ECDC needs to be able to provide hands-on support to Member States, and the Agency's scientific recommendations for appropriate health measures need to address Member State-specific elements. The ECDC needs to become a real EU Health Agency that Member States can entrust to deal with crisis preparedness and response as appropriate.

EMA also plays an essential role in the EU's health security framework, particularly regarding the assessment of safe and effective treatments and vaccines. However, the COVID-19 pandemic has shown that EMA lacks a strong system to monitor and mitigate shortages of critical medicines, as well as a solid framework for crisis response. As a result,

¹⁴Decision No 1082/2013/EU <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1082>

the Agency's ability to fast track scientific advice, procedures and obligations on Member States and developers has been hampered.

The COVID-19 pandemic has thus clearly shown that there are opportunities to further strengthen and improve the EU health security framework to be ready for all health threats. Significant gaps and an evident need for more EU coordination have become apparent in public health preparedness and response. Inconsistencies in the application of health measures – such as the use of masks, social distancing requirements, testing strategies and isolation/quarantine requirements – have led citizens to question the scientific basis for these policies. Capacity shortages, shortfalls in equipment, shortcomings in testing and contact tracing, and a failure to protect the most vulnerable groups have all pointed to a lack of readiness and preparation, as well as to structural weaknesses and lack of resources. EU solidarity mechanisms offered ways to offset these problems, but were not extensively used. For example, the EU Civil Protection Mechanism could have been drawn on far more effectively¹⁵. Such disparities when dealing with an identical threat, which threatens all of us, cannot be maintained.

While the pandemic is still ongoing, early lessons learnt have identified these challenges and are being addressed herewith. It is evident that further investments and reforms are necessary in health systems to ensure that they have the required means and resources to come out of the current crisis, as well as to strengthen their longer-term resilience in order to manage public health crises in the future.

3. ENFORCING COORDINATED RESPONSE AT THE EU LEVEL

Coordination of health measures is central not only to an effective practical response by the authorities but also to ensure that citizens understand that action is evidence-based and grounded in consensus. The EU's health security framework sets out the work of the Commission through the EU Health Security Committee and the Early Warning and Response System (EWRS). At Council level, the EU Integrated Political Crisis Response (IPCR) arrangements have been used to carry out coordination and to support the EU's political response.

The Health Security Committee¹⁶ is a key body where EU Member States consult each other in liaison with the Commission with a view to coordinating preparedness and response planning, national responses, and risk and crisis communication related to serious cross-border threats to health.

¹⁵ For example, the response capacity of the Union Civil Protection Mechanism (UCPM) was initially hindered due to the scale of the outbreak, which hit simultaneously all the Member States at a time when markets for personal protective equipment were saturated. As a result, several requests for assistance went unfulfilled for some weeks in the early stages of the outbreak in Europe. This experience demonstrated that the need to further enhance the UCPM and prompted the Commission to propose targeted amendments to the legal framework in June 2020.

¹⁶ The HSC is composed of public health representatives of Member States, and observers from European Economic Area (EEA) countries, EU agencies, most importantly the European Centre for Disease Prevention and Control (ECDC), as well as international partners such as the World Health Organization.

In response to COVID-19, the Health Security Committee convened, from January to November 2020, more than 40 times, to discuss risk assessments, guidance from ECDC, preparedness and response measures implemented, as well as capacities and needs in Member States¹⁷. The Committee proved to be a key forum for exchange of information and developing common positions in certain areas, such as the Health Security Committee agreement on recommendations for COVID-19 testing strategies. This was a prerequisite for effectively communicating to citizens, at EU but also at national level. On the other hand, it became apparent that the Health Security Committee has a limited ability to enforce or coordinate the national responses around control measures or to implement the agreed common approaches. This is exemplified by the wide variety of national control measures that exist and that were implemented across the EU, such as social distancing, mask wearing or measures at points of entry. The imposition of export restrictions on personal protective equipment, the implementation of border restrictions without mechanisms to ensure the necessary flow and exchange of goods and people, or the use of therapeutics outside of the context of clinical trials, further showed the plethora of measures identified.

Moreover, the coordination of communication aspects, under the remit of the Health Security Committee Communicators' Network, proved to have limited EU efficacy. This was partly a consequence of different national approaches taken. However, it may also be a result of the minimal engagement of Member States, exemplified by low rates of attendance in Network meetings.

In addition, experience has shown that the interplay between technical discussions in European structures, such as the Health Security Committee, and the Ministries of Health in Member States, is not always straightforward and this has a clear impact on decisions taken at national level. Moreover, given that health crises like COVID-19 are multi-sectoral in nature, a key priority will be to enhance cross-sectoral linkages and coordination with other relevant structures and constituencies beyond the Health Security Committee, for instance in the area of civil protection, which has a cross-cutting emergency and disaster preparedness as well as response function.

In light of this, it has become apparent that the Health Security Committee must be strengthened to allow the triggering of a common EU-level response and enhanced coordination of risk communication¹⁸. Based on this, the proposals present a strengthened mandate to enforce coordinated response at EU level in the Health Security Committee. This will be enabled by **targeted recommendations on response measures by the ECDC** and relevant EU decentralised Agencies, incorporated in the risk assessments provided to the Health Security Committee. In turn, **the Health Security Committee can formally adopt guidance and opinions complemented by Commission recommendations**. Crucially, the adoption of these recommendations would translate into actual implementable measures

¹⁷ Practically speaking, this has provided an additional means to keep Member States informed of joint procurements and their practicalities, as well as supporting the practical implementation of Emergency Support Instrument funded activities, such as the distribution of the masks for healthcare workers and treatment courses of Veklury (remdesivir).

¹⁸ This also relates to the research aspect of the response.

within countries. It is essential that Member States commit to implement the work of the Health Security Committee. In order to underline the increased role of the Health Security Committee and in analogy to the Economic and Financial Committee (EFC), Deputy Health Ministers will meet in the high-level working group of the HSC, in particular when politically sensitive issues are on its agenda.

The legal framework for the recognition of an emergency at the EU level will also be amended. The new rules will enable the activation of EU emergency response mechanisms, in close coordination with the World Health Organization (WHO), without making it contingent upon the WHO's own declaration of a Public Health Emergency of International Concern (PHEIC). This will give further flexibility to the EU when tackling health crises. For example, the recognition of an emergency situation at EU level would allow for the flexible development, manufacturing, stockpiling and procurement of critical products during a crisis, as well as the adoption of immediately applicable implementing acts by the Commission concerning the protection of human health and to ensure the smooth functioning of the internal market. This should be done ensuring full complementarity with the Union Civil Protection Mechanism, including its Emergency Medical Teams.

The Commission will not act unilaterally in such a recognition, with the process supported by an **independent Advisory Committee** to provide advice on the recognition and termination of a public health emergency as well as on response measures. The Advisory Committee will be essential in ensuring evidence-based health policy, covering diverse scientific areas and policies, composed of a multidisciplinary group of members as well as representatives of Union bodies or agencies relevant to the specific threat, which will participate as observers. The identification of the pool of experts will be in place prior to any future emergencies, so that they are immediately available and are ready to collaborate across their sectorial expertise.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ Recommendations on response measures by ECDC as part of rapid risk assessments	ECDC
➤ Commission Recommendation on response measures	Commission
➤ EU recognition of an emergency situation and advice on response measures, supported by an independent Advisory Committee	Commission; EU Agencies

4. MEDICAL COUNTERMEASURES¹⁹

The COVID-19 pandemic has revealed the lack of medical countermeasure stockpiles at EU and Member State level and the vulnerability of EU supply chains for critical medical countermeasures. It has also highlighted the lack of a coordinated and systematic EU-level approach to support the development, production, procurement and purchase of necessary vaccines, therapeutics, diagnostics as well as personal protective equipment (PPE) and medical devices. Given the lack of up-to-date, reliable and comparable information on the level of demand per Member State, it has been challenging to predict and meet the demand across the EU for certain products that are key in fighting the disease, but also essential raw materials, components and accessories used during production. The EU lacked effective mechanisms and structures to have an overview of demand and supply of critical medical countermeasures and to monitor and support Member States in addressing shortages.

Moreover, in the context of an outbreak or pandemic caused by a novel pathogen, the pressure is high for research to deliver results that can be acted upon rapidly, to be integrated in the emergency response. Further support and coordination are needed at EU level to facilitate the conduct of large scale, multi-centric clinical trials, to allow for their rapid implementation in times of crisis and save precious time towards making the necessary countermeasures available²⁰. Rules on the conduct of clinical trials need to allow for their rapid implementation in times of crisis and save precious time towards making the necessary countermeasures available.

Despite these shortcomings, several measures were introduced to facilitate access to medical countermeasures. In order to facilitate this access the Commission introduced the strategic rescEU stockpile of emergency medical equipment as part of the UCPM in March 2020²¹. This tool acts as an emergency mechanism to provide countries with needed medical countermeasures, such as PPE, laboratory supplies and intensive care unit medical devices when national capacities are overwhelmed, and complementing the capacities available in the EU Civil Protection Pool. A number of actions were introduced to better monitor and maintain the supply of critical medicines or medical devices, by providing regulatory flexibility, while maintaining safety standards. Specific guidance has been published and continuously updated to inform stakeholders about expectations and flexibilities²². The

19 Medical countermeasures relevant for public health response include pharmaceutical products, as well as non-pharmaceutical products, such as, but not limited to, medical devices, personal protective equipment, vaccination supplies, testing material and kits, and laboratory equipment.

20 COVID-19 illustrated suboptimal coordination and decision making as regards multinational clinical trials. The process has been slow and inefficient, causing delays in the adoption of research outcomes and eventually delays and unequal patient access to new or repurposed medicines. A very high number of trials were submitted for medicines on Covid-19, both therapeutic and vaccines (454 distinct clinical trial applications submitted in at least one EU MS or the UK from March to end of September 2020); the high proportion of trials (88%) takes place in only one Member State and is performed by non-commercial researchers (75%); even well-known international clinical trial protocols are submitted to individual Member States as a separate project – leading to differences in approach and potentially a lesser comparability of the results. Lastly, the experience to date has shown a need for clear, fast and streamlined positioning and communication on therapeutic and prophylactic “candidate” medicines.

21 The system of civil protection relies on solidarity among Member States, in the sense that it depends on their voluntary requests and offers of assistance. This voluntary system works very well in emergencies of limited scope, which affects one or a few Member States. But, as we have come to learn, it is ineffective in cases where a large number or all Member States are affected at the same time. That is why reinforced rescEU to create strategic stockpiles of medical and personal protective equipment has been created. The rescEU strategic stockpile of emergency medical equipment is a last resort capacity under the Union Civil Protection Mechanism.

22 https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

Commission Clearing house for COVID-19 medical equipment was established on 1 April 2020 to facilitate matching the supply and demand of PPE, medical devices and medicines and address regulatory and other supply chain issues. The activation of the Emergency Support Instrument, research funding and advanced purchase agreements with vaccine developers under the EU's vaccine strategy are other concrete examples of decisive actions. Through the Emergency Support Instrument, the Commission helped in responding to needs that can be best addressed in a strategic, coordinated manner at European level. Over €2 000 million from the instrument has thus been made available for the advanced purchase agreements for vaccines, €70 million for the purchase and distribution to Member States of Veklury (the therapeutic remdesivir), and €100 million will be used for rapid antigen tests.

All together, these measures have helped in building the response to the on-going crisis, to fill in the gaps of the existing framework. However, they do not address the EU's long-term structural challenges with regards to medical countermeasures.

Joint Procurement

The EU's Joint Procurement Agreement for medical countermeasures, enabled by Decision 1082/2013/EU, was used throughout 2020 in response to the COVID-19 crisis. However, the Joint Procurement Agreement is predominately a preparedness tool and, as such, is not designed to deal with an on-going crisis. It aims at improving Member States' preparedness to mitigating serious cross-border threats to health, allowing for a more equitable access to specific medical countermeasures and an improved security of supply, together with more balanced prices for participating Member States.

However, in the proposed Regulation for serious cross-border threats to health, elements of the legal framework of the joint procurement agreement will be enhanced, as it remains a key tool for preparedness. Specifically, the participation to European Free Trade Association (EFTA) States and Union candidate countries is formally envisaged. Moreover, it will be strengthened as a key EU procurement process, whilst mitigating the risk of internal competition for limited resources or parallel national tracks, through an "exclusivity clause". This exclusivity approach, implemented in the EU vaccines strategy, has proven successful²³. Complementarity should be ensured with the strategic rescEU stockpiling of emergency medical equipment under the Union Civil Protection Mechanism.

Addressing shortages through the European Medicines Agency

The pandemic has also demonstrated that the Union's ability to coordinate work to ensure the availability of medicinal products and medical devices and facilitate the development of new treatment is currently limited. EMA has played a crucial role by setting up temporary mechanisms to monitor shortages of medicines and offer scientific advice to developers. Ad hoc solutions, including contingent arrangements between the Commission, the European

23 A similar clause was successfully included in the Agreement between the Commission and the Member States as regards the Advanced Purchase Agreements on the purchase of vaccines against COVID-19.

Medicines Agency, marketing authorisation holders, manufacturers and Member States have been used. In addition, a scientific task force facilitated the development of potential treatments and vaccines for COVID-19. Such temporary solutions need to be formalised, as a key element of an improved EU health security framework. For medical devices it became apparent that there is no mechanism at the EU level providing for the monitoring of their availability in times of crisis.

On medicinal products, during the COVID-19 pandemic, the EU Executive Steering Group on Shortages of Medicines Caused by Major Events²⁴ was set up to urgently ensure a better overview of real needs. The group has provided strategic direction for the process in case of potential supply shortages. This includes dealing with emerging issues, agreeing remedial action where necessary, addressing shortages in a coordinated way, including crisis communication and overseeing the implementation of agreed actions. The proposed Regulation will therefore **formalise and reinforce the current structure of the Steering Group on medicines**, as well as its two-way fast-track communication channel between the European medicines regulatory network and marketing authorisation holders. Specifically, the proposed changes will result in a permanent structure within the EMA to monitor events related to the pharmaceutical area, which could lead to future crises, as well as monitoring and mitigating the risk of shortages of key medicines once a crisis is declared. To support such work obligations will be placed on marketing authorisation holders and Member States to provide the necessary data through streamlined IT tools and fast-track procedures already established in view for future crises.

In April 2020, the EMA also established an ad hoc COVID-19 EMA pandemic Task Force as part of its health threat plan. The Task Force contributes to direct scientific advice on clinical trials design and product development and provides a rolling review²⁵ of incoming evidence to allow a more efficient assessment approach of promising therapies or vaccines for COVID-19²⁶. These measures are crucial to ensure timely authorisation of products and the compilation of robust data. The Task Force also offers scientific support to COVID-19 products' clinical trials and contributes to activities on emerging safety issues related to COVID-19 products. In the medium-term, strengthened access of EMA to health data, in the context of the upcoming European Health Data Space, should support its regulatory capacity. To reinforce the work of EMA, the legal proposal builds on the above and intends to replace the current ad hoc arrangements, by **introducing permanent structures within the EMA** with a clear and unambiguous mandate. For clinical trials, the legal proposal includes a role for the Task Force in **providing advice on clinical trial protocols**, but also a broader role in the coordination and facilitation of clinical trials in the European Union. It also implies a

24 The group is chaired by the European Commission, with representatives from the Heads of Medicines Agencies, European Medicines Agency, the chairs of the Coordination groups for Mutual-recognition and Decentralised Procedures (human and veterinary), as well as risk communication specialists.

25 In general, all data on a medicine's effectiveness, safety and quality and all required documents must be submitted in the initial formal application for marketing authorisation. In the case of a "rolling review" data is reviewed as they become available from ongoing studies, before a formal application is submitted. Once the data package is complete, the developer submits a formal marketing authorisation application to be assessed under a shortened timetable. That significantly shortens the time needed to make the medicine available, while maintaining the principles of quality, safety and efficacy.

26 By October 2020, EMA had finalised 39 scientific advice procedures to provide developers with direction on the most appropriate methods and study designs for potential COVID-19 medicines. A further 14 such procedures are ongoing. The European Medicines Agency continuously updates on the activities of the Task Force on its website: www.ema.europa.eu

stronger role in providing recommendations with regard to the use of both centrally and nationally authorised medicinal products, which may have the potential to address public health emergencies. The proposal will also include tools to ensure that companies and Member States submit the necessary data to facilitate the assessment, given the crucial importance of robust and comprehensive evidence for sound scientific advice and regulatory decision-making. Moreover, after the authorisation of vaccines, it is necessary to have safety and effectiveness data to complement the set of data generated by industry to support the authorisation. The proposals therefore provide for **an IT platform to allow EMA and ECDC to coordinate vaccines safety and effectiveness studies** – a major element in the current landscape of pandemic management.

In the area of medical devices, the legal proposal builds on lessons learnt from the ad hoc work undertaken during the COVID-19 pandemic by the Commission Clearing House given the EMA currently has no competence in the area of medical devices. The purpose is to improve the Union's crisis preparedness and facilitate a coordinated Union-level response by setting a **permanent structure to monitor and mitigate shortages of medical devices** (a Steering Group for Medical Devices) and to ensure that industry and Member States submit the necessary data to facilitate the monitoring and possible mitigation measures.

Additionally, the EMA will **host on a permanent basis the medical device Expert Panels**, which could play an essential role in crisis preparedness and crisis management, in particular by providing scientific, technical and clinical assistance to the Commission, the Medical Device Coordination Group (MDCG), Member States, notified bodies and manufacturers.²⁷ At the beginning of the COVID-19 crisis, when availability of medical devices such as ventilators and protective devices was essential for saving lives and containing the pandemic, such advice would have been invaluable, for example, in the context of repurposing production lines for fast production of ventilators with the associated minimal technical and safety specifications.

This approach will benefit from the long-founded expertise of the Agency in the management of various scientific committees and working groups.

In order for the EMA to carry out these further tasks in addition to its current mandate, a swift increase in the number of permanent staff in this agency is required.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ A reinforced joint procurement agreement beyond the EU	Commission
➤ A permanent EU Executive Steering Group on shortages of	EMA

²⁷ In addition, the panels are entrusted with other functions, including providing various types of scientific advice to Commission, Medical Devices Coordination Group, Member States, Notified Bodies and manufacturers. Such advice may cover safety and performance aspects, Common Specifications, clinical strategies, conformity assessment in relation to the state of the art for biocompatibility, mechanical, electrical, electronic and toxicological testing.

medicines	
➤ A new EU Executive Steering Group on medical devices	EMA
➤ A permanent EMA emergency Task Force	EMA
➤ New EMA Expert Panels on high risk medical devices	EMA
➤ A stronger EU clinical trials infrastructure	EMA; ECDC
➤ Creation of a vaccine monitoring platform	EMA; ECDC

5. PREPAREDNESS & RESPONSE PLANNING AND REPORTING

Under the current Decision on cross-border threats to health, the Commission's monitoring of Member States preparedness and response planning is primarily based on Member States reporting, every three years, on their respective plans. This includes the intersectoral dimensions at the EU level and supporting the implementation of core capacity requirements under the World Health Organization's International Health Regulations.

COVID-19 has revealed that national-level preparedness and response capacities were sub-optimal. This was illustrated, for example, when many EU Member States were confronted with inadequate stockpiling (e.g. PPE), the lack of immediately available surge capacities for healthcare systems, testing, contact tracing and surveillance and the lack of implementable business continuity plans for healthcare provision (to avoid postponement of inpatient scheduled treatments) as well as shortages of qualified medical staff.

COVID-19 has also shown that there was a clear lack of an overall vision on the operationalisation of Member State preparedness and response plans, as well as an incoherence with regards to their compatibility. This was greatly a result of the EU's inability to compare plans in a uniform manner across the EU due to a lack of EU baseline standards and indicators²⁸, a lack of EU knowledge on national level capacities to implement plans and incoherent feedback from Member States on respective preparedness and response plans. The situation was further exacerbated by the absence of an overarching EU pandemic preparedness plan.

It is therefore proposed to strengthen coordination mechanisms for preparedness, via the development of a **binding EU health crisis/pandemic preparedness and response plan**. This plan will include clear provisions for the EU and Member States to adopt similar and interoperable plans at national and local levels. To ensure these plans are actually operable in times of crisis, **regular full-scale exercises and carry-out after-action reviews to implement corrective measures will be organised**.

²⁸ With regards to assessing preparedness and response plans and corresponding capacities.

To further strengthen the operationalisation of these plans, an **EU audit process on national level capacities will be launched**. The audit process will be led and coordinated by the Commission with the technical implementation primarily undertaken by the ECDC to further ensure, preparedness, transparency and adequate operationalisation. The Commission will report on these findings to the European Parliament and the Council.

The conclusions will be drawn upon **to address the gaps identified during this reporting and auditing process** and to ensure optimal use of **financial support through the future EU4Health programme, as well as the Structural Funds and support to research and innovation under Horizon Europe**.

Another area of actions concerns support to Member States to improve the resilience, accessibility and effectiveness of their health systems. This may include knowledge brokering, best practice exchange, hands-on technical support as well as financing from EU programmes to initiate and implement relevant health system reforms in order to overcome structural weaknesses and address challenges identified in the European Semester. The **Social Scoreboard** that monitors Member States' performance in relation to the European Pillar of Social Rights²⁹, will further help to detect key problems, including in healthcare and skills and deliver on implementation of the EPSR. The Recovery and Resilience Facility³⁰ offers an unprecedented opportunity for Member States to carry out structural reforms supported by investments, aiming at, amongst others, enhancing the preparedness and resilience of their national health systems and ensuring equal access to affordable and quality health care³¹.

Targeted actions may concern, for instance, reorganising hospital networks with flexible capacity for surge in demand, the cross-border transport and treatment of patients during health emergencies, sufficient availability of primary care structures, good integration of all levels of health and social care, availability of sufficient and up-skilled healthcare staff who can be redeployed to new roles in case of emergency, deployment and financial coverage of eHealth tools (including telemedicine).

In order for the ECDC to carry out these further tasks in addition to its current mandate, a swift increase in the number of permanent staff in this agency is required.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ Development and implementation of an EU health crisis/pandemic preparedness and response plan ³² .	Commission; ECDC; Member

²⁹ https://ec.europa.eu/info/strategy/priorities-2019-2024/economy-works-people/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

³⁰ The establishment of the Recovery and Resilience Facility is subject to the agreement of the European Parliament and of the Council on the proposal for a Regulation establishing a Recovery and Resilience Facility, COM(2020) 408 final

³¹ In this context, it is also important to ensure that persons with disabilities have access to essential social support services as well as access to information on protective measures.

³² This plan must take into consideration the intersectoral dimensions and critical sectors at the EU level, such as those that exist for such as for transport, mobility, energy, communication and civil protection. These plans should include a section on research preparedness.

	States
➤ Development and implementation of national level preparedness and response plans following common structures, standards and indicators.	Member States;
➤ Enhanced Member State reporting of preparedness and response plans coupled with EU auditing process	Commission; Member States
➤ Strengthened transparency with the Commission preparing reports, including results from the audits and recommendations to Member States, transmitted to the European Parliament and the Council.	Commission; EU decentralised agencies
➤ Regular public health and cross sector stress tests carried out at national and EU levels with corrective measures.	Member States
➤ Through the Technical Support Instrument ³³ , targeted training and knowledge exchange activities for healthcare staff and public health staff to provide knowledge and skills to develop and implement the national preparedness plans, implement activities to strengthen crisis preparedness and surveillance capacities.	Commission; ECDC; Member States
➤ Support to Member States to strengthen the resilience, accessibility and effectiveness of health systems through co-operation, best practice exchange, training schemes, technical support, resilience dashboards ³⁴ and financing from EU programmes ³⁵	Commission; Member States

6. EPIDEMIOLOGICAL SURVEILLANCE

Reinforcing the European Centre for Disease Prevention and Control

Several communicable diseases and special health issues³⁶ are under mandatory epidemiological surveillance at the EU level. The network for this epidemiological surveillance is operated and coordinated by the ECDC, including support to national reference laboratories. COVID-19 has demonstrated a lack of comparable data and understanding of the situation on which to base decision-making. Furthermore, it has prompted investigation of the value of monitoring infectious agents in urban waste water as a means of tracking infections, and as a possible early warning mechanism.

EU surveillance systems must be bolstered with capacities for detecting, monitoring and the surveying of emerging diseases. The experience from COVID-19 also highlighted the important ability to increase capacity of frontline diagnostic laboratory testing, from which further data is accessible and necessary for the management of novel diseases. Up-to-date surveillance data enables the monitoring of trends in the incidence of communicable diseases

³³ The establishment of the Technical Support Instrument is subject to the agreement of the European Parliament and of the Council on the proposal for a Regulation establishing a Technical Support Instrument, COM(2020) 409 final

³⁴ The JRC is developing resilience dashboards with Member States and other stakeholders, with health as an important element. These dashboards will serve as a proper monitoring tool for assessing the resilience. Informed by strategic foresight, they can help identify emerging challenges and propose new forward-looking indicators to assess vulnerabilities or capacities

³⁵ Such as EU4Health, Recovery and Resilience Facility, Cohesion Policy and the Technical Support Instrument.

³⁶ Special health issues are antimicrobial resistance and healthcare-associated infections related to communicable diseases

over time and across Member States, and allows rapid detection and monitoring of cross-border outbreaks.

The rapidly evolving technological environment and digital solutions (AI, High Performance Computing, computational models and simulation system) provides an opportunity to **update surveillance systems**, integrating data from new and different sources³⁷, and to create sensitive systems that detect early signals³⁸. A modern approach to surveillance should be used, relying on linking and integrating relevant surveillance systems, using electronic health records and harmonised datasets, environmental data, data analytics and artificial intelligence, social media - linked with modelling and forecasting capacity and dedicated high-performant digital computing platforms³⁹. Enhancing these technologies will increase the capacity of the EU and its Member States for accurate risk assessments, rapid response and informed decision-making. The ECDC's key role in establishing **integrated surveillance and monitoring systems at the EU level**, including research data⁴⁰ and data on health systems capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patient safety, should therefore be reinforced, as should its interaction with other relevant agencies including the European Food Safety Authority and the European Environment Agency.

National reporting of timely, complete and comparable data to ECDC, including health systems indicators, based on common EU case definitions, is an integral element in this wider system of surveillance. To support Member States, the **upcoming EU4Health programme will provide financing to improve national surveillance systems**, whilst EU decentralised Agencies will support Member States via tailored technical advice and guidance.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ A new high performing epidemiological surveillance system at the EU level, using artificial intelligence, harmonised datasets and digital tools for accurate modelling, risk assessment and response for the surveillance of novel pathogens based on common EU case definitions	ECDC; Commission
➤ Strengthen access of ECDC to health data for research and epidemiological aspects, in the context of the European Health Data Space.	ECDC; Commission

37 Such as from space, including Earth Observation data from EU Copernicus and geolocation data from Galileo applications

38 Such as from the surveillance of infectious agents in waste water

39 These systems may also benefit from and use services and data enabled or generated by EU initiatives such as the EU Space Programme. The experience of COVID-19 has shown that space enabled services, such as those enabled by EU Galileo, which could provide valuable services and data i.e. geolocation services to map contagion areas, warn about restricted or quarantined areas and alert authorities in case of major gatherings. Specifically in response to COVID-19, Galileo, the EU Satellite Navigation System was used for the development of a new Galileo-enabled application "Galileo for Green Lane" to allow monitoring in real time the circulation of goods between EU Member States and facilitate freight traffic at borders.

40 Integration of Research into policy recommendations, through closer and more active of EU Agencies, is important.

➤ Reinforced surveillance linked to other available information sources and data (e.g. research, environmental, trade, transport, economic data, health systems data, pharmaceutical supplies, contact tracing.)	ECDC; Commission
➤ More detailed and timely reporting requirements for Member States on health care data and performance (e.g. hospital beds availability, specialised treatment and intensive care capacity, number of medically trained staff, contact tracing).	Member States

7. LABORATORY FINDINGS, TESTING & CONTACT TRACING

The Commission and ECDC support Member States to comply with existing EU legislation in the area of surveillance, for which they are required to submit comparable and compatible data based inter alia on laboratory findings. However, whilst there are extensive national laboratory systems in place, there is currently no coordinated EU-wide system of reference laboratory networks for human pathogens. This has resulted in a lack of coordination for consolidated microbiological testing standards.

The diversity in testing strategies and approaches put in place by Member States during the current pandemic has been a consistent challenge and has significantly hampered the EU's coordination efforts to respond to the disease. The reasons behind such diversity in approaches depends on factors such as the epidemiological situation, transmission dynamics, resources and testing capacities. Efficient testing strategies, coordinated between countries, are a pre-condition to ensuring the effective implementation of mitigation measures⁴¹. This work can draw on the long experience in EU cooperation on research and innovation, and on the specific opportunities provided by the Horizon Europe programme.

New EU networks are necessary⁴² to remediate these challenges and ensure these capacities can aptly respond to future serious cross-border threats to health:

- a new network of EU reference laboratories⁴³ allowing the alignment on diagnostics, serological testing, testing methods and use and validation of certain tests will be established;
- a new network including Member State services supporting transfusion, transplantation and medically assisted reproduction to allow for the continuous and rapid access to sero-epidemiological data.

A key pillar for mitigating the transmission of diseases is the implementation of efficient **contact tracing measures**, particularly to enable the control of localised outbreaks. In the current framework, contact tracing was solely included as one of the elements for Member

⁴¹ To this end, the Commission, EU Agencies and Member States put forward recommendations via the Health Security Committee for a common EU testing approach for COVID-19

⁴² To be operated by ECDC with support of the JRC Commission service

⁴³ This network will, amongst other things, provide a framework for evaluation and approval of diagnostics and seek to ensure mutual EU recognition in the field of diagnostics.

States to coordinate via EWRS⁴⁴. Based on lessons learnt from COVID-19, additional efforts are needed at the EU level⁴⁵, to reinforce EU capacities for contact tracing across borders. To begin with, contact tracing will be a required element of the EU health crisis/pandemic preparedness and response plan. To complement the feasibility of contact tracing and to support Member States in this endeavour, the **ECDC will be additionally mandated to set up an automated system⁴⁶ for contact tracing**, building upon the contact tracing technologies developed by the Member States context of contact tracing and warning applications⁴⁷. Finally, contact tracing will also be incorporated into the epidemiological surveillance network of the ECDC. Given these developments, engagement with, and information sharing from Member States to the ECDC will be a prerequisite for ensuring the success of bolstering this capacity.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ Creation of an EU reference laboratories' network that would allow alignment on diagnostics, serological testing, testing methods, use of certain tests	ECDC; Commission
➤ Creation of a network including Member State services supporting transfusion, transplantation and medically assisted reproduction	ECDC; Commission; Member States
➤ A robust system for automated contact tracing, using modern technologies ⁴⁸ , building on contact tracing and warning applications	ECDC; Commission; Member States

8. EARLY WARNING AND RISK ASSESSMENT CAPACITY

The Early Warning and Response System (EWRS) is a rapid alert system for serious-cross border threats to health, enabling the Commission and Member States to be in permanent communication for the purposes of alerting and assessing public health risks and determining measures that may be required to protect public health. EWRS has supported the sharing of notifications and information on COVID-19 cases and response measures. The platform has proven useful and responded to the needs required. By illustration, since 9 January, when the Commission formally alerted EU Member States to COVID-19 via the first alert message, the platform has processed over 2 700 COVID-19 messages⁴⁹, from Member States and the Commission. Moreover, it has facilitated over 30 COVID-19 medical evacuation operations -

⁴⁴ EWRS has operationally supported the sharing of contact tracing information for COVID-19

⁴⁵ The Emergency Support Instrument has financed European Federation Gateway Service for the purpose of contact tracing and warning apps and in July 2020, the Commission also introduced an implementing Decision to enable interoperability of mobile tracing and warning apps across the EU

⁴⁶ This should allow the use of modern technologies, such as digital mobile applications, artificial intelligence models, or other applicable tools that emerge.

⁴⁷ Respect will be ensured as to GDPR

⁴⁸ Such as, but not limited to, space-enabled applications

⁴⁹ These messages, for example, relate to sharing information with regards to contact tracing, epidemiological updates, sharing of technical expertise and updates on health measures implemented.

involving the Member States, the Commission and the World Health Organization - of healthcare workers⁵⁰.

At the same time, the scope of alerts will be broadened to **include needs for or shortages of medical countermeasures, as well as requests and/or offers for cross-border emergency assistance**. This responds directly to the needs revealed during the outbreak of COVID-19 and to ensure coordination of EU mechanisms, notably with strategic reserve EU stockpile under the UCPM, as well as with the Mobility Package under ESI framework⁵¹. The EWRS will further support this coordination amongst countries and the Commission, complementing the UCPM and avoiding duplication and conflicting actions, and it will be enhanced to include functionalities relevant for preparedness planning and reporting, as well as interlinking the platform with other EU level crisis management alert systems.

Finally, the Commission will reinforce an all hazard approach to risk assessment in the new proposals. The proposed Regulation on serious cross-border threats to health will entrust all relevant EU decentralised agencies with risk assessment, scientific advice and recommendations for response measures, incorporating a mandated responsibility for the Commission⁵² and Union agencies.

<u>PROPOSED ACTIONS</u>	
Proposal	Responsibility
➤ A new risk assessment framework for all hazards, including rapid and appropriate recommendation for response measures that Member States should implement	EU decentralised Agencies; Commission

9. INTERNATIONAL COOPERATION AND COORDINATION

COVID-19 has shown that serious threats to health are inherently cross-border. The EU and its Member States provided to, and also received assistance from, third countries in responding to the crisis. As Team Europe, they have so far mobilised over EUR 36 billion with emergency aid and longer-term health and socio-economic support to partner countries in need, with a particular focus on vulnerable people. It has also set up an EU Humanitarian Air Bridge to maintain vital transport links for humanitarian and emergency health workers and supplies

⁵⁰ The Commission has in place a dedicated medical evacuation system (MEDEVAC) with the World Health Organization to facilitate the medical evacuation of healthcare workers for viral haemorrhagic fevers. In 2020, this was extended to include COVID-19. The EWRS platform is used for the Commission to coordinate medical evacuations between the WHO and Member States.

⁵¹ EWRS has been integrated into the EU 'mobility package' for the purpose of cross border transport of medical teams and the transfer of COVID-19 patients: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1118

⁵² Where the risk assessment needed is totally or partially outside the mandates of the agencies and it is considered necessary for the coordination of the response at EU level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

As such, the Commission and EU decentralised Agencies work, and continue to do so, with international stakeholders as well as partner countries. This includes, for example, close collaboration with the WHO, non-EU centres for disease control and prevention, Participating States in the Union Civil Protection Mechanism, as well as engagement in coordination platforms such as the Global Health Security Initiative and GloPiD-R, the network of preparedness research funders. The Commission also actively promotes the need for continued political attention and coordination of public health preparedness and response, via frameworks such as the G7 and G20.

The EU has a leading role to play to strengthen health systems including global health security preparedness and response capacity.

In direct response to COVID-19, the Commission provided the EU's enlargement countries and priority Eastern neighbouring countries access to the Health Security Committee and EWRS, access that was also given to Switzerland. This was undertaken to maximise the protection of citizens and support the response of the EU by clearly acknowledging that the virus does not stop at borders, and that the strongest response and crisis management is via regional and international solidarity and cooperation. The European Parliament and the Council have recently strongly affirmed EU's commitment to scaling up global health emergency preparedness, and the 16 October 2020 European Council committed to strengthening EU support to health systems and the reinforcement of partners' preparedness and response capacity in Africa. Furthermore, the Commission and EU Agencies also initiated regular exchanges of experience with prevention and control measures with China and other third countries.

To consolidate and underpin the benefits of international cooperation and coordination on serious cross-border threats to health, the new proposals confirm the EU's leading role in the global sphere of public health preparedness and response, with the objective of addressing outbreaks at the source via a two-pronged approach: (1) reinforced and targeted international cooperation and coordination; and (2) on the ground support to Member States and third countries, in times of need. On the global level, the ECDC will pursue a leading role and build an international network with other major Disease Control Centres, such as the US Centers for Disease Control and Prevention (CDC).

This will be translated by a **reinforced capacity for ECDC to mobilise and deploy the EU Health Task Force to assist local response in particular in the Member States and greater involvement in international response teams**⁵³, including ECDC support to build more resilient health systems for sustainable health security preparedness in EU partner countries.

PROPOSED ACTIONS

⁵³ These capacities will be interlinked with the UCPM and notably the work of the European Medical Corps, which already gathers Member States medical response capacities.

Proposal	Responsibility
➤ Establishment of the EU Health Task Force within ECDC, to mobilise and deploy to assist local response to outbreaks of communicable diseases in Member States and third countries	ECDC; Commission
➤ Framework for the mobilisation of the EU Health Task Force to provide contribution within international response teams mobilised by the WHO Health Emergencies Programme mechanism, the Global Outbreak Alert and Response Network (GOARN) and the Union Civil Protection Mechanism	ECDC; Commission; Member States
➤ Development of field response capabilities and crisis management expertise among ECDC's staff and experts from EU and EEA countries, EU pre-accession countries, and European Neighbourhood Policy and EU partner countries, upon request of the Commission	ECDC; Commission; Member States; EEA; EU-pre-accession countries; EU Neighbourhood policy and EU partner countries

10. AN EU HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA)

The COVID-19 pandemic has demonstrated the need for and value of co-ordinated EU level action. EU-level advanced purchase agreements for vaccines increase the likelihood that we will exit the crisis together, and stockpiling of medical countermeasures has already lessened its impact. At the same time, the pandemic has revealed structural weaknesses and market failures in our foresight, preparedness and ability to respond coherently, rapidly and appropriately to protect our citizens from health crises.

COVID-19 is unlikely to be the only global or pan-European health crisis of our century. Anticipating this calls for a dedicated European authority that will strengthen the EU's preparedness and response capability for new and emerging cross-border threats to human health.

The authority's mission will be to enable the EU and its Member States to rapidly deploy the most advanced medical and other measures in the event of a health emergency, by covering the whole value chain from conception to distribution and use.

To that effect, it will, for example, undertake horizon scanning and foresight to anticipate specific threats, identify promising potential countermeasures and underpinning competencies, and generate and disseminate knowledge on these. It will monitor and pool production capacity and development facilities, raw material requirements and availability, and ensure that supply chain vulnerabilities are addressed. It will support the development of crosscutting technologies and solutions sustaining multiple potential future threat responses (e.g. vaccine platform technologies, or the application of digital tools and artificial

intelligence) as well as the development of specific countermeasures, including through clinical trials and data infrastructure. It will ensure that sufficient production capacity will be available when necessary, as well as arrangements for stockpiling and distribution.

The European authority will plan, co-ordinate and assemble ecosystems of public and private capabilities that jointly enable a rapid response when the need arises. When an EU health emergency is declared, it will acquire specific additional resources required to adequately react in the interest of all Member States.

Building on the experience with COVID-19 vaccines development and the central clearing house for medical equipment, the Commission will launch a preparatory action focusing on emerging biological threats to human health, such as corona-related transmissible diseases and anti-microbial resistance. In parallel, it will launch an impact assessment and consultation on the establishment of an EU authority, with a view to proposing in 2021 a properly mandated and resourced dedicated structure to start operations in 2023. Synergies and complementarity with existing EU bodies and relevant spending programmes will be ensured.

11. CONCLUSION AND NEXT STEPS

Health is central to people's well-being. They rightly expect it to be one of the major priorities of public policy. Governments must do everything they can to deliver health services and to protect from health threats. This means working together, and using the EU's potential to improve the health response and to support Member States to fulfil their responsibilities. This needs clear direction at EU level, close coordination with the Council and the European Parliament, and the updating of key tools and legislation as set out in this Communication.

The upcoming Conference on the Future of Europe, with its emphasis on outreach to citizens and its aim to create a forum to address their concerns and priorities, provides an optimal platform to ignite discussions provide impetus on the evolution of the EU's role on health in the future, in order to respond to citizens' expectations towards the Union. In addition, the Global Health Summit scheduled for 2021 in Italy will allow the EU to steer the worldwide reflection on how to strengthen global health security in the "age of pandemics".

The coronavirus has touched every single aspect of personal, professional, social and economic life. To effectively address the threat it poses, European health authorities need to work seamlessly together, to pool their resources and expertise, and to operate as jointly as possible and in close coordination with the economic authorities. This is the only way to counter the cross-border health threat of COVID-19 effectively.

This Communication sets out the additional actions that need to be taken in the immediate future, both at the European and the national level to increase our resilience to all cross-border health threats and provide all European citizens with the high level of public health they expect and deserve. It is our shared and urgent responsibility to take forward these measures quickly and thoroughly, and to overcome the fragmentation and gaps in instruments, information, and mind-sets, which will otherwise continue to make us collectively vulnerable and endanger our way of life.

The European Health Union will be as strong as its Member States' commitment to it.