

# Review <sup>NO</sup> 01

EN

## The EU's initial contribution to the public health response to COVID-19



EUROPEAN  
COURT  
OF AUDITORS

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## Executive summary

I Chinese officials informed the World Health Organisation (WHO) of a cluster of cases of ‘viral pneumonia of unknown cause’ in Wuhan on 3 January 2020. The WHO classified COVID-19 as a pandemic on 11 March 2020. By 30 June 2020, there were 1.5 million COVID-19 cases and 177 000 deaths declared in the EU/EEA/UK.

II The Treaty on the Functioning of the European Union assigns limited responsibilities to the EU for public health, which remains primarily a Member State competence. The 2013 legal framework for EU level actions to deal with serious cross-border health threats, including pandemics, gives the EU a supporting and coordinating role and establishes legal obligations on Member States in a number of areas, including alerts, surveillance, preparedness and coordination of response:

- The Commission fosters information exchange between Member States through the Health Security Committee and organises joint procurement framework contracts for medical countermeasures.
- The European Centre for Disease Prevention and Control (ECDC) conducts epidemiological surveillance, provides risk assessment and scientific advice, and liaises with other Centres for Disease Control around the world and the World Health Organisation.

III In addition to the actions foreseen by the 2013 EU framework for cross-border health threats, the Commission and EU agencies – as an initial response to the crisis – took action to facilitate the supply of medical supplies, promote testing, treatment and vaccine research and facilitate information exchange between Member States. The EU budget supported a range of actions including stockpiling medical equipment, COVID-19 research and vaccine advanced purchase agreements. The EU expanded the range of spending eligible for cohesion funding to cover COVID-19 related public health spending.

**IV** This is not an audit report, it is a review of the EU's initial response to the pandemic mainly based on publicly available information or material specifically collected for this purpose. We cover actions taken from 3 January to 30 June 2020. We chose this timeframe in order to focus on the EU's initial response to the pandemic. We focused on:

- the use of the EU framework for dealing with cross-border threats to health;
- the additional actions taken by the Commission and EU agencies to support the provision of supplies of medical and personal protective equipment;
- EU support for the research and development of COVID-19 tests, treatments and vaccines.

**V** The ECDC produced 11 rapid risk assessments on COVID-19 by the end of June 2020, with broad scenario-based assessments of COVID-19 transmission risks for the EU/EEA/UK region. Member States used national procurement pathways to buy the vast majority of the protective and medical equipment they needed while by 30 June 2020, approximately €4.5 billion was allocated from the EU budget to support public health related measures. Most of this money had not been used by 30 June.

**VI** We highlight some of the challenges faced by the EU in its support to Member States' public health response to COVID-19. These include setting an appropriate framework for cross-border health threats such as the COVID-19 pandemic, facilitating provision of appropriate supplies in a crisis and supporting the development of vaccines.

# Introduction

**01** The first declared cases of COVID-19 in China in December 2019 were associated with an animal market in the city of Wuhan. The earliest known symptoms of these cases dated to 8 December 2019<sup>1</sup>. Subsequently, earlier cases of COVID-19 were identified in China dating from November 2019<sup>2</sup> as well as possible cases in France<sup>3</sup> the same month. A World Health Organisation (WHO) spokesperson confirmed that the virus was likely circulating but unrecognised before December 2019<sup>4</sup>. On 20 January 2020, China's National Health Commission confirmed that the coronavirus could be transmitted between humans. France identified the first confirmed case of COVID-19 in Europe on 24 January<sup>5</sup>. Neighbouring Member States reported their first cases shortly after as the virus spread across Europe. The WHO declared the coronavirus outbreak a Public Health Emergency of International Concern on 30 January 2020<sup>6</sup>. By early March, Europe had become the centre of the global pandemic before the Americas became the region with the highest number of cases in April (see [Figure 1](#)). The WHO classified the COVID-19 outbreak as a pandemic on 11 March 2020. By 30 June 2020, there were 1.5 million COVID-19 cases and 177 000 deaths declared in the EU/EEA/UK<sup>7</sup>.

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<sup>1</sup> WHO: '[Novel Coronavirus – China](#)', disease outbreak news 12.1.2020.

<sup>2</sup> South China Morning Post: '[Coronavirus: China's first confirmed Covid-19 case traced back to November 17](#)', 13.3.2020.

<sup>3</sup> Hôpital Albert Schweitzer: [Communiqué de presse Coronavirus/Covid-19](#), 7.5.2020.

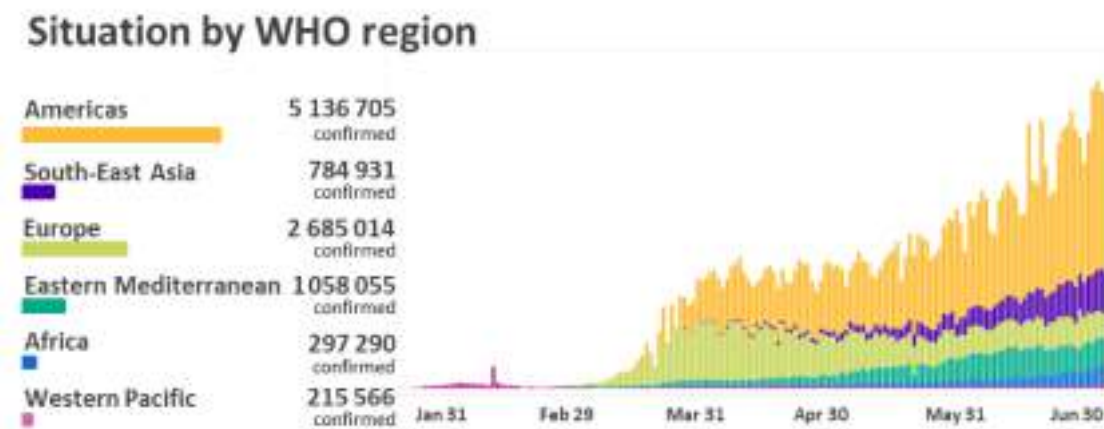
<sup>4</sup> United Nations: [Bi-weekly press briefing](#), 5.5.2020.

<sup>5</sup> ECDC: [Timeline of ECDC response to COVID-19](#).

<sup>6</sup> WHO: [Director-General's statement on IHR Emergency Committee on Novel Coronavirus \(2019-nCoV\)](#), 30.1.2020.

<sup>7</sup> ECDC: [Rapid Risk Assessment](#), 2.7.2020.

**Figure 1 – COVID-19 case comparisons by WHO region up to 30 June 2020**



Source: [WHO](#) (the WHO Europe region comprises more countries than the EU/EEA/UK).

**02** The commonest clinical features are fever plus a respiratory illness. Severe illness and death are more likely to occur in older individuals, and in those with certain pre-existing clinical illness<sup>8</sup>. The virus spreads directly through inhalation of aerosol droplets and indirectly through contact with contaminated surfaces. The lack of knowledge and data on the disease, especially in the early days of the pandemic, represented a considerable challenge for public authorities.

## **Member States are responsible for managing health services and allocating resources to them**

**03** All EU Member States are members of the WHO and signatories of the 2005 WHO International Health Regulation (IHR). The IHR requires signatory states to have pandemic preparedness plans and to inform the WHO of public health risks that may have an impact outside their territory<sup>9</sup>.

**04** Each Member State is responsible for managing and funding health services and medical care on its territory. All the Member States put in place a range of public-health measures to tackle the spread of the virus (see [Figure 2](#)).

<sup>8</sup> Ibid.

<sup>9</sup> WHO: [International Health Regulation Brief No 1](#).

**Figure 2 – Typical public health measures taken in response to COVID-19**

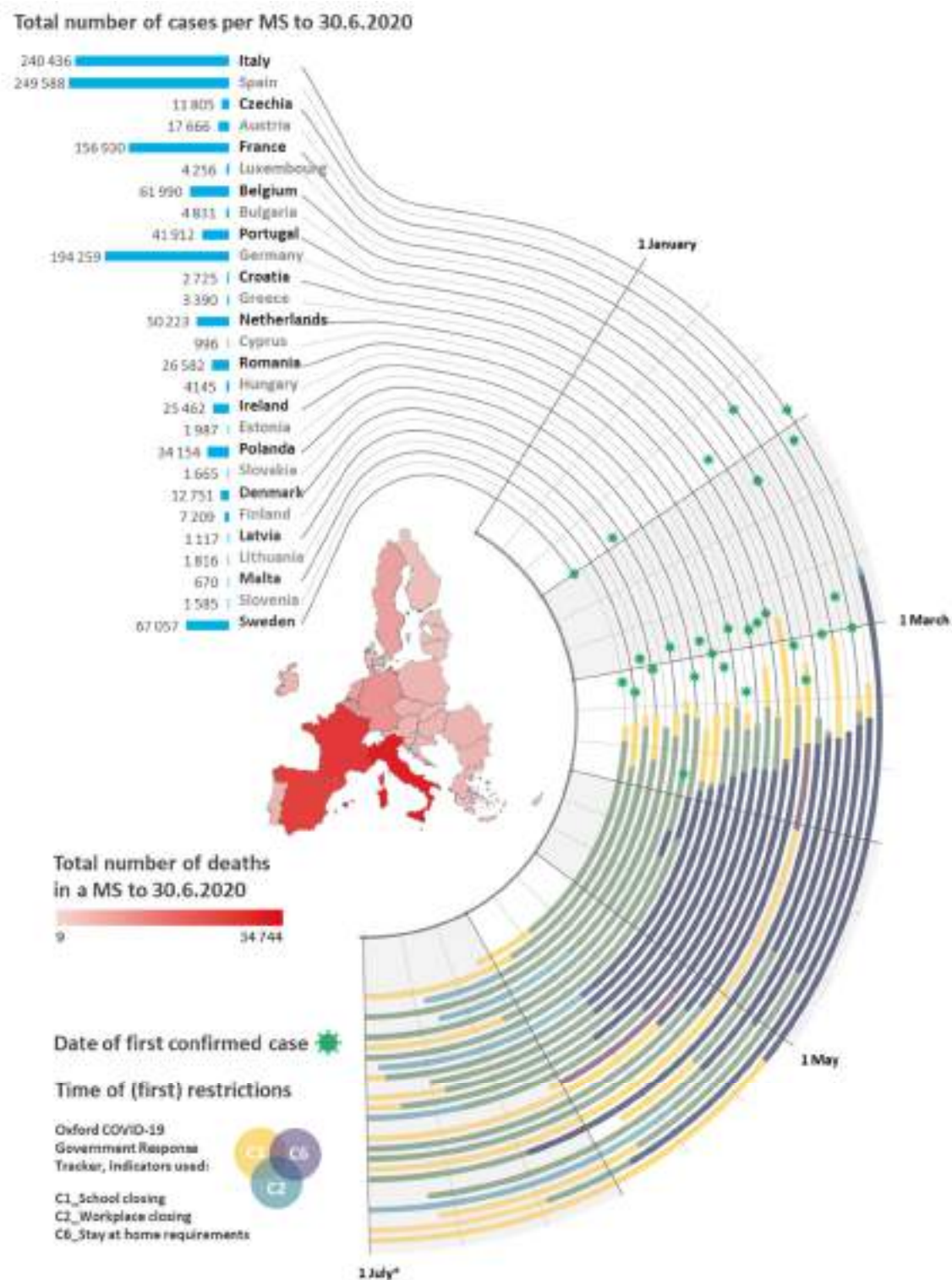


Source: ECA.

**05** These measures included social distancing, the use of facemasks, testing and contact tracing and creating temporary hospitals to help overburdened healthcare systems cope with the influx of COVID-19 patients. As the pandemic spread, Member States introduced 'lockdowns' or other movement restrictions, closing schools and non-essential businesses and introducing 'stay-at-home' policies for all but the most essential needs (see [Figure 3](#)). There have also been public education campaigns to encourage people to adopt the right behaviour to minimise the risk of infection. The extent and duration of these measures varies across the EU.



**Figure 3 – Timeline of first confirmed COVID-19 cases per Member State and duration of nationwide restrictions to June 2020**



\* The graph gives an overview of the first restrictions. After 30 June, there were further local restrictions within some Member States.

Sources: Definitions and data from WHO and Oxford COVID-19 Government Response Tracker, image by ECA.

## The EU has a defined and limited role in public health

**06** The Treaty on the Functioning of the EU assigns limited responsibilities to the EU for the area of human health<sup>10</sup>. The Union should encourage cooperation between the Member States and, if necessary, lend support to their action. The EU has defined – but limited – responsibilities for serious cross-border health threats such as pandemics established by Decision 1082/2013<sup>11</sup> (“the 2013 Decision”). This Decision sets out the roles of the Member States, European Centre for Disease Prevention and Control (ECDC), the Health Security Committee (HSC) and the Commission. It establishes mechanisms for EU action on different aspects of pandemic response and management: preparedness, risk assessment, early warning, risk management, communication and international cooperation.

**07** The European Council conclusions of 17 March 2020<sup>12</sup> set focus areas for the response to COVID-19 that concentrated mainly on public health. *Figure 4* sets out the EU’s emergency response to COVID-19 up to 30 June.

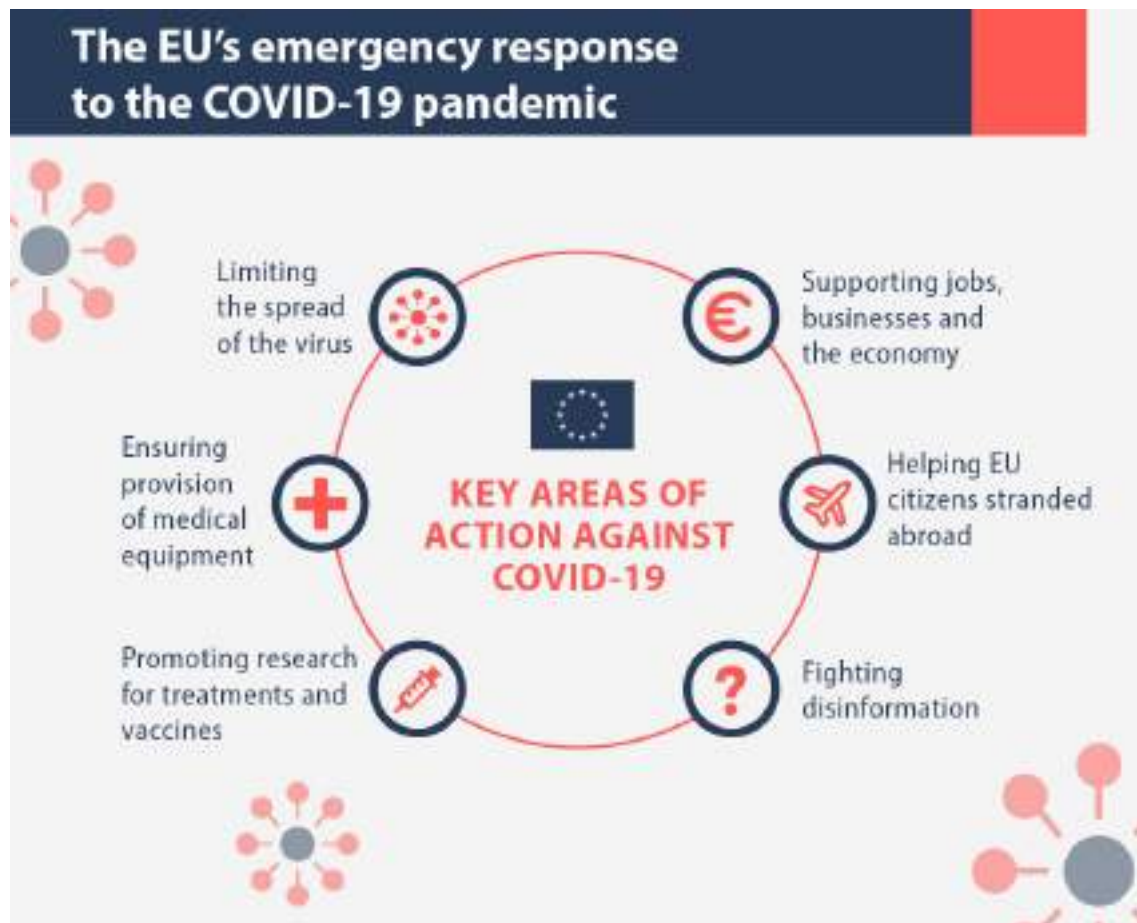
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<sup>10</sup> Articles 6 and 168 Treaty of the Functioning of the European Union.

<sup>11</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

<sup>12</sup> EU Council conclusions, 17 March 2020.






















**Figure 4 – The EU’s emergency response to the COVID-19 pandemic**



Source: EU Council.

**08** By 30 June 2020, the Commission and EU agencies had taken a range of measures to address the Council’s priorities and support the Member States’ emergency response to COVID-19 (see [Figure 5](#)). This included co-financing the repatriation of EU citizens through the EU Civil Protection Mechanism (UCPM).

**Figure 5 – Main public health related measures taken by the Commission and EU agencies up to 30 June 2020**

		 Council focus areas:
<b>European Commission</b>	Providing financial and material contributions to Member States' public health COVID response	
	Supporting coordination between the Member States (e.g. through the Health Security Committee) and international stakeholders	
	Adapting and explaining the regulatory framework	
	Launching several rounds of joint public procurement of medical countermeasures for the Member States, while limiting their export from the EU	
	Creating stockpiles of medical equipment	
	Facilitating, through a "clearing house", the matching of demand with supply for medical equipment	
	Supporting research on COVID-19 treatments and vaccines	
	Tackling disinformation about the pandemic	
		
<b>European Centre for Disease prevention and control</b>	Regular risk assessments and scientific advice on infection prevention and control	
	Providing technical support and guidance to Member States (covering surveillance, testing and diagnostics, cross-border cooperation, contact tracing, non-pharmaceutical interventions and vaccination strategies)	
		
<b>EMA: European Medicines Agency</b>	Monitoring current or anticipated medicine shortages	
	Providing advice to developers of treatments and vaccines	
	Evaluating new treatments and vaccines	
		 Limiting the spread of the virus  Ensuring Provision of medical equipment  Promoting Research for Treatment and Vaccines  Fighting disinformation

Source: ECA.

## The EU provided financial support for public health measures

**09** Approximately €4.5 billion was allocated from the EU budget up to end of June 2020 to support the Member States' public health related efforts (see [Table 1](#)). This represents 0.4 % of the €944 billion Member States' spent on public health in 2018<sup>13</sup>. The EU had not yet paid out most of this money up to 30 June. The €4.5 billion excludes funds allocated to provide general economic support to address the COVID-19 crisis and funds announced by the EU at the Coronavirus global response pledging event of 4 May 2020. See the ECA's report on "[Risks, challenges and opportunities in the EU's economic policy response to the COVID-19 crisis](#)" which examined the main economic policy responses to COVID-19 in the EU.

**10** The EU financial support for public health measures was mainly sourced from:

- the Emergency Support Instrument (ESI): used to finance measures such as vaccine advanced purchase agreements, procurement of medical equipment and therapeutics, and support for cross-border transport of medical equipment, medical personnel and patients;
- rescEU capacities: part of the EU's Civil Protection Mechanism (UCPM) which prepares for and responds to disasters and emergencies;
- The Coronavirus Response Investment Initiatives (CRII and CRII+): Cohesion funding reallocated to finance COVID-19 related health sector expenditure;
- EU Solidarity Fund (EUSF): set up to respond to major natural disasters (and expanded to cover public health emergencies) and express European solidarity;
- Horizon 2020: the financial instrument implementing the EU's research and innovation policy.

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<sup>13</sup> Eurostat: [Government expenditure on health](#), data extracted February 2020.

**Table 1 – EU funding specifically allocated for COVID-19 public health related measures up to 30 June 2020**

Programme	Billion euros
<b>Emergency Support Instrument</b> A crisis response fund to support and complement Member States' efforts (funds allocated in budget amendment 2/2020)	2.70
<b>Coronavirus Response Investment Initiatives (CRII and CRII+)</b> Cohesion funds financing COVID-19 related health sector expenditure (funds reallocated by the Member States)	0.86*
<b>rescEU stockpiling</b> Creates stockpiles of medical equipment for distribution to the Member States (funds allocated in budget amendments 1/2020 and 2/2020)	0.38
<b>R&amp;D</b> Research on COVID-19 treatments and vaccines (Horizon 2020 funds committed to relevant projects)	0.55
<b>Total</b>	<b>4.49</b>

\* The amount of 0.86 billion represents cohesion funds reprogrammed by seven Member States by June 2020. By year-end most Member States had done such reprogramming, see: <https://cohesiondata.ec.europa.eu/stories/s/CORONAVIRUS-DASHBOARD-COHESION-POLICY-RESPONSE/4e2z-pw8r/>

Source: ECA based on Commission data.

## Review scope and approach

**11** We reviewed the Commission and EU agency actions supporting the Member States' public health response to COVID-19 up to the end of June 2020. Our review covered:

- the application of the EU's existing framework for dealing with pandemics;
- actions aimed at obtaining medical supplies to combat COVID-19;
- actions aimed at promoting development of tests, treatments and vaccines.

**12** This is not an audit report; it is a review mainly based on publicly available information or material specifically collected for this purpose. It is too soon to audit ongoing actions or assess the impact of COVID-19 related public health EU initiatives. This review clarifies the role of the EU and Member States in response to the pandemic, provides an overview of the main EU public health activities in the early stages of the pandemic from the perspective of the external auditor and can inform future policy development.

**13** We obtained information from DG SANTE, the lead Commission Directorate-General for public health, and other Commission services: DG Communications, DG Research and Innovation, the Secretariat General, DG Budget, DG ECHO (Civil Protection and Humanitarian Aid Operations) and the DG for Regional and Urban Policy as well as the EMA and the ECDC. We reviewed legal acts, relevant documentation from Member States, international organisations and Non-Governmental Organisations. We sent a survey to all Member State public health authorities about the use of the Commission-led joint public procurement of medical equipment, to which public health authorities from 18 Member States replied.



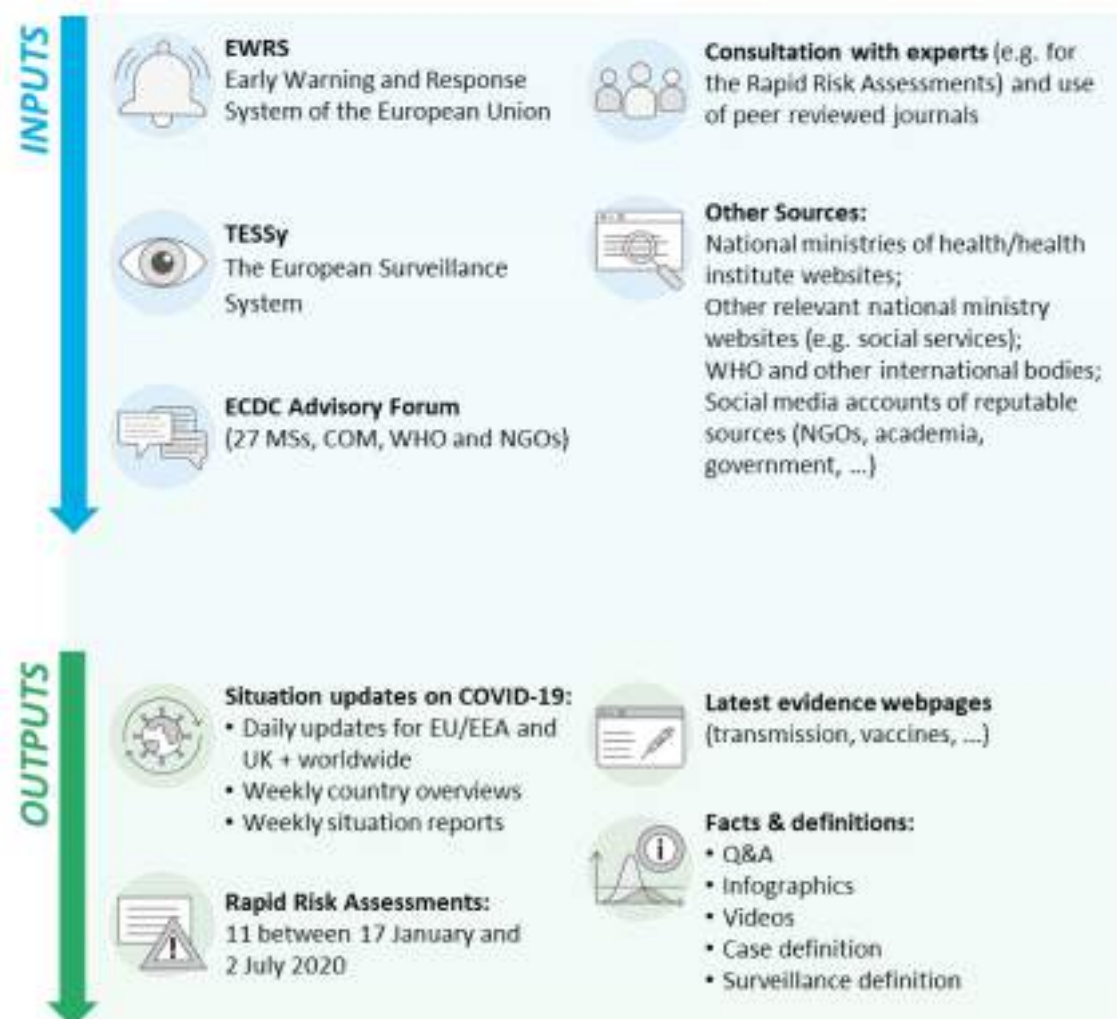
## The European Centre for Disease Prevention and Control cooperated with international partners, monitored the pandemic and provided risk assessments

**14** The ECDC provides scientific advice and risk assessments to assist the Commission and the Member States in their response against infectious diseases, operates the network for epidemiological surveillance of communicable diseases and the Early Warning and Response System (EWRS).

**15** The ECDC activated its Public Health Emergency plan in response to COVID-19 on 9 January 2020. The ECDC collaborates with its international partners, in particular the WHO Regional Office for Europe, and other Centres for Disease Prevention and Control in third countries and exchanges information and examples of best practices. It monitors the pandemic and produces situation updates, risk assessments and factual or guidance documents about COVID-19. The ECDC provides risk assessments, options for response and scientific advice but does not issue instructions. *Figure 6* summarises ECDC's various COVID-19 activities.



**Figure 6 – ECDC’s work on COVID-19**



Source: ECA based on ECDC data.

## It liaised with other Centres for Disease Prevention and Control around the world

**16** The ECDC’s cooperation with the Chinese and American Centres for Disease Prevention and Control (CDC) is based on Memorandums of Understanding signed in 2007. The ECDC was in contact with both its American and Chinese counterparts from the beginning of the outbreak in Wuhan in January 2020. In the first months of the pandemic, the ECDC was in regular contact with the Chinese CDC, which provided translations of its weekly report to the ECDC as well as updates on scientific developments such as case definition. The ECDC told us that while the Chinese CDC was very active in sharing national epidemiological data, once available to them, epidemiological information such as the number of infected healthcare workers and case fatality rates were forthcoming only after intense media reporting on the topics.

**17** The ECDC was in contact with the US CDC from the end of January onwards, initially to exchange information on the repatriation of citizens from China. In February, following a request from the US CDC, the ECDC started sharing daily situation updates in the EU with figures, maps and graphs on COVID-19. The ECDC and US CDC exchanged information on the use of facemasks in public spaces, on the de-escalation of mitigation measures, on contact tracing and on the topic of reinfections. Additionally, the ECDC and US CDC have weekly contact through the Global Health Security Agenda initiative and ad-hoc contacts for data enquiries (e.g. cases on cruise ships in the EU with US citizens).

**18** In June 2019, a number of CDCs across the globe agreed to establish an international forum, the Network of major CDCs, for regular information and expertise exchange to respond effectively to threats posed to public health. In the first half of 2020, four meetings between CDCs were held – on 6 February, 27 March, 19 May and 29 June. The ECDC, the Chinese, American, Canadian, African Union, Caribbean, Korean, Israeli and Singaporean CDCs participated in these meetings where they shared information, expertise and best practices on dealing with COVID-19.

## **It monitored the pandemic based on information from the Member States and other sources**

**19** The ECDC collects Member States' information on preparedness and response planning in relation to serious cross-border threats to health on behalf of the Commission. It did this in 2014 and in 2017. The ECDC told us that all Member States have an influenza pandemic preparedness plan but not all of them include this information in the regular reporting template, since they are only required to include reference to such plans in the section on business continuity<sup>14</sup>. The ECDC published guidance<sup>15</sup> on the revision of pandemic influenza preparedness plans to take into account the lessons learnt from the 2009 A(H1N1) pandemic in November 2017. In our 2016 audit on the EU's framework for dealing with cross-border threats to health, we found weaknesses in the coordination of preparedness planning. Our follow-up audit

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<sup>14</sup> Commission Implementing Decision 2014/504/EU of 25 July 2014 implementing Decision No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on preparedness and response planning in relation to serious cross-border threats to health.

<sup>15</sup> ECDC: Guide to revision of national pandemic influenza preparedness plans.

in 2019 concluded that the Commission had taken adequate actions to implement the related audit recommendations.

**20** The ECDC established a COVID-19 network with contact points nominated by each Member State. The network works with the WHO Regional Office for Europe and has met on a weekly basis since February 2020. In view of the scale and severity of the pandemic, on 9 April 2020 the ECDC published a COVID-19 surveillance strategy, endorsed by the Member States through the ECDC's COVID-19 network, to monitor:

- the intensity, geographic spread and severity of COVID-19 to estimate the burden of disease, and inform appropriate mitigation measures;
- viral changes to inform drug and vaccine development, and to identify markers of severe infection;
- changes in groups most affected (to better target prevention efforts);
- the epidemic's impact on the healthcare system to predict the trajectory of the epidemic curve and inform resource allocation;
- the impact of any mitigation measures.

**21** The ECDC collects COVID-19 related data through the EWRS and the European Surveillance System (TESSy). Member States use the former to report numbers of laboratory-confirmed cases of COVID-19 every 24 hours and the latter to provide more detailed epidemiological information on a weekly basis<sup>16</sup>.

**22** The ECDC told us that it was challenging for them to manage the timeliness, quality and completeness of the data received from Member States since the start of the pandemic. In addition, the Member States' different surveillance and testing strategies makes it difficult for ECDC to compare the epidemiological situation across the EU. The ECDC complements the data it receives with its own research, screening many sources every day to collect COVID-19 figures from around the world<sup>17</sup>. The Director of the ECDC has stated the current system of infectious disease surveillance is too dependent on human labour, which could be fixed with a greater use of artificial

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<sup>16</sup> ECDC: [The European Surveillance System \(TESSy\)](#), page last updated 7.2.2019.

<sup>17</sup> ECDC: [How ECDC collects and processes COVID-19 data](#), page last updated 1.4.2020.

intelligence, e-health and digitalisation to minimise human input requirements<sup>18</sup>. The Director informed the European Parliament that innovative digital solutions were particularly necessary for surveillance<sup>19</sup>.

**23** These data gathering efforts have enabled the ECDC to produce daily updates (*Figure 7*) and detailed reports on the pandemic but it has nevertheless cautioned that “considerable work still needs to be done to establish and strengthen robust population-based surveillance [...] to monitor the intensity, geographical spread, severity and impact of COVID-19 in the EU/EEA and the UK”<sup>20</sup>.

**Figure 7 – Example of an ECDC COVID-19 situation update**



Source: ECDC.

<sup>18</sup> Politico: ‘Nothing would have prevented’ virus spread, says health agency chief’, 8.4.2020.

<sup>19</sup> European Parliament’s Environment, Public Health and Food Safety Committee hearing of 2 September 2020.

<sup>20</sup> ECDC: ‘COVID-19 surveillance report. Week 28, 2020’, 19.7.2020.

## It provided broad risk assessments

**24** The ECDC produces rapid risk assessments intended to help national health authorities prepare for and respond to public health threats. The rapid risk assessments draw on a wide range of EU and worldwide information sources. The ECDC's policy is to conduct them in the initial stages of an event such as the COVID-19 pandemic to provide an estimate of the scale of the health threat, while documenting the level of uncertainty of this assessment<sup>21</sup> and to continue issuing them as the epidemiological situation changes. The ECDC published its first risk assessment for COVID-19 on 9 January 2020, as part of a broader threat assessment. This estimated the risk to be low (on the basis of the early information from Chinese authorities that there was no indication of human-to-human transmission<sup>22</sup>). The first full rapid risk assessment published on 17 January 2020 stated that there was “no clear indication of sustained human-to-human transmission” but also cautioned that there was a “substantial level of uncertainty” concerning the epidemiology of COVID-19 and that there was limited information on the cases identified so far<sup>23</sup>.

**25** The ECDC updated the rapid risk assessment ten times by end of June 2020. It cautioned from the time of the first update on 22 January 2020 that the risk of the virus spreading could be high if Member States did not put in place appropriate Infection Prevention and Control (IPC) measures<sup>24</sup>. Most rapid risk assessments addressed several risks (e.g. risk of healthcare system being overwhelmed, risk to health if COVID-19 is contracted and risk of widespread transmission). Since the fifth update on 2 March 2020, the rapid risk assessments have assessed the risk of widespread transmission to be moderate or high/very high, depending on the containment strategy adopted by the Member States and on population groups (see [Figure 8](#)).

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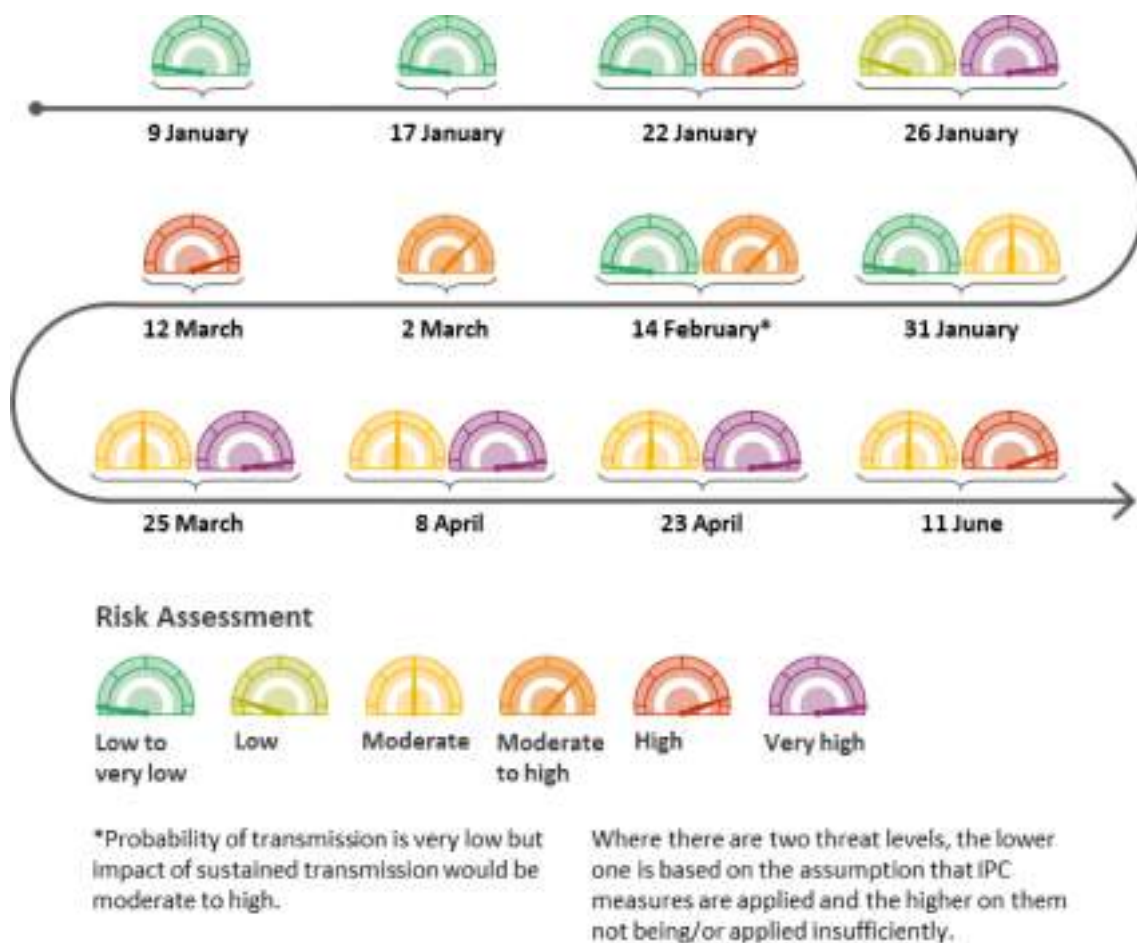
<sup>21</sup> ECDC: ‘Operational tool on rapid risk assessment methodology’, March 2019.

<sup>22</sup> ECDC: ‘Threat assessment brief: Pneumonia cases possibly associated with a novel coronavirus in Wuhan, China’, 9.1.2020.

<sup>23</sup> ECDC: ‘Rapid Risk Assessment’, 17.1.2020.

<sup>24</sup> ECDC: ‘Rapid Risk Assessment’, 22.1.2020.

**Figure 8 – ECDC risk assessment of COVID-19 spreading for all Member States up to June 2020**



Source: ECA based on ECDC rapid risk assessments.

**26** The scope and detail of the rapid risk assessments has grown as the pandemic spread in the EU and they now include recommendations on a range of actions to mitigate the risk. The tenth update on 11 June 2020 included:

- an epidemiological overview of the pandemic, including distribution of cases;
- a background on the disease including considerations on population immunity;
- a risk assessment broken down by population category (e.g. general population, at-risk population, healthcare workers) and options for response, including testing strategies, contact tracing and non-pharmaceutical intervention (e.g. use of face masks, travel restrictions etc.);
- an outline of the importance of risk communication and the issues it could focus on.

**27** The ECDC launched its own performance analysis of its response to the COVID-19 pandemic in July 2020. The Director of the ECDC informed the European Parliament that the COVID-19 response has required almost its entire scientific staff to be assigned to COVID-19 related work and for other tasks to be put on hold<sup>25</sup>.

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<sup>25</sup> European Parliament Committee on the Environment, Public Health and Food Safety (ENVI), [exchange of views with Dr Andrea Ammon, Director of the European Centre for Disease Prevention and Control \(ECDC\)](#), 2.9.2020.



## The EU addressed urgent issues and allocated 3 % of the annual budget for COVID-19 response by 30 June 2020

### EU level export authorisations supported the single market

**28** In March 2020, a Commission communication on the economic consequences of COVID-19 dealt with the supply of medical and personal protective equipment<sup>26</sup>. The Commission recognised that Member States would need to take measures at national level to secure this supply but warned against actions that could affect supply chains and thus the availability of key products. This warning was given as some Member States did unilaterally introduce export bans of Personal Protective Equipment (PPE) and medical equipment in March (see [Figure 9](#)), including to other EU Member States. The Commission gave the example of a Member State that banned or restricted the export of 1 324 products including paracetamol to illustrate a measure that could put peoples' health at risk<sup>27</sup>. EU Member States were not alone in instituting such bans. The WTO reported in April that 80 countries had brought in export restrictions on medical supplies but only 13 had notified it of the measures<sup>28</sup>.

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<sup>26</sup> European Commission Communication: '[Coordinated economic response to the COVID-19 Outbreak](#)', 13 March 2020.

<sup>27</sup> Ibid.

<sup>28</sup> WTO: '[Export prohibitions and restrictions](#)', information note, 23.4.2020.



**Figure 9 – Countries that introduced export restrictions of medical supplies from January to March 2020**



Source: [Global Trade Alert](#).

**29** In order to provide an EU framework for export authorisations, ensure adequate supply of such products in the EU and secure the integrity of the single market, the Commission introduced a six-week temporary export authorisation scheme to control PPE exports out of the EU/EEA on 15 March 2020<sup>29</sup>. The Member States administered the scheme and were responsible for granting or denying the export authorisation. The Commission revised and extended the scheme for a further 30 days from 26 April 2020.

**30** The revised scheme<sup>30</sup> required Member States to consult the Commission before they granted export authorisations between 26 April and 25 May. The Commission's clearing house for medical equipment was involved in this process. After the expiry of the export authorisation scheme, the clearing house continued to monitor the availability of medical equipment in the EU, including imports, and export restrictions in partner countries.

<sup>29</sup> European Commission: [implementing Regulation \(EU\) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation](#).

<sup>30</sup> European Commission: [implementing Regulation \(EU\) 2020/568 of 23 April 2020 making the exportation of certain products subject to the production of an export authorisation](#).

**31** Exporters requested more than 1 300 authorisations based on the scheme that entered into force on 26 April, 95 % of which were approved. According to the data provided by Member States to the Commission, approximately 13 million protective masks, 1 million protective garments and more than 350 000 protective spectacles and visors were exported from the EU between 26 April and 26 May 2020<sup>31</sup>. The Commission gave negative opinions on exports of around four million gloves, protective garments and other items. There is no data on EU-wide facemask production capacity but in June 2020 the EU nonwoven material industry association expected total EU production capacity of three-layer surgical masks to increase 20 fold by November 2020 to reach 1.5 billion masks per month<sup>32</sup>.

## The Commission started creating stockpiles of medical equipment

**32** The Council conclusions on COVID-19 of 13 February 2020 asked the Commission to “continue examining all available possibilities to facilitate access to personal protective equipment needed by Member States”<sup>33</sup>. In response the Commission created a strategic stockpile of medical and other equipment aimed at combating serious cross-border threats to health<sup>34</sup>. This stockpile is developed through the rescEU reserve, a part of the Union Civil Protection Mechanism (UCPM). The UCPM aims to strengthen cooperation between its participating states (Member States and certain neighbouring and third countries<sup>35</sup>) in the field of civil protection, to improve prevention, preparedness and response to disasters.

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<sup>31</sup> European Commission: [Coronavirus: requirement for export authorisation for personal protective equipment comes to an end](#), 26 May 2020.

<sup>32</sup> EDANA: [European producers set for a 20 fold increase in nonwoven face mask output by November](#), 23.6.2020.

<sup>33</sup> Council conclusions on COVID-19, 13 February 2020.

<sup>34</sup> European Commission: [implementing Decision \(EU\) 2020/414 of 19 March 2020 amending as regards medical stockpiling rescEU capacities](#).

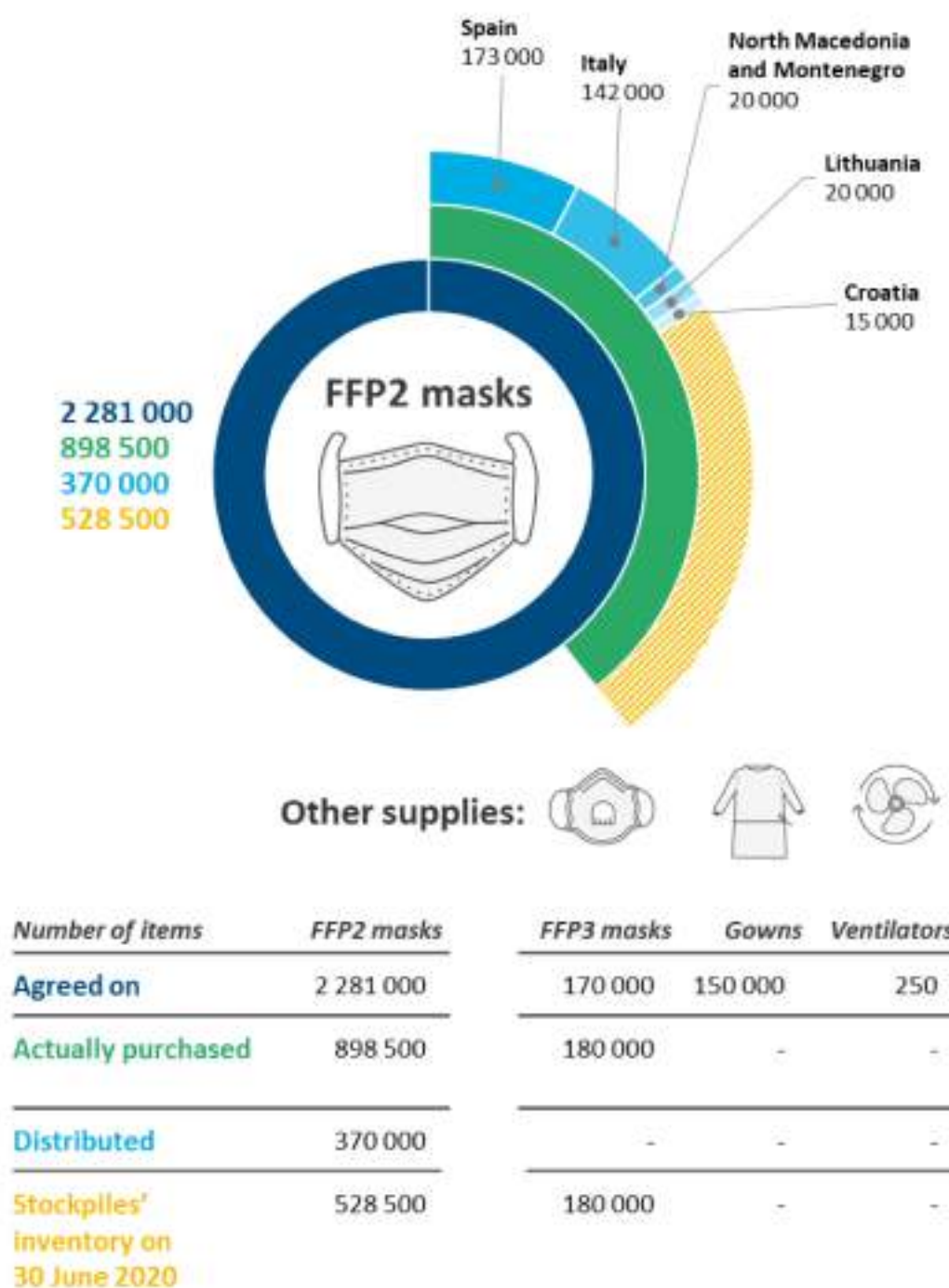
<sup>35</sup> There are currently six non-EU Member States participating in the UCPM: Norway, Iceland, Serbia, North Macedonia, Montenegro and Turkey.

**33** The Commission allocated progressively larger amounts to the development of rescEU capacities to reach a total budget of €380 million in April 2020. Member States wishing to host stockpiles can apply for a 100 % financing direct grant (for purchase and management of stocks) from the Commission. The host Member State is responsible for procuring the equipment and has to apply EU and national procurement procedures. The Commission takes decisions on allocation from the stockpile in coordination with the Member States hosting the stockpile, and those Member States and participating countries that requested assistance.

**34** The Commission signed two grant agreements for rescEU stockpiles up to 30 June: with Romania for €10 million on 31 March for 1 381 871 masks (surgical and Filtering Face Piece [FFP]2) and 250 ventilators, and with Germany for €6 million on 19 May for 900 000 FFP2 masks, 170 000 FFP3 masks and 150 000 gowns. The Commission stated their intention to maintain these stockpiles beyond their initial funding period through further grants.

**35** EU Member States, UCPM participating states, and third countries submitted requests for deliveries from these stockpiles. By 30 June 2020, 370 000 masks had been delivered from the Romanian and German stockpiles to Italy, Spain, Croatia, Lithuania, Montenegro and North Macedonia (see [Figure 10](#)). The Commission also directly procured 10 million masks for healthcare workers through the Emergency Support Instrument (see paragraph [10](#)) at a cost of €29.5 million to deliver to 19 Member States. No deliveries were made to the Member States up to 30 June. In our 2016 audit on the EU's framework for dealing with cross-border threats to health, we found that there was no mechanism at EU level to address urgent needs for medical countermeasures.

Figure 10 – Status of rescEU stockpiles on 30 June 2020



Source: ECA based on Commission data.

**36** The Commission intends to set up more rescEU medical stockpiling across the EU. It launched an invitation to apply for grants for such stockpiles on 14 May 2020 to all Member and participating states. It received nine proposals by 5 June 2020, four of which were accepted. Denmark, Greece, Hungary and Sweden will each host rescEU stockpiles for which they will receive grants of between €15.5 and €60 million.

**37** On 2 June, the Commission proposed to reinforce rescEU with €2 billion over the budgetary period 2021-2027 to strengthen the EU's capacity to respond to cross-border emergencies, such as COVID-19<sup>36</sup>. The additional funding would create reserves of strategic equipment to cover health emergencies, forest fire outbreaks, chemical, biological, radiological, nuclear incidents or other major emergencies.

## The EU provided fora to exchange information and coordinate actions

### The Health Security Committee

**38** The HSC was created at the request of EU Health Ministers in 2001<sup>37</sup> and operated as an informal advisory group until 2013. The 2013 Decision formalised the Committee and defined its role: supporting exchanges of information between Member States and the Commission, and coordinating national preparedness and response planning. The HSC's role focuses on discussions, information exchange and coordination. The HSC reports on the discussion of each meeting are publicly available.

**39** The HSC, composed of one representative per Member State as well as the Commission and WHO, first convened to discuss COVID-19 on 17 January 2020 and held 25 meetings up to the end of June. The ECDC presented all its updated rapid risk assessments as well as other relevant documentation to the HSC. The Commission and Member States use HSC meetings to discuss COVID-related initiatives, to share information and develop common positions. The most frequently discussed topics were travel restrictions and non-pharmaceutical interventions, medical countermeasures, testing and contact tracing, vaccines and preparedness plans<sup>38</sup>. Member States are usually represented at technical level. The work of the HSC was complemented by that of the Emergency Response Coordination Centre (ERCC) that organised four virtual meetings of Ministers of Health and 40 meetings of Member State civil protection authorities on COVID-19 in the period to 30 June.

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<sup>36</sup> European Commission: 'EU budget for recovery: €2 billion to reinforce rescEU direct crisis response tools', 2.6.2020.

<sup>37</sup> Presidency Conclusions of 15 November 2001 on bioterrorism.

<sup>38</sup> Health Security Committee reports on COVID-19 outbreak.

**40** The minutes from the second HSC meeting on COVID-19 on 22 January 2020 state that the Commission would use a survey developed by ECDC to learn about Member States' preparedness and capacities to manage COVID-19<sup>39</sup>. The minutes from the next meeting on 27 January show that the Member States indicated an overall strong level of preparedness (some gaps notwithstanding) and that national health systems had plans for the eventuality of managing COVID-19 cases<sup>40</sup>. The Member States did not indicate any need for additional personal protective equipment (PPE). As the pandemic developed, subsequent HSC meetings focused again on the issue of PPE supply. By the thirteenth HSC meeting on 30 March 2020, discussions on exit strategies from lockdowns started for which the ECDC, together with the Joint Research Centre, began modelling lockdown de-escalation scenarios.

### The Commission clearing house for medical equipment

**41** One of the challenges Member States faced in addressing the COVID-19 pandemic was the supply of sufficient medical equipment. The Commission's clearing house for medical equipment (CCH) started operating on 1 April 2020 for a period of six months. It served as a platform for dialogue and information sharing with Member States' representatives on the demand and supply of medical equipment at EU level and on the means to overcome shortages and build capacity. The CCH also gathered information from industry on production or supply issues and provided technical and regulatory guidance to private actors to help them adapt their production to meet COVID-related needs. The CCH was coordinated by the Commission's Secretariat General and drew on experts in other departments forming five product clusters. It reported directly to the Commissioner for Internal Market. Every Member State designated a point of contact for the CCH.

**42** The CCH did not have a mandate to match offers with demand or to carry out any procurement itself. It repurposed an existing Commission online platform to allow Member States to indicate their needs for medical equipment and producers to place their offers. Participation in and use of this platform by suppliers and Member States was voluntary. The platform had five categories of products, mirroring the thematic focus of the CCH's five working groups: PPE, ventilators, other medical and hospital equipment, test materials, therapeutics and vaccines (see [Figure 11](#)). Up to 30 June 2020, seven Member States had used the platform to upload needs for 269 products. The CCH does not have information on how many purchases the

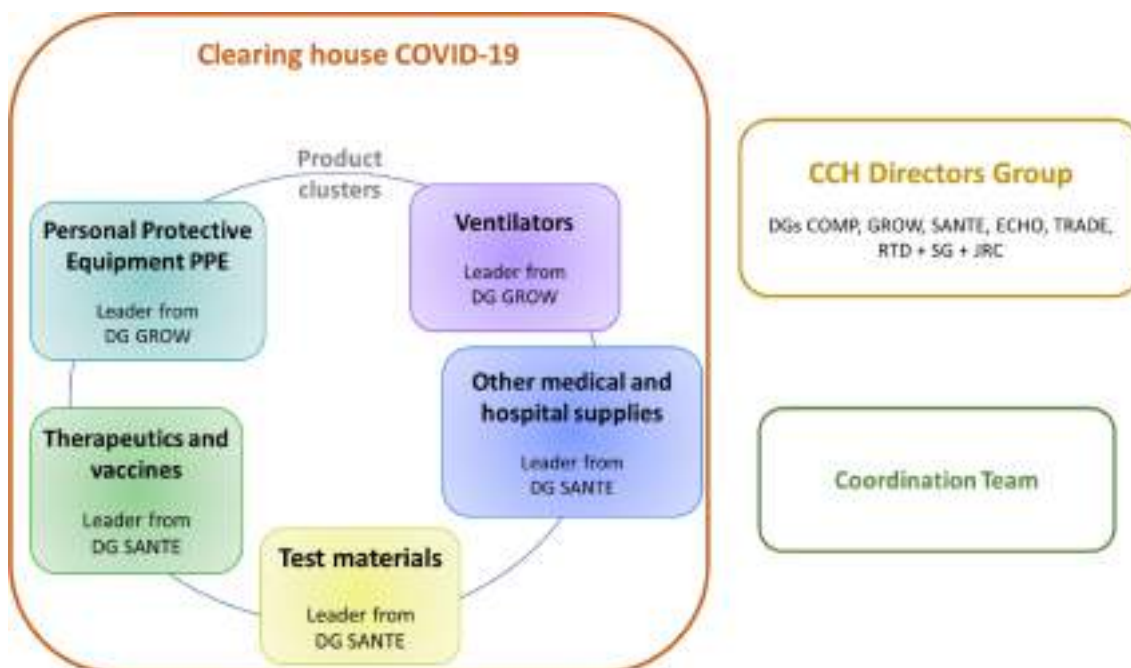
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<sup>39</sup> European Commission: 'Health Security Committee Summary Report', 22.1.2020.

<sup>40</sup> European Commission: 'Health Security Committee Summary Report', 27.1.2020.

platform facilitated. The CCH conducted a survey on the use of the platform during July and August that found that, while 63 % of CCH national contact points classified the platform as good or very good, fewer than 20 % used it to consult offers or buy equipment.

**Figure 11 – CCH organisation**



Source: ECA based on Commission data.

**43** Manufacturers in third countries supplied most of the facemasks, and much of the other medical supplies and equipment Member States used to deal with COVID-19 up to 30 June 2020. The CCH tried to create an EU-wide overview of the current and future needs through a series of surveys of the national contact points. These surveys touched upon strategic fields at a very sensitive time and many Member States participated on the condition that they could respond anonymously and their responses were confidential. The surveys provided an overview of the expected shortages aggregated at EU level for various product categories and time-periods (very short, short, mid- and long-term). Member States indicated to the CCH that, with the proper safeguards, such a survey could be repeated more regularly to support and coordinate preparedness efforts. The CCH also established a structured dialogue with relevant industry associations, notably for medical devices and PPE, in order to better understand disruptions and main challenges which affected the supply chain.



## Member States use national procurement pathways to meet their PPE needs

**44** Following the 2009 A/H1N1 pandemic, the European Parliament<sup>41</sup> and the Council<sup>42</sup> highlighted the need for a legal basis to enable the joint procurement by Member States of medical countermeasures. The 2013 Decision, designed to improve preparedness for serious cross-border health threats across the EU, provides for such a mechanism. It enables voluntary joint procurement by Member States, with the support of the Commission. In our 2016 audit on the EU's framework for dealing with cross-border threats to health<sup>43</sup>, we noted that there was little interest in using this joint procurement mechanism for pandemic vaccines.

**45** In view of the surging demand for PPE and medical equipment triggered by the COVID-19 pandemic, the Commission completed four joint procurement calls for tenders by end of June 2020 (see [Table 2](#)) for medical and protective equipment at the Member States' request. The Commission provided EU-level coordination, collated the needs of the participating Member States, drew up all the documents needed to launch the procedure, evaluated the offers received with the support of evaluators from the Member States and awarded framework contracts to the successful tenderers. These framework contracts offer the participating Member States the choice (not the obligation) to purchase the supplies using their national budgets. With the agreement of the Specific Procurement Procedure Steering Committee (SPPSC) of participating Member States that oversees joint procurement procedures, the Commission signed the framework contract on behalf of all the participating contracting parties and Member States were allowed to join the Joint Procurement after the launch of the procedure.

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<sup>41</sup> European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI)).

<sup>42</sup> Council conclusions on Lessons learned from the A/H1N1 pandemic – Health security in the European Union, 13.9.2020.

<sup>43</sup> Special report 28/2016: 'Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done'.



**46** In total, Member States ordered 5.5 million masks, 1 million gloves, 55 ventilators and various laboratory equipment via the joint procurement framework up to 30 June 2020. The maximum value of the joint procurement contract for facemasks is approximately €475 million (i.e. the suppliers commit to providing facemasks up to that value if orders are placed) for the 12 month duration of the framework contract<sup>44</sup>. **Table 2** shows the orders that participating Member States placed under the joint procurement agreement by the end of June 2020.

**Table 2 – Joint calls for tender for medical countermeasures until 30 June**

Supplies	No. of Member States	First contract signed	Quantities Ordered
Goggles, Respiratory Protection, Gloves and Coveralls (SANTE/C3/2020/015)	20	8 April	1 000 000 gloves
Goggles/Visors, Respiratory Protection and Surgical Masks (SANTE/2020/C3/017)	25	2 April	5 550 000 masks
Ventilators (SANTE/2020/C3/018)	26	15 April	55 ventilators
Laboratory equipment (SANTE/2020/C3/019)	20	4 May	Various laboratory equipment

Source: ECA, based on information provided by the Commission.

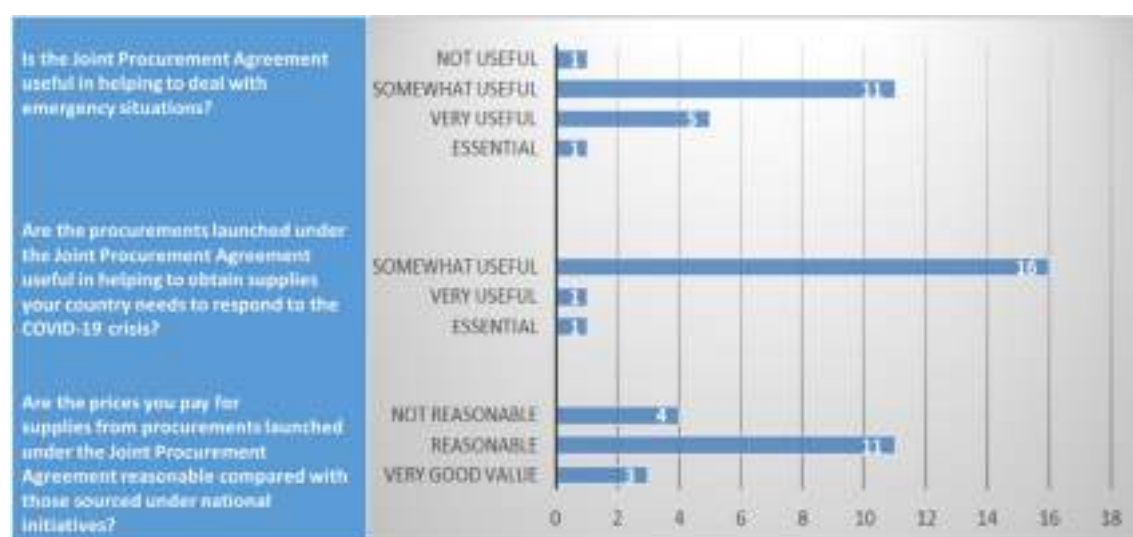
**47** The orders placed by the Member States under the joint procurement mechanism up to 30 June 2020 mainly concerned masks, and represented a small proportion of their needs. Member States use national procurement pathways to meet the majority of their needs. As an illustration, the 27 Member States combined

<sup>44</sup> Official Journal of the European Union: [2020/S 100-238632](#), 15.5.2020.

imported €14 billion worth of masks in the first semester of 2020<sup>45</sup>. One Member State ordered 3.4 billion masks at a cost of €2.5 billion on 28 May<sup>46</sup>.

**48** As part of our review, we sent a short questionnaire to all Member States to obtain their views on the joint procurement procedure. *Figure 12* shows that most of the Member States that answered found the joint procurement system somewhat useful and the prices reasonable. Although the volume of medical equipment the Member States ordered through the joint procurement procedure up to 30 June is small relative to total needs, the framework contracts are valid for at least 12 months and during their period of validity they can be used for further orders without the need to repeat the joint procurement procedure.

**Figure 12 – Result of Member State survey on the joint procurement procedure**



Source: ECA, based on replies received from 18 Member States.

## Use of funds was at an early stage by 30 June 2020

**49** Of the €4.5 billion specifically allocated to public health related measures up to 30 June 2020, €3.5 billion was for two programmes: The Coronavirus Response Investment Initiative (CRII) and the Emergency Support Instrument (ESI) (see *Table 1*). The Commission did not disburse most of this €4.5 billion, which represents approximately 3 % of the EU's annual budget, in the period to 30 June 2020.

<sup>45</sup> Eurostat: 'Which country imported the most face masks?', accessed 7.10.2020.

<sup>46</sup> Assemblée Nationale: *Rapport d'information*, 3.6.2020.

## The Coronavirus Response Investment Initiative and the European Solidarity Fund can contribute to Member States' public expenditure on COVID-19 health related measures

**50** The Coronavirus Response Investment Initiatives (CRII and CRII+) were adopted in April 2020<sup>47</sup> to extend the scope of programmes financed under cohesion funds to cover all COVID-19 crisis related expenditure, including medical and healthcare expenditures related to the COVID-19 pandemic<sup>48</sup>. Member States reallocated their cohesion programmes to fund relevant medical and testing equipment. Eligibility was retroactively applied to spending from 1 February 2020 onwards. Seven Member States<sup>49</sup> had made such amendments to some or all of their cohesion funding programmes by 30 June, reallocating €860 million in EU cohesion policy funding to COVID-19 related healthcare expenditure. This process continued after 30 June with further financial support being made available to the Member States.

**51** The EUSF, established in 2002, aims to express European solidarity with Member States and candidate countries affected by natural disasters. The co-legislators can allocate up to €500 million a year for this fund in response to emergencies. This money can be carried over to the following year. The EU legislators extended the EUSF's scope to cover major public health emergencies following the outbreak of the pandemic<sup>50</sup>. It covers part of Member State public expenditure on rapidly assisting people affected by COVID-19, including medical help. The Commission estimated that up to €800 million could be available to the EUSF to support Member States' COVID-19 related public health expenditure<sup>51</sup>, though no financial commitment was made up to 30 June 2020.

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<sup>47</sup> [Regulation 2020/460 of 30 March 2020](#) and [Regulation 2020/558 of 23 April 2020](#).

<sup>48</sup> Other eligible support such as SME and workers schemes under CRII pertain to economic measures subject to the ECA review "Risks, challenges and opportunities in the EU's economic policy response to the COVID-19 crisis".

<sup>49</sup> Italy, Poland, Romania, Slovakia, Bulgaria, France and Lithuania.

<sup>50</sup> [Regulation \(EU\) 2020/461](#) of the European Parliament and of the Council of 30 March 2020 amending Council Regulation (EC) No 2012/2002 in order to provide financial assistance to Member States and to countries negotiating their accession to the Union that are seriously affected by a major public health emergency.

<sup>51</sup> European Commission: [COVID-19 EU Solidarity Fund](#).

**52** The Commission received 22 applications for EUSF financial support from 19 Member States<sup>52</sup> and three accession countries<sup>53</sup> by the deadline of 24 June 2020. To be eligible for EUSF support, a country must have spent either €1.5 billion or more than 0.3 % of its gross national income within four months of the first measure it took to tackle the pandemic<sup>54</sup>. Eligible expenditure includes medicines, equipment and medical devices, laboratory analyses, personal protective equipment, special assistance to the population and development of vaccines or medicines<sup>55</sup>. The maximum amount of EUSF contribution a Member State can receive is:

- 2.5 % of the total amount of eligible public spending below €1.5 billion at 2011 prices, or 0.3 % of its GNI, plus
- 6 % of the total amount of eligible public spending above the same threshold.

### **The EU's Emergency Support Instrument complements Member State and Commission actions**

**53** The Emergency Support Instrument (ESI) is a complementary instrument directly managed by the Commission. It can be used to intervene on top of the efforts made under rescEU, Decision No 1082/2013/EU on serious cross-border health threats, or other national and EU initiatives. A total budget of €2.7 billion was provided when ESI was activated for COVID-19 in April 2020. The Commission allocated almost €2 billion to ESI actions by June 2020 (see [Figure 13](#)). The Commission allocated €220 million to a 'Mobility Package' to support the transport of medical equipment and the transfer of patients and medical teams between Member States. The Commission also allocated €100 million for a facility for procuring essential health-related products for distribution to Member States and €1.5 billion to fund vaccine advanced purchase agreements.

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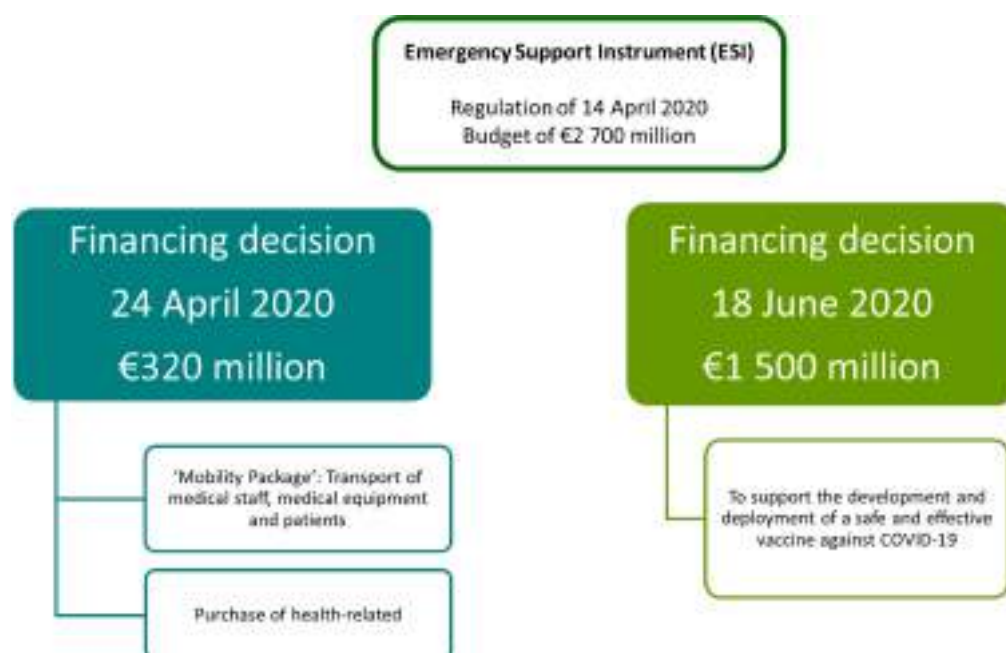
<sup>52</sup> Belgium, Czechia, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Latvia, Lithuania, Luxembourg, Hungary, Austria, Poland, Portugal, Romania and Slovenia.

<sup>53</sup> Albania, Montenegro and Serbia.

<sup>54</sup> European Commission: [COVID-19 EU Solidarity Fund](#).

<sup>55</sup> [Council Regulation \(EC\) No 1012/2002 establishing the European Union Solidarity Fund](#), Article 3, paragraph 2(e).

**Figure 13 – Allocation of Emergency Support Instrument funds up to 30 June 2020**



Source: ECA based on Commission financing decisions C(2020) 2794 final and C(2020) 4193 final.

# The EU supports the development of COVID-19 treatments and vaccines

## The European Medicines Agency evaluates COVID-19 treatments and vaccines

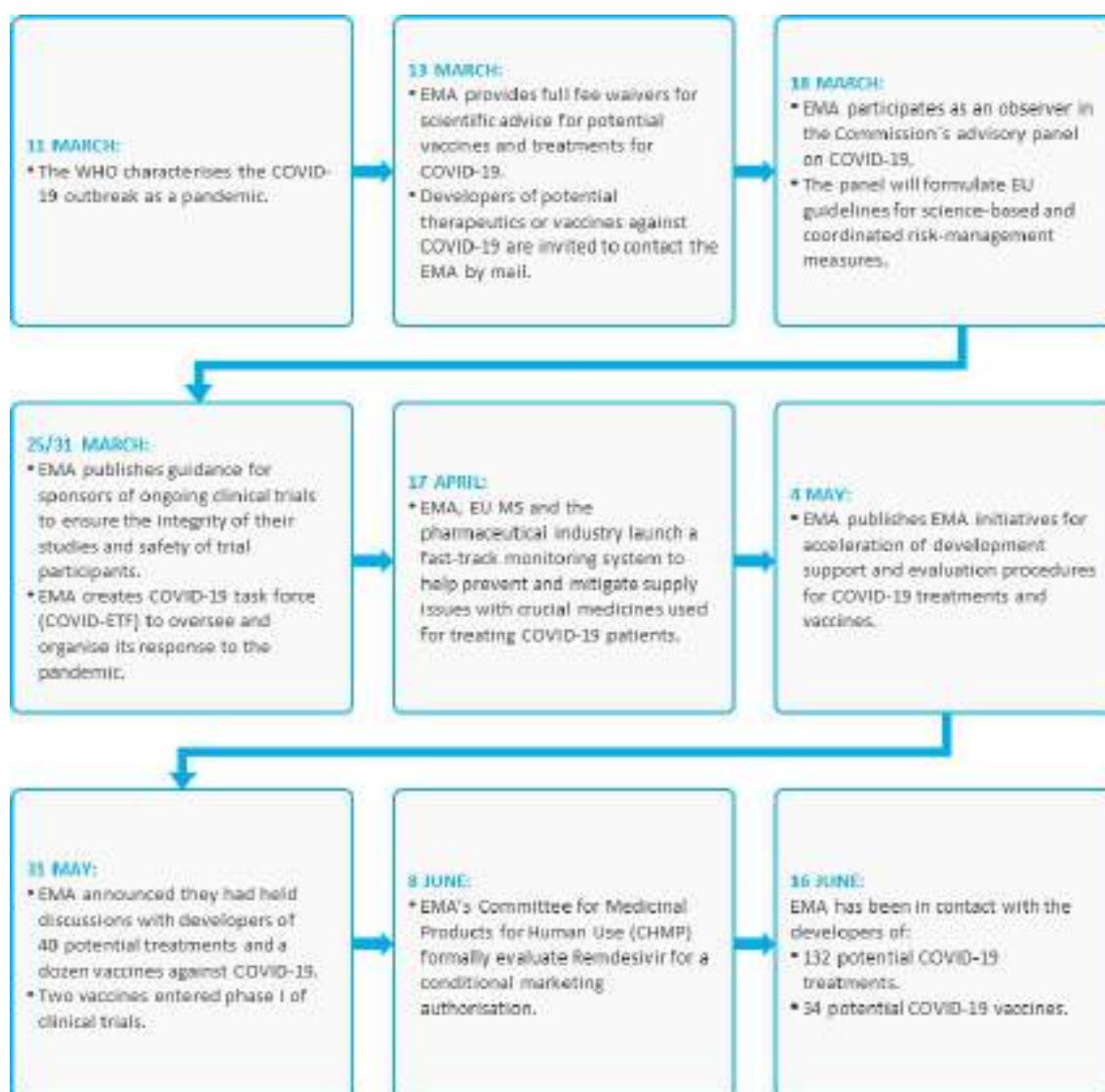
**54** The European Medicines Agency (EMA) is a decentralised scientific agency responsible for protecting and promoting public and animal health through the evaluation and supervision of medicines for human and veterinary use. It coordinates the evaluation and monitoring of medicinal products, develops technical guidance and provides scientific advice to sponsors. The Commission, on the basis of an EMA scientific opinion establishing a positive benefit/risk ratio for a certain medicinal product, grants the marketing authorisation for that product. In 2018, the EMA published a plan for preparing and responding to emerging health threats, building on the lessons learnt from the 2009 influenza H1N1 pandemic and the 2014-16 West African Ebola outbreak. The health threat plan aims to meet the following objectives:

- initiate and coordinate scientific and regulatory activities involving all interested parties (such as EMA experts, national competent authorities, ECDC, Commission);
- manage discussions on development, authorisation and surveillance of relevant medicinal products (for example vaccines and antivirals for pandemic influenza);
- provide to the Commission, the National Competent Authorities, Member State Public Health Authorities and ECDC the outcome of their documentary review on potential pandemic influenza vaccines and influenza antivirals;
- provide support to international partners (such as the WHO) and stakeholders involved in the research and development of medicinal products.

**55** In line with its preparedness plan, the EMA took a number of actions in response to the pandemic. These focused on preventing and mitigating possible disruptions to the supply of medicines and supporting quick regulatory action on the development, authorisation and safety monitoring of COVID-19 treatments and vaccines (see [Figure 14](#)). A COVID-19 task force supported by four cross-agency work streams manages the EMA's response to the pandemic. There are weekly coordination meetings with the Commission and the ECDC. The EMA did not report any supply

disruptions to medicines used in the treatment of COVID-19 or other conditions in the period up to 30 June.

**Figure 14 – Timeline of main EMA actions in response to COVID-19 to June 2020**



Source: ECA based on EMA data.

**56** The EMA told us that it is in regular contact with the developers of COVID-19 treatments and vaccines and finalised nine scientific advice procedures (on the appropriate tests and studies required) by 30 June 2020. The EMA is using a fast-track method for the scientific evaluation of COVID-19 vaccines and therapeutics to facilitate the rapid marketing of such products. According to the EU pharmaceutical legislation, the standard timeline for the evaluation of a medicine is a maximum of 210 working days. However, EMA and the Commission will treat applications for marketing authorisation for COVID-19 products in an expedited manner that can reduce the timeline for approval to approximately 150 working days. The EMA performs a rolling



review of evidence from the new medicine, reviewing data as it becomes available during the development process, which allows it to expedite the subsequent formal marketing authorisation application assessment even further. The EMA assessed the first medicine for treating COVID-19, Remdesivir, in this way, providing a scientific opinion on 25 June 2020 and allowing authorisation by the Commission on 3 July 2020 (see [Box 1](#)).

### Box 1

#### Accelerated procedure for authorising COVID-19 treatments

Conditional marketing authorisation is an EU regulatory mechanism designed to facilitate early access to medicines that fulfil an unmet medical need, including in emergencies such as the current pandemic. This type of approval allows the EMA to recommend a medicine for marketing authorisation with less complete data than normally required, if the benefit of a medicine's immediate availability to patients outweighs the risk inherent to the fact that not all the data is yet available. Further data, for example on the quality of the medicine, as well as final data on mortality, has to be submitted subsequently.

An example of this was the accelerated timeline for Remdesivir, an experimental antiviral drug first developed in 2009. After recommending the compassionate use (i.e. use without marketing authorisation) of Remdesivir for certain COVID-19 patients in April 2020, the EMA recommended it for a conditional marketing authorisation by mid-2020.

#### Timeline of Remdesivir approval



Source: ECA based on EMA.



## The EU budget supports COVID-19 vaccine and treatment development

**57** The European Council of 10 March 2020 identified research and innovation on COVID-19, notably for a vaccine, as a top priority in the response to the pandemic<sup>56</sup>. On 7 April 2020, the Commission published a short-term action plan with ten priority actions to structure and coordinate research activities in the EU<sup>57</sup>. The plan focuses on mobilising funding for COVID-related research and coordinating efforts across the EU. For example, the Commission created the Coronavirus Research and Innovation platform to give an overview of EU supported research and innovation projects and initiatives to tackle the spread of coronavirus and boost preparedness for other outbreaks<sup>58</sup>. The Commission has structured its support for research and innovation in response to the pandemic around seven broad themes: preparedness and response, diagnostics, treatments, vaccines, equipment and manufacturing, gender equality in the pandemic and global cooperation.

### EU funding for health research projects on COVID-19

**58** The Commission committed a total of €547 million from the EU budget for COVID-19 research and innovation funding up to 30 June 2020 (see [Table 3](#)).

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<sup>56</sup> Conclusions by the President of the European Council following the video conference on COVID-19, 10 March 2020.

<sup>57</sup> European Commission: ‘ERAvsCoronavirus’ Action Plan, 7.4.2020.

<sup>58</sup> [https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation\\_en](https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en)

**Table 3 – EU funds committed for health related COVID-19 R&D up to 30 June 2020**

Programme	Millions of euros
H2020 COVID-19 expression of interest for projects January and May 2020	178
Innovative Medicines Initiative	72
Contribution to Coalition for Epidemic Preparedness Innovations	100
European and Developing Countries Clinical Trials Public-Private Partnership focusing on infectious diseases research in sub-Saharan Africa	25
European Institute of Innovation and Technology Health 2020 COVID-19 Rapid Response Call	6
European Innovation Council Accelerator pilot	166
<b>Total committed</b>	<b>547</b>

Source: European Commission.

**59** The Commission first committed €10 million H2020 funding for research on COVID-19 on 31 January 2020, using the provision in its work programme that had already committed this budget in case of a public health emergency (in accordance with the financial regulation<sup>59</sup>). This funding was increased to €48 million by the end of March to support 18 projects (out of 89 eligible applications) developing vaccines, diagnostics, new treatments and monitoring systems<sup>60</sup>. The Commission launched a further call for funding applications in May 2020, with a total budget of €130 million, to support 23 projects<sup>61</sup>. The Innovative Medicines Initiative, a public-private partnership between the Commission and the pharmaceutical industry, also launched a call for funding applications in March. It selected eight projects focusing on diagnostics and treatment development, which will receive in total €117 million, €72 million of which in grants from the European budget<sup>62</sup>. The Commission

<sup>59</sup> Regulation 2018/1046, Article 195.

<sup>60</sup> European Commission press release, 6.3.2020.

<sup>61</sup> European Commission press release, 19.5.2020.

<sup>62</sup> European Commission press release, 12.5.2020.

committed another €166 million of funding in April 2020 via an EU business accelerator programme, the European Innovation Council, to 72 companies working on innovative projects related to COVID-19<sup>63</sup>.

## Supporting vaccine research and development

**60** Two of the 18 H2020 projects selected for funding in March 2020 are for the development of vaccines. They will together receive €5.7 million<sup>64</sup>. In addition, the Commission provided loan guarantees in March and June to two other companies researching COVID-19 vaccines through the H2020 InnovFin programme administered by the European Investment Bank. The European Investment Bank negotiated these guarantees under mandate from the Commission as part of loan packages of €80 million for one company<sup>65</sup> and €100 million for the other<sup>66</sup>.

**61** On 17 June 2020, the Commission published its vaccine strategy aimed at supporting and accelerating the global effort to develop and deploy vaccines against COVID-19 in a 12 to 18 months timeframe<sup>67</sup>. Under an agreement between Member States and the Commission, the Commission is mandated to conclude Advance Purchase Agreements with vaccine manufacturers. All 27 Member States are parties to this Agreement. Delivering on this undertaking will require running clinical trials in parallel with investing in production capacity to rapidly produce millions of doses of vaccines. The strategy rests on two pillars:

- securing the production of vaccines in the EU and sufficient supplies for its Member States through Advance Purchase Agreements (APAs) with vaccine producers;
- adapting the EU's regulatory framework to the current urgency and making use of existing regulatory flexibility.

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<sup>63</sup> [European Commission press release](#), 8.6.2020.

<sup>64</sup> [European Commission webpage on Coronavirus vaccine initiatives](#), accessed 31.7.2020.

<sup>65</sup> [European Commission press release](#), 16.3.2020.

<sup>66</sup> [European Commission press release](#), 11.6.2020.

<sup>67</sup> European Commission Communication: [EU strategy for COVID-19 vaccines](#), 17.6.2020.

**62** The Commission negotiated APAs with a number of vaccine producers to secure the right to buy a specified number of vaccine doses in a given timeframe in return for financing part of the upfront costs faced by producers. By the end of November, it reached agreement with six vaccine producers to procure up to 2 billion doses<sup>68</sup>. This transfers some of the risk of the vaccines' development from the private to the public sector. By 30 June 2020, the Commission had allocated €1.5 billion to funding these APAs from the EU's €2.7 billion Emergency Support Instrument<sup>69</sup>. This money will be a down payment on the vaccines that the Member States will purchase, using the procurement conditions negotiated by the EU in the APA. To mitigate the inherent risk linked to vaccine development, and in order to obtain vaccines rapidly and in sufficient quantities, the Commission is investing in a range of vaccine technologies and companies. The €100 million grant given to the Coalition for Epidemic Preparedness Innovations (see [Table 3](#)) falls within this strategy.

**63** The Commission and EMA can support the development of vaccines by making use of existing flexibility in the regulatory process for the approval of medicines, such as: accelerated procedure for authorisation, flexibility in relation to labelling and packaging, and temporary derogations from certain provisions of the Genetically Modified Organism (GMO) legislation for vaccines and medicines containing GMOs.

**64** Disinformation spread about the virus and its treatment represents a risk to the effectiveness of the EU's actions and funding in support of COVID-19 vaccine development. In March and April 2020, the European Council<sup>70</sup> and European Parliament<sup>71</sup> identified COVID-19 related disinformation as a public health challenge and reiterated their commitment to countering disinformation. The High Representative of the Union for Foreign Affairs and Security Policy, and the

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<sup>68</sup> European Commission press releases, [14.8.2020](#); [18.9.2020](#); [8.10.2020](#); [11.11.2020](#), [17.11.2020](#), [25.11.2020](#).

<sup>69</sup> Commission Decision of 18.6.2020 amending Decision C(2020)2794 as regards the financing of the Vaccine Instrument.

<sup>70</sup> Joint statement of the Members of the European Council, 26.3.2020.

<sup>71</sup> European Parliament Resolution of 17 April 2020.

Commission, jointly communicated in June 2020<sup>72</sup> that the COVID-19 pandemic was accompanied by an unprecedented “infodemic” – a flood of often false or inaccurate information that can create confusion and distrust and undermine an effective public health response. This included “foreign actors and certain third countries, in particular Russia and China, [that] have engaged in targeted influence operations and disinformation campaigns around COVID-19 in the EU, its neighbourhood, and globally”<sup>73</sup>.

**65** While the impact of the exposure to COVID-19 related disinformation cannot be calculated with precision, a drop in vaccination coverage of even a few percentage points can have a significant impact on public health, as the rise in measles cases in the EU in recent years demonstrates<sup>74</sup>. An opinion poll carried out in July-August 2020 found that a little more than half of people surveyed in Poland (56 %), Hungary (56 %) and France (59 %) would accept a COVID-19 vaccine<sup>75</sup>. Following a call for projects which closed in June 2020, the Commission will fund research on low vaccine uptake and vaccine hesitancy.

**66** The Joint Research Centre informed us that, since February 2020, it has identified several thousand items of COVID-19 related misinformation and disinformation spread per day. They are clustered into dozens of narratives, with some recurring themes (such as 5G technology, Bill Gates, hydroxychloroquine, vaccination hesitancy) and some evolving themes (for example infections among migrants). The Joint Research Centre found the highest volumes of such items in Italy, Germany, Spain, Bulgaria and France up to 30 June 2020. The Commission launched on 30 March 2020 the ‘Fighting disinformation’ web page<sup>76</sup>.

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<sup>72</sup> Joint communication of the Commission and the High Representative of the Union for Foreign Affairs and Security Policy: Tackling COVID-19 disinformation - Getting the facts right, 10.6.2020.

<sup>73</sup> Ibid.

<sup>74</sup> WHO: Measles cases spike globally due to gaps in vaccine coverage, 29.11.2018.

<sup>75</sup> IPSOS: Global Attitudes on a COVID-19 Vaccine, August 2020.

<sup>76</sup> [https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/fighting-disinformation\\_en](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/fighting-disinformation_en)

## Closing remarks

**67** This review does not intend to conclude on the outcomes and impact of the actions taken by the Commission and EU agencies to support the public health response to COVID-19, especially as at the time of writing these are still evolving. We can nevertheless draw attention to certain issues faced by the EU in its support for Member States' public health response to COVID-19.

**68** The scale and speed of the required response to the pandemic was a challenge for all public authorities. The EU remit in responding to cross-border health threats, including this pandemic, was set in 2013 and, consistent with its Treaty obligations, is relatively limited. It focuses on supporting Member State action and coordination (through the Health Security Committee), facilitation (by creating joint procurement framework contracts to be used by the Member States) and information gathering/risk assessment (through the ECDC). The pandemic represented an unprecedented test of these roles, as illustrated by the limited use of joint procurement, and the challenge the ECDC faced with data collection and analysis.

**69** It was a challenge for the EU to rapidly complement the measures taken within its formal remit, by additional actions to support the public health response to the crisis. These experiences can provide lessons for any future reform of the EU's competences in this field.

**70** The procurement of medical supplies for the pandemic was a challenge. EU level procurement of PPE was limited, whether through the joint procurement mechanism or the rescEU stockpiles, compared to what Member States bought through national procurement pathways. The Commission's CCH allowed for dialogue and sharing of information with Member States and industry on the demand and supply of medical equipment. Member States made limited use of the Commission's matchmaking tool for PPE procurement.

**71** Another challenge is to support the development and ensure the supply of COVID-19 tests, treatments and vaccines. In addition, the successful use of vaccines may be put at risk by COVID-19 related disinformation and its negative effects on public health, notably through vaccine hesitancy.

This Review was adopted by Chamber I, headed by Mr Samo Jereb, Member of the Court of Auditors, in Luxembourg on 21 December 2020.

*For the Court of Auditors*

Klaus-Heiner Lehne  
*President*

# Acronyms and abbreviations

**APA:** Advanced Purchase Agreement

**CCH:** Commission clearing house

**CDC:** Centres for Disease Control and Prevention

**CEPI:** Contribution to Coalition for Epidemic Preparedness Innovations

**CRII:** Coronavirus Response Investment Initiative

**ECDC:** European Centre for Disease Prevention and Control

**EMA:** European Medicines Agency

**ERA:** European Research Area

**EUSF:** European Union Solidarity Fund

**EWRS:** Early Warning and Response System

**FFP:** Filtering Face Piece

**GMO:** Genetically Modified Organism

**H2020:** Horizon 2020

**HSC:** Health Security Committee

**IHR:** International Health Regulation

**IMI:** Innovative Medicines Initiative

**JPA:** Joint Procurement Agreement

**PPE:** Personal Protective Equipment

**SPPSC:** Specific Procurement Procedure Steering Committee

**TESSy:** the European Surveillance System

**UCPM:** Union Civil Protection Mechanism

**WHO:** World Health Organization



# Glossary

**A/H1N1:** The 2009 swine flu pandemic was an influenza pandemic that lasted for about 19 months, from January 2009 to August 2010, and was the second of two pandemics involving H1N1 influenza virus (the first being the 1918–1920 Spanish flu pandemic).

**Disinformation:** Verifiably false or misleading information that is created, presented and disseminated for economic gain or to intentionally deceive the public, and may cause public harm.

**Filtering Face Piece:** Respirators that are entirely or substantially constructed of filtering material. For a mask to be classified as FFP2 according to European standards it must filter at least 94 % of airborne particles. For a mask to be classified as FFP3 according to European standards it must filter at least 99 % of airborne particles.

**Global Health Security Agenda:** A group of 69 countries, international organizations and non-government organizations, and private sector companies that have come together to achieve the vision of a world safe and secure from global health threats posed by infectious diseases.

**International Health Regulation:** A legally binding instrument of international law, first adopted by the World Health Assembly in 1969 and last revised in 2005, that aims for international collaboration to prevent, protect against, control, and provide a public health response to the international spread of disease.

**Medical countermeasures:** A broad spectrum of medical assets, including biological products and personal protective equipment, critical for minimising morbidity and mortality in the event of a large-scale public health emergency.

**Misinformation:** Information that is false regardless of the intention to deceive or cause harm.

**Vaccine hesitancy:** a delay in acceptance or refusal of vaccines despite availability of vaccination services.

## ECA team

### **ECA Review: The EU's initial contribution to the public health response to COVID-19**

This report was adopted by Chamber I, headed by ECA Member Samo Jereb. The task was led by ECA Member Joëlle Elvinger, supported by Ildikó Preiss, Head of Private Office and Charlotta Törneling, Private Office Attaché; Colm Friel, Principal Manager; Nicholas Edwards, Head of Task; Márton Baranyi, Manuel Dias, Malgorzata Frydel and Jan Huth, Auditors. Marika Meisenzahl provided graphical support.

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The COVID-19 pandemic poses challenges to public health systems worldwide. This review looks at actions taken by the Commission and EU agencies to support the Member States' public health response to COVID-19. We reviewed their use of the existing EU framework for dealing with such threats, plus the main additional actions taken by the Commission and EU agencies by June 2020. The review discusses the actions taken, and flags key challenges.

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