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Dear Chair,

The Commission would like to thank the Special Committee of the House of Representatives of Belgium, charged with examining the Belgian approach to the COVID-19 pandemic, for its written questions and hopes that the attached replies address the issues raised.

Yours sincerely,

S. Kyriakides

Mr Robby De Caluwé
President of the Special Committee examining the Belgian approach on the COVID-19 epidemic
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QUESTIONNAIRE OF THE BELGIAN CHAMBER OF REPRESENTATIVES ENQUIRY COMMITTEE ON THE MANAGEMENT OF THE COVID-19 CRISIS

1. **Were precautions taken at international level to deal with a pandemic? Are risk assessments available? If so, were plans made for an international approach to that risk? Were there exercises/training courses (that you are aware of) to assess the scale of the problem, and what were the most important outcomes of those exercises/training courses?**

   In 2005, with the signing of the revised International Health Regulations (2005)[1], a global framework to coordinate preparedness and response was established. The 196 States Parties committed to reporting public health emergencies of international concern and to strengthening national preparedness and response systems.

   At the European level, the Early Warning and Response System (EWRS) and network for the epidemiological surveillance and control of communicable diseases in the Community was set up at the end of the 1990s (Decision No 2119/98/EC).

   The European Centre for Disease Prevention and Control (ECDC) was established in 2005 and various initiatives focused on the development of preparedness plans[2,3]. These building blocks were integrated through the Decision 1082/2013/EU on serious cross-border threats to health. This decision was created to strengthen capacities for the monitoring, early warning and assessment of, and response to health emergencies. The decision supports sharing best practice and experience in preparedness and response planning, provides a backbone for developing national plans to address different types of health threats (e.g. infectious disease like pandemic influenza, or other events caused by biological or unknown agents, accidents caused by chemical agents, natural events of environmental origin, or deliberate acts), helps ensure the inter-operability of national plans through coordination mechanisms, analysis and communication tools and supports the implementation of core capacity requirements for the World Health Organization International Health Regulations (IHR) to detect, assess, report, and respond to public health emergencies. In addition, the decision includes provisions for the joint procurement of medical countermeasures (JPA), which ensures high levels of preparedness and a tool to support the coordinated response to health threats as well as strengthens the Health Security Committee (HSC).

   Previous to this, in 2000, the Global Outbreak Alert and Response Network (GOARN)[4] was created to improve the coordination of international outbreak responses and to provide an operational framework to focus the delivery of support to countries.

   All initiatives aimed at drawing lessons from the COVID-19 crisis and improving the world's capacity to prevent, prepare and respond to health emergencies are welcome. The EU supports the recently-established Independent Panel for Pandemic Preparedness and Response (IPPR), as well the Review Committee on the Functioning of the International Health Regulations (IHR).

[1] https://www.who.int/publications/i/item/9789241580496
[2] https://ec.europa.eu/health/ph_threats/Bioterrorisme/keydo_bio_01_en.pdf
[3] https://www.ecdc.europa.eu/en/seasonal-influenza/preparedness/influenza-pandemic-preparedness-plans
[4] https://extranet.who.int/goarn/#banner

2. **What measures were taken by the European Union in response to the crisis, specifically in terms of public health?**

Public health matters are the competence of the EU Member States and EU level action is limited by the EU Treaties. On this basis, the European Commission is coordinating a common European response to the coronavirus outbreak, taking resolute action to reinforce public health sectors and mitigate the socio-economic impact in the European Union. It is mobilising all means at its disposal to help the Member States coordinate their national responses, providing objective information about the spread of the virus and making effective efforts to contain it. Further information on the activities of the European Commission regarding the COVID-19 response can be find here: https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en

The Commission's main initiatives in the field of health include:

- Recommendation on conformity assessment and market surveillance procedures within the context of the COVID-19 threat;
- Joint Procurements of COVID medical countermeasures;
- Establishment of rescEU stockpiles of PPEs and other medical equipments;
- Establishment of a COVID-19 Clearing House for medical equipment;
- Amendment of the Medical Devices Regulation;
- Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak;
- Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis;
- Recommendation on apps for contact tracing;
- Communication on Tourism and transport in 2020 and beyond;
- Guidance on the collection and transfusion of convalescent COVID-19 plasma;
- Activation of the Emergency Support Instrument (ESI);
- Guidelines on COVID-19 in vitro diagnostic tests and their performance;
- Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection;
- Communication on towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls — COVID-19;
- Communication on the third assessment of the application of the temporary restriction on non-essential travel to the EU;
- Guidance on the management of clinical trials during the Covid-19 pandemic;
- Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures;
- European Strategy on vaccines;
- Communication on short-term measures to strengthen EU health preparedness for potential future COVID-19 outbreaks;
- Communication on additional COVID-19 response measures;
- Supporting the training of healthcare professionals;
- Commission joins the COVID-19 Vaccine Global Access Facility (COVAX);
- Recommendations for a common COVID-19 testing approach in Europe;
- Preparedness for COVID-19 vaccination strategies and vaccine deployment;

- Health Union Package, comprising three legislative proposals (reinforcement of the mandates of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) and the adoption of Decision 1082/2013 on serious cross-border threats to health);
- Staying safe from COVID-19 during winter;
- Communication on a united front to beat COVID-19;
- Communication on the HERA Incubator;
- Organising a global response for the most fragile countries with weak health systems and on the most vulnerable populations
- Launch of the Access to COVID-19 Tools Accelerator with other global health partners, for equitable access to COVID-19 tools globally;
- Initiating a global response through hosting the Coronavirus Global Response Conference to support the Access to COVID-19 Tools Accelerator, raising almost EUR 16 billion[5];
- Providing support of over EUR 2.2 billion to the COVAX Facility for rolling out COVID vaccines worldwide[6].

3. What relations does the European Commission have with the WHO? How is the flow of information organised?

The collaboration between the European Commission and the World Health Organization (WHO) is built on an exchange of letters (published in the Official Journal of 4 January 2001). In addition, the Commission and the World Health Organization Regional Office have issued joint statements on their cooperation, most recently in September 2020[7].

Cooperation between the World Health Organization and the European Commission is also facilitated by high-level annual meetings. These regular Senior Official Meetings (SOM) take place with the political and strategic oversight of World Health Organization Director-General, World Health Organization Regional Director for Europe and the European Commissioner in charge of health[8]. In addition, high-level officials from both parties frequently meet bilaterally and at the occasion of multilateral meetings. The Commission provides substantial financial support to the World Health Organization.

In the field of emergency response preparedness, a practical cooperation with World Health Organization Emergency Medical Teams Secretariat also takes place, regarding the classification and certification of Emergency Medical Teams (EMT) from Member States, which are then offered to the European Civil Protection Pool/European Medical Corps. With regard to development cooperation support to strengthen health systems in partner countries, the Commission works with the WHO through the EU-WHO Health Systems

[5] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_en
[6] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_en
[7] https://ec.europa.eu/health/sites/health/files/international_cooperation/docs/2020_who_euro_cooperation_en.pdf
[8] https://www.euro.who.int/en/about-us/partners/the-european-union-and-its-institutions/european-commission-ec/senior-officials-meeting-som

Strengthening for Universal Health Coverage Partnership Programme, that also addresses sustainable health security preparedness and response.

4. **What is your assessment of the role played by the WHO in the earliest days, weeks and months of the crisis? Did the WHO raise the alarm late, as some people claim?**

At the 73rd World Health Assembly in May 2020, its members adopted an EU-led resolution on COVID-19 Response. The resolution called on World Health Organization to initiate an independent, impartial and comprehensive evaluation of the World Health Organization - coordinated international health response to COVID-19. This should, among others, review the effectiveness of the mechanisms at World Health Organization's disposal and the functioning of the International Health Regulations (IHR). To implement the resolution, on 9 July 2020 the Director-General of the World Health Organization announced the initiation of the Independent Panel for Pandemic Preparedness and Response to undertake this review. The Panel began its review in September 2020. It will present a report to the 74th World Health Assembly scheduled for May 2021. The World Health Organization's IHR Review Committee and the Independent Oversight and Advisory Committee for the World Health Emergencies Programme will also carry out reviews.

The Commission will await the outcome of these reviews before drawing conclusions.

In February 2021, the EU has taken the lead in consultations between World Health Organization countries to prepare a resolution on strengthening World Health Organization preparedness for and response to health emergencies. The adoption of the resolution by the World Health Assembly is foreseen in May 2021.

5. **Why was there no real leadership by an international body in this crisis?**

The COVID-19 pandemic, and its health, social and economic consequences, have further underlined the need, among others, for strong global multilateral cooperation, for strong global health capacities and for a global health challenge response. The World Health Assembly Resolution on COVID-19 Response reiterated that the World Health Organization (WHO) has the constitutional mandate to act as the directing and coordinating authority on international health work, and recognised the Organization's key leadership role within the broader United Nations response and the importance of strengthened multilateral cooperation in tackling the COVID-19 pandemic and its extensive negative impacts. As outlined in the reply to question 4, the EU and Member States are involved in the ongoing processes aimed at strengthening the coordinating and leading role of the WHO in pandemic preparedness and response, and reinforcing the organization's independence, normative work, technical capacity, accountability, efficiency, effectiveness and transparency. One important outcome of the leadership of the World Health Organization, with the support of the European Commission and other leaders, is the Access to COVID-19 Tools (ACT) Accelerator[9]. ACT-A is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

[9] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_en#access-to-covid-19-tools-act-accelerator

6. **What is the difference between the objective, mission and task of the WHO and that of the ECDC? To what extent do they overlap, and to what extent are they complementary?**

Enjoying the status of a United Nations Specialized Agency, the World Health Organization is a multilateral organisation with a legal mandate to set norms and standards. A good example are the International Health Regulations, which are legally binding for all the World Health Organization state parties. The World Health Organization works worldwide to promote health, keep the world safe, and serve the vulnerable.

The European Centre for Disease Prevention and Control (ECDC) is an EU agency aimed at strengthening Europe's defences against infectious diseases as set out in its Founding Regulation[10] and Decision 1082/2013 EU on serious cross border threats to health. Its main task is to provide advice and guidance on risk assessment to the EU Member States, whereas - unlike the World Health Organization - it has no mandate to engage in risk management. The core functions cover a wide spectrum of activities: surveillance, epidemic intelligence, response, scientific advice, microbiology, preparedness, public health training, technical cooperation with international organisations and third countries, health communication, and the scientific journal Eurosurveillance. The ECDC's disease programmes cover antimicrobial resistance and healthcare-associated infections; emerging and vector-borne diseases; food- and waterborne diseases and zoonoses; human immunodeficiency virus (HIV), sexually transmitted infections and viral hepatitis; influenza and other respiratory viruses; tuberculosis; and vaccine-preventable diseases.

Over the years, the ECDC has developed a very close collaboration with the World Health Organization, particularly with the World Health Organization Regional Office for Europe. Collaboration with the World Health Organization Regional Office for Europe takes place within the framework of the ECDC and the World Health Organization Europe Administrative Arrangement (2011). Experts from the ECDC and the World Health Organization communicate on a daily basis, however strategic discussions and alignment of activities are taking place during annual programmes' coordination meetings, as well as during high-level meetings between the Directors. The ECDC works in synergy with the World Health Organization and aligns its activities accordingly including for example on the case definition and case reporting of communicable diseases.

Throughout the COVID-19 pandemic, the ECDC has been working very closely with the World Health Organization headquarters and Regional Office for Europe. A concrete example of collaborative work was a joint World Health Organization - ECDC mission to Italy. When Italy saw a sharp increase in numbers of COVID-19 cases in late February/early March 2020, a joint World Health Organization-ECDC team was in Italy to support the national and regional authorities in their efforts to control the outbreak. This a clear example of how synergy and complementarity between the two organisations can bring added value to our respective member states.

[10] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32004R0851

7. **Will there be a report comparing how the EU Member States reacted, how fast they reacted and what the effect is on the statistics and on the policy implemented in those Member States (in comparison with the others)?**

The issue of Member State's response to the COVID-19 pandemic has been discussed during Health Security Committee meetings[11].

On 11 November 2020, the European Commission's independent Group of Chief Scientific Advisors (GCSA), the European Group on Ethics in Science and New Technologies (EGE) and Mr Peter Piot, special advisor to the President Ursula von der Leyen on the response to COVID-19, published a joint Opinion on Improving pandemic preparedness and management. The advisor's opinion advises policy making by the European Commission in relation to pandemics and its recommendations have informed the plans for a European Health Union: Stronger EU preparedness and response for health crises. The advisors' collaboration is planned to continue in 2021, with a third joint advice on how Europe can develop towards stronger resilience to crises in general.

The European Commission proposed under the European Health Union package[12] that, on the basis of the information provided by the Member States and of the results of the audits, the Commission should by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.

The Health System Response Monitor (HSRM) has been designed in response to the COVID-19 outbreak to collect and organize up-to-date information on how countries are responding to the crisis. It focuses primarily on the responses of health systems but also captures wider public health initiatives. This is a joint undertaking of the World Health Organization Regional Office for Europe, the European Commission, and the European Observatory on Health Systems and Policies[13].

8. **How often did the Health Security Committee meet in the period up to the end of March 2020? What were the conclusions of those meetings?**

There have been 54 meetings of the Health Security Committee (HSC) dedicated to COVID-19 response (end of March 2021), of which 13 were held until the end of March 2020. These meetings take place on average once a week. They give the opportunity to update Member States on the latest development of the pandemic and the Commission's response to it as well as to exchange views, share best practices and reach a consensus regarding countermeasures.

The main conclusions/ follow-up of the last meeting in March 2020 included the following:

- Update on ECDC Rapid Risk Assessment. The risk of severe disease associated with COVID-19 for people in the EU/EEA and the United Kingdom was considered moderate for the general population and very high for older adults and individuals with chronic underlying conditions. A shortage of testing materials and personal protective equipment for laboratory and health care workers treating COVID-19 patients; and the importance of validated rapid tests were indicated. Among control measures, the

[11] https://ec.europa.eu/health/hsc_covid19_en
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0727
[13] https://eurohealthobservatory.who.int/?

importance of hand washing routine, social distancing, increasing surge capacities and implementing infection prevention and control (IPC) measures in long-term care facilities were highlighted.

- The ECDC will update on the work on exit strategies and to facilitate linking up with modelling teams in Member States.
- The Member States were asked to provide feedback to the Commission on potential areas to be covered by its guidance on the application of existing rules as regards cross border healthcare to further facilitate such care, covering aspects including coordination of requests, transport, reimbursement, and treatment.
- The Member States were encouraged to join multicentre clinical trials and to revert with nominations to the HSC working group on clinical case management and to express their interest for the joint procurement for investigational therapeutics, and specific needs.

The minutes of the meetings of the Health Security Committee, including key conclusions can be found at: https://ec.europa.eu/health/hsc_covid19_en

9. There was a meeting of the Health Security Committee on 31 January 2020. The minutes state that not one Member State reported a shortage of personal protective equipment. Only 4 countries stated there was "the potential need for PPE in case of an expanding situation in the EU." Which countries were they? Did the EU take steps to obtain more personal protective equipment?

Since the beginning of the pandemic the EU has supported manufacturers to ensure availability of the essential medicines and medical equipment needed in the fight against COVID-19. This has included joint procurement and strategic medical stockpiling to build up key supplies. The Commission launched seven calls for tenders for the supply of medical countermeasures - including personal protective equipment (PPE) for gloves and coveralls on 28 February; and for goggles, face shields and masks (as well as ventilators) on 17 March[14]. By 3 February the Commission had indications from 7 countries regarding their desire to explore possibilities connected with obtaining additional PPE. Contact was made with these countries to get further information on their precise needs in terms of the kind and quantity of PPE and timescale. The Commission immediately asked the Member States via HSC contacts if there were possibilities to provide PPE bilaterally to those countries which had provided information on their needs.

In March 2020, under the framework of the Union Civil Protection Mechanism (UCPM), the strategic rescEU stockpile of medical countermeasures and personal protective equipment was created to combat serious cross-border threats to health. The overall objective of the rescEU stockpile is in fact, to support Member States and Participating States to the UCPM, to build systemic resilience in response and in preparation for current and future pandemics. So far, the Commission has signed 10 grant agreements with 9 countries across Europe (Belgium, Denmark, Germany, Greece, Hungary, Netherlands, Romania, Slovenia and Sweden) that are now hosting these stockpiles. A large part of the items stored is made up of PPE. Moreover, since its creation, 9 countries have benefitted from the items present in the stockpile (Croatia, Czech Republic, France, Italy, Lithuania, Montenegro, North Macedonia, Serbia and Spain), these rescEU deployments have once again mostly entailed PPE.

[14] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en; https://ec.europa.eu/info/sites/info/files/communication-additional-covid-19-response-measures.pdf

10. **At the end of January, the WHO declared the epidemic to be a Public Health Emergency of International Concern (PHEIC). Were adequate precautions taken in the course of February to prevent this crisis in Europe? Was too much attention not paid to a potential outbreak in Africa?**

    The ECDC took immediate action in coordination with the Commission and EU/EEA Member States much in advance of the World Health Organization declaring COVID-19 a PHEIC. The ECDC's actions are documented in the various risk assessments, epidemiological updates, meetings with relevant Member States authorities, and guidance. The internal course of action was guided by a well-established and repeatedly tested Public Health Emergency (PHE) plan. Furthermore, the ECDC and the European Commission had been working on an ongoing basis in supporting preparedness in EU/EEA countries within the framework of the Commission Decision 1082/13 on cross-border health threats. The coordination between ECDC and Centres for Disease Control and Prevention (Africa CDC) was well established since the very beginning of the pandemic and proper attention was paid to the situation in the continent. Dedicated health security support of EUR 10 million[15] was provided to the Africa Centres for Disease Control and Prevention for capacity building measures. Furthermore, the combined response of the Commission and Member States has resulted in allocating at least EUR 8 billion[16] for Africa of which EUR 6.2 billion for Sub-Saharan Africa.

11. **At a meeting on 13 February 2020, it was stated that there was sufficient laboratory capacity in Europe. Based on which statistics was that conclusion reached? Was each country expected to decide for itself whether testing capacity was adequate, or was a minimum level set by the ECDC?**

    In the early phase of the pandemic the ECDC did a capacity assessment of the Member States on their ability to detect the novel coronavirus in their laboratories, following the methods published after the initial characterisation of the virus was made mid-January 2020. The assessment of the readiness of EU/EEA laboratories for molecular detection of 2019-nCoV demonstrated a fast implementation of molecular diagnostics by the European specialised laboratory networks with a good geographical coverage for testing. Overall, 38 laboratories with capacity at a minimum of 8,275 tests per week was reported. At country level, 24 of 30 EU/EEA countries had already implemented molecular tests for 2019-nCoV while the laboratories in the remaining six countries had arranged to ship clinical specimens of suspected cases to a specialised laboratory abroad, while planning to implement assays between 30 January and 17 February 2020. The overall conclusion from the assessment was that, while molecular testing for 2019-nCoV was quickly implemented in EU/EEA countries there was room for improvement especially in the aspect of clinical validation of such tests, i.e. their specificity and sensitivity.

12. **When the crisis erupted in early March, some Member States (France and Germany) decided to reserve personal protective equipment for themselves. What was the European Commission's reaction to that decision? How can that be avoided in future? Was there a lack of solidarity?**

[15] https://eeas.europa.eu/delegations/african-union-au/86578/team-europe-supports-africa%E2%80%99s-covid-19-response-14-million-test-kits-donated-germany-and_ar

[16] https://ec.europa.eu/international-partnerships/news/european-union-and-african-union-sign-partnership-scale-preparedness-health-emergencies_en

Public health matters are the competence of the EU Member States and it is national governments that decide on the specific measures based on each country's national epidemiological and social situation.

Since the start of the outbreak, the Commission has been continuously cooperating with and supported all the relevant stakeholders in order to ensure the availability of sufficient quantities of essential personal protective equipment ('PPE') needed in the fight against the COVID-19 virus.

In the beginning of March 2020 and throughout the following weeks, as part of the national responses to fight the COVID-19 outbreak, many Member States decided to unilaterally introduce export restrictions of PPE and other COVID-related products. Such measures heavily disrupted supply-chains, increased shortages of essential products, and had a domino effect among Member States who felt compelled to adopt similar protectionist approaches. In many cases, the Member States used Directive (EU) 2015/1535 (Single Market Transparency Directive) to notify, under the urgency procedure, the national measures which had already been adopted.

Following bilateral contacts between the Commission and the Member States concerned, most of the export restrictions were lifted or subject to frequent adjustments. This work has included providing guidance to facilitate the entry and circulation of the relevant products to the market. Furthermore, these efforts were also coupled with the adoption of a temporary EU-wide export authorisation scheme for PPE, which applied from 15 March 2020 and was extended one time until 26 May 2020. Finally, the Commission has been maintaining constant contacts with all relevant stakeholders in order to monitor the availability of essential PPE products.

These efforts have included help in ensuring that these products reach those who need them the most (in particular the healthcare workers and other first line responders), and in preventing their export justified restrictions hampering their free movement across the internal market and also globally.

The Commission launched seven calls for tenders for the supply of medical countermeasures on 28 February (gloves and coveralls), 17 March (goggles, face shields and masks, as well as ventilators), 19 March (laboratory equipment, including testing kits), 17 June (Intensive Care Unit medicines), 11 September (therapeutic remdesivir – veklury) and 28 September (medical equipment for COVID-19 vaccination) - with participation of up to 36 countries. Framework contracts following the first four joint procurement procedures have been signed and the Member States can place orders among others for personal protective equipment (coveralls, gloves, googles, face-shields and masks).

Since March 2020, under the rescEU stockpile, the Commission has signed 10 grant agreements for the procurement of medical equipment and PPE, with 9 Member States. A large part of the items procured constitute PPE (surgical masks, FFP2, FFP3, googles/eye protection, face shields, overalls, gowns, aprons, gloves shoe covers, head covers). These items are fully financed by the Commission.

13. **How did ECDC advice on the use of face masks evolve? Who needed to be provided with those masks (medical personnel and/or the general public)? What type of masks needed to be provided, and how many? How did that change over time?**

The ECDC provided advice on face masks for healthcare workers in healthcare settings in the 'Infection prevention and control for the care of patients with 2019-nCoV in healthcare settings' published on 2 February 2020[17]. This guidance has been updated five times with the latest update published on 6 October 2020. The recommendation on face masks has been consistent in these documents. Respirators (FFP2/3) have been recommended in all these documents for the care of COVID-19 patients. In the second update, published on 31 March, medical face masks were recommended in case there was a shortage of respirators. In the same update, the ECDC recommended considering the use of surgical 'medical' face masks by all healthcare workers for personal protection and source control.

In addition, the ECDC produced a checklist for hospitals preparing for the reception and care of COVID-19 patients[18] to support the public health preparedness planning for hospitals.

Use of masks in the community was addressed by the ECDC in a technical report with the title 'Using face masks in the community' published on 8 April[19]. The recommendation was that 'The use of face masks in the community could be considered, especially when visiting busy, closed spaces, such as grocery stores, shopping centres, or when using public transport, etc.' and that ' The use of nonmedical face masks made of various textiles could be considered'. The issue was further addressed in the 'Guidelines for the implementation of non-pharmaceutical interventions against COVID-19' published on 24 September[20]. The recommendation was that 'implementation of the use of face masks in the community when physical distancing cannot be guaranteed should be strongly considered, both indoors (e.g. supermarkets, shops and public transport) and in crowded outdoor settings in areas with community transmission of COVID-19. In addition, use of face masks should be strongly recommended for groups at risk of developing severe complications if infected (e.g. individuals in older age groups or having underlying conditions) and in people whose occupations involve extensive face-to-face contact with the public in areas where there is ongoing transmission. The use of non-medical ('community') face masks was considered an acceptable option that may successfully address the issue of availability and cost.

In February the ECDC provided guidance on needs assessment for personal protective equipment including respiratory protection to support preparedness planning in healthcare settings[21].

14. The 'case definition' in Belgium was based initially on ECDC advice. In February and early March, this case definition was very limited. It had to involve clear symptoms, and there needed to be a link to an infected region (China and some regions of Northern Italy). Why was it so restrictive? Did this not lead to a much larger outbreak in Europe?
The approach in Europe was at Member State level. ECDC updates the statistics of the various countries, and harmonises them. How do the figures for Belgium relate to those in our neighbouring countries and other EU Member States? Has ECDC already carried out an evaluation of which measures seemed to be effective in the approach to the pandemic?

[17] https://www.ecdc.europa.eu/sites/default/files/documents/nove-coronavirus-infection-prevention-control-patients-healthcare-settings.pdf
[18] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-checklist-hospitals-preparing-reception-care-coronavirus-patients.pdf
[19] https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-use-face-masks-community.pdf
[20] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-guidelines-non-pharmaceutical-interventions-september-2020.pdf
[21] https://www.ecdc.europa.eu/sites/default/files/documents/novel-coronavirus-personal-protective-equipment-needs-healthcare-settings.pdf

The ECDC, following also the advice from the Health Security Committee and the ECDC Advisory Forum, aligned the COVID-19 case definition for the EU/EEA countries with the global case definition established by the World Health Organization. When the ECDC proposed to expand the case definition to China and other countries in East Asia, there was significant pushback from the Member States, based on the limited resources available for testing at that point in the crisis. Nonetheless, the ECDC expanded its case definition before the World Health Organization. At the same time, the geographical restrictions for testing referred only to mild presentations. As from 2 March 2020, individuals with severe symptoms were recommended to be tested regardless of an epidemiological link to the affected areas.

Figures for Belgium and other Member States are available on the ECDC's website (COVID-19 country overviews)[22].

The ECDC reviewed the literature on evaluation of non-pharmaceutical interventions applied during the COVID-19 pandemic in the 'Guidelines for the implementation of non-pharmaceutical interventions against COVID-19'[23].

15. How did the EU assess the consequences of different counting methods for deaths in Belgium compared with other European countries?

To address differences in surveillance strategies, testing rates, response measures, and sentinel surveillance systems, the ECDC publishes country-specific details to help public health practitioners and decision makers understand the epidemiological situation within each country. Surveillance systems and methodologies vary between countries and the ECDC recommended in all Risk Assessments to interpret the data with caution[24].

The ECDC has consistently argued against comparing data across the Member States due to differences in public health systems, testing strategies, surveillance systems and definitions.

16. What critical analysis has there been of the handling of the crisis in Belgium (including epidemiological surveillance)?

It is not under the remit of the European Commission to provide a critical analysis on how the crisis has been handled in Belgium.

17. After the first lockdown, European borders were re-opened, and it was possible to travel within the EU. Why did the ECDC not arrange subdivision into different zones (red, orange, etc.), leaving this to be done by the Member States themselves? Europe did not create any framework for the Member States for issuing positive or negative travel advisories. How is that possible? Is there no mandate for setting up crisis coordination? Are there no bodies for this purpose in existence? Why was there no harmonisation in terms of definitions of red or orange zones, etc. within the European Union, particularly during this summer?

[22] https://www.ecdc.europa.eu/en/covid-19/country-overviews
[23] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-guidelines-non-pharmaceutical-interventions-september-2020.pdf
[24] https://www.ecdc.europa.eu/en/covid-19/surveillance/weekly-surveillance-report (in particular in section 6)

As far as travel advice is concerned, the issuance of such advice to their nationals is a competence of the Member States. At European level, the Member States exchange information as to the travel advice they issue, via the Consular On-Line platform operated by the European External Action Service (EEAS), but there is no harmonisation of the advice issued.

To limit the spread of the COVID-19 outbreak, the Member States have adopted various measures, some of which have had an impact on citizens' right to move freely across the EU. These measures often included restrictions on entry to another Member State or other specific requirements (such as undergoing quarantine) applicable to cross-border travellers. While such public health measures are primarily a Member State competence, they must comply with the EU law and in particular with the principles of non-discrimination and proportionality insofar as they constitute a restriction to EU citizens' right to free movement.

Since the outbreak of the pandemic, the Commission has worked closely with the Member States on travel-related measures. The Commission and the Member States engaged in regular exchange of information and good practice in a variety of fora, including at the technical level through the 'COVID-19 Information Group – Home Affairs' and the Health Security Committee.

Already in March 2020, the Commission issued Guidelines for border management measures to protect health and ensure the availability of goods and essential services[25] and Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak[26], containing guidance on the free movement of frontier workers, seasonal workers and self-employed persons exercising critical occupations.

On 13 May 2020, the Commission adopted, as part of a package of guidelines and recommendations, a Communication towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls[27], referring also to the flexibility to reintroduce certain measures if required by the epidemiological situation.

As part of this package, the Commission launched, on 15 June 2020, Re-open EU, an online platform that contains essential information about the safe travel across Europe. It provides information on borders, available means of transport, travel restrictions, public health and safety measures, such as physical distancing or wearing of facemasks and other practical information for travellers.

On 11 June 2020, the Commission adopted a Communication to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU[28], in which it encouraged the Member States to finalise the process of lifting restrictions to free movement within the EU as soon as the epidemiological situation allows it.

On 7 August 2020, the Commission's services sent an administrative letter to the Member States, in which they recalled principles applicable to restrictions and limitations to free movement to inform possible decisions on pandemic-related restrictions to free movement. Taking into account the evolution of the pandemic, some Member States had maintained or

[25] OJ C 86I , 16.3.2020, p. 1.
[26] OJ C 102I , 30.3.2020, p. 12.
[27] OJ C 169, 15.5.2020, p. 30
[28] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0399

had reintroduced certain restrictions to free movement within the EU at the end of the summer, requiring further progress and additional coordination efforts among Member States. While entry bans had been lifted to a large extent, businesses and citizens were still confronted with a wide array of diverging measures.

To address this situation, the Commission adopted, on 4 September 2020, a proposal for a Council Recommendation to improve the coordination and communication of measures that restrict free movement within the EU due to the coronavirus pandemic, based on preparatory work carried out during the summer. The proposal set out four key points where a more coordinated approach among Member States was needed: 1. Common criteria and thresholds for the Member States when deciding whether to introduce travel restrictions, 2. Mapping of common criteria using an agreed colour code; 3. A common approach to measures applied to travellers from high-risk areas; and 4. Clear, comprehensive and timely information to the public on any restrictions and requirements.

There is no scientific evidence for categorising countries in different zones for the purpose of informing border measures at the stage of significant transmission of COVID-19. A decision to do so is a political decision and therefore not within the mandate of the ECDC.

Since the adoption of the proposal by the Council on 13 October 2020[29], the ECDC has been publishing the common traffic-light map according to the agreed criteria and thresholds. The maps are based on data reported by EU Member States to the European Surveillance System (TESSy) database every Tuesday.

On 25 January 2021, the European Commission proposed additional safeguards and requirements for international travellers into the EU and to update the Council Recommendation (of October 13) on coordinated measures affecting free movement within the EU (adopted by the Council). The Council Recommendation was amended on 1 February 2021 adding a fourth level to the 3 colour traffic light system[30].

At their last video conference of 26 February 2021, the members of the European Council agreed that non-essential travel needed to be restricted. In this context, several Member States have adopted very tight measures.

On 16 February 2021, the Commission's services sent letters to all Member States to remind them to follow the common approach adopted under the Council Recommendation (of October 13) on travel restrictions.

On 22 February 2021, the Commission's services sent administrative letters to 6 Member States (Belgium, Denmark, Germany, Hungary, Finland and Sweden) to address specific concerns regarding their measures.

The Commission is currently analysing the replies and deciding on the next steps.

On 17 March 2021, the Commission adopted a legislative proposal for a common approach to "digital green certificates" to facilitate free movement in the EU. The proposal puts in place an EU-wide interoperable framework for the issuance, verification and acceptance of vaccination certificates, test certificates and certificates of recovery within the EU for the duration of the pandemic.

[29] OJ L 337, 14.10.2020, p. 3–9
[30] OJ L 36I , 2.2.2021, p. 1–6

Further alignment on the travel restrictions within the EU, such as regarding quarantine and testing requirements, has not been possible so far, given the lack of agreement among the Member States on this issue of national competence.

18. On 15 July 2020, the European Commission published short-term recommendations for containing a second wave. These documents and recommendations contain proposals for the Member States for the period July-September. Few countries have applied these recommendations. What are the reasons for that?

The European Commission is coordinating a common European response to the coronavirus outbreak. It has taken resolute action to reinforce public health sectors and mitigate the socio-economic impact in the European Union. It is mobilising all means at its disposal to help the Member States coordinate their national responses, provides objective information about the spread of the virus and makes effective efforts to contain it. Public health matters (the responsibility for the organisation of and the delivery of healthcare services) however, are the competence of the EU Member States and it is national governments that decide on the specific measures based on each country's national epidemiological and social situation.

19. Do some of the powers of the Member States for health care need to be transferred to the European level (e.g. pandemic management)?

On 11 November the European Commission proposed the revision of the serious cross-border threats to health Decision[31]. The revision includes:

- Strengthening preparedness: an EU health crisis and pandemic preparedness plan and recommendations will be developed for the adoption of plans at national levels, coupled with comprehensive and transparent frameworks for reporting and auditing. The preparation of national plans would be supported by the European Centre for Disease Prevention and Control and other EU agencies. The plans would be audited and stress tested by the Commission and EU agencies.

- Reinforcing surveillance: A strengthened, integrated surveillance system will be created at the EU level, using artificial intelligence and other advanced technological means.

- Improving data reporting: the Member States will be required to step up their reporting of health systems indicators (e.g. hospital beds availability, specialised treatment and intensive care capacity, number of medically trained staff, etc.)

- The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis relevant products.

The European Commission is also proposing to reinforce the mandates of the European Centre for Disease Prevention and Control (ECDC)[32] and the European Medicines Agency (EMA)[33].

[31] COM(2020) 727 final
[32] COM(2020) 726 final
[33] COM(2020) 725 final

Furthermore, the Communication on 'Building a European Health Union - preparedness and resilience' sets out the main elements of the future Health Emergency Preparedness and Response and Preparedness Authority (HERA), an important new element to support a better an EU level response to cross-border health threats[34]. To prepare Europe for an increased threat of coronavirus variants, the Commission launched the "HERA Incubator" on 17 February[35].

The proposed measures should complement existing Union provisions in the fields of crisis response and health, such as the strategic stockpiling under the rescEU scheme (Article 12 of Decision No 1313/2013/EU on a Union Civil Protection Mechanism). As it is necessary to ensure that the Commission in liaison with the Member States, coordinates information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under the different mechanisms established at Union level.

These proposals and initiatives remain within the boundaries of the EU Treaty which reserves the competence for health matters as a prerogative of the Member States.

The forthcoming Conference on the Future of Europe may be an appropriate forum to discuss, in an inclusive manner, more fundamental questions about the division of labour between the national and EU level in health policy.

[34] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN
[35]https://ec.europa.eu/commission/presscorner/detail/en/ac_21_666