

# Novel Coronavirus Outbreak

## State of Play, and the EU's Public Health Response

The novel coronavirus pandemic spreads globally, and the whole world, including the countries of the European Union are facing a serious public health, economic and financial, and social crises. This paper takes stock of how the pandemic evolved, and what response action the Union has taken and prepares to take, in the field of public health. It follows up on the briefing which was published in February 2020.

### Coronavirus basics

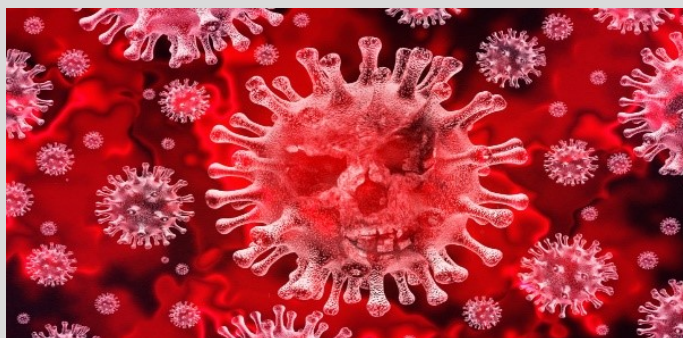
A **new coronavirus strain** that had not been identified in humans before, was detected in Wuhan, a city in Central China's Hubei province. An animal source from a live animal market was, most likely, responsible for some of the first reported human infections.

Research is currently undergoing to detect **the animal origin of the new coronavirus**. An earlier study suggested snakes but later it was discarded. According to [current knowledge](#), the virus might come from bats, and transmitted to humans via an intermediary host animal, probably the pangolins, but this needs further investigation and confirmation. **Human-to-human transmission** occurs via droplets from sneeze or cough, in personal contact. The virus can also stay alive on different surfaces, therefore infection can also occur by touching those contaminated surfaces (such as doorknobs, product packaging, counter tops, elevator buttons, just to name a few) and then touching one's face. It is currently not known how long the virus lives on surfaces.

Given the year of the outbreak, and due to the fact that it is a new virus strain that has not been identified in humans before, the virus was named by the World Health Organisation (WHO) temporarily as the novel coronavirus, 2019-nCoV. On some occasions, it was also referred to as the novel

#### Coronaviruses

Coronaviruses are a family of viruses that can be found in humans and animals. These viruses originate from animals, transmitted from animals to humans (zoonotic viruses), and then spread from one individual to the other. In humans, they cause various respiratory infections, from the common cold to more severe, potentially lethal respiratory diseases. The virus is named after its morphology, as the spikes on the surface of the virus create an image similar to a crown or a solar corona.



Studies identified that the 2012-2013 Middle-East Respiratory Syndrome coronavirus (MERS-CoV) came from dromedary camels, and the 2002-2003 Severe Acute Respiratory Syndrome (SARS) from civet cats.

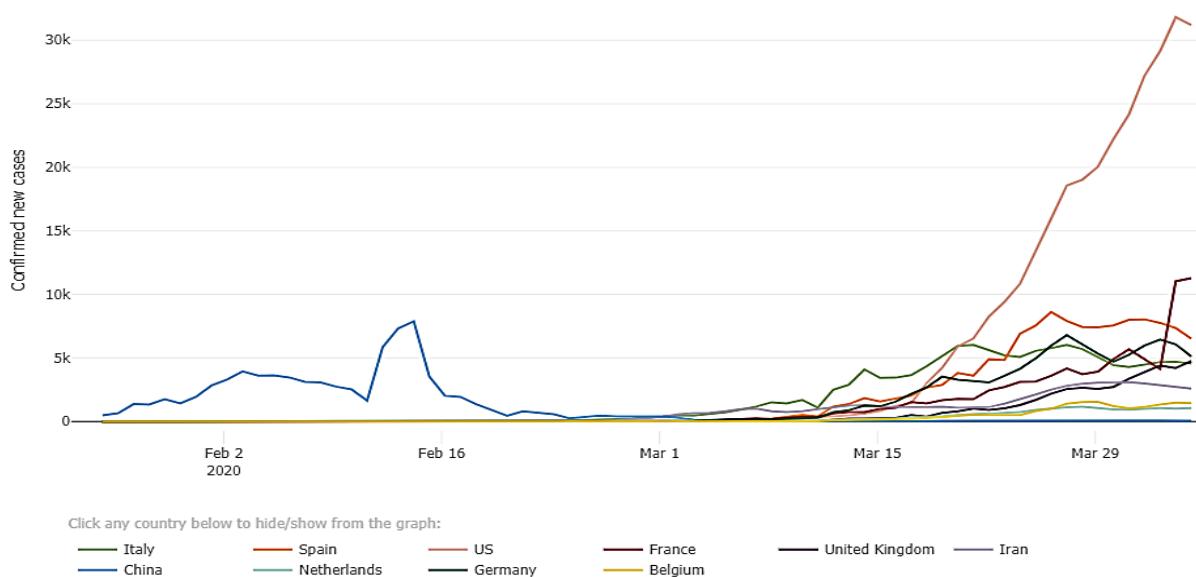


coronavirus pneumonia or NCP. On 11 February 2020, the [WHO announced](#) that they named the virus **COVID-19**, corona virus disease. The [International Committee on Taxonomy of Viruses](#) classified the new virus as severe acute respiratory syndrome coronavirus 2, **SARS-CoV-2**.

## Global situation and response

Given the rising case numbers, the WHO [declared](#) a **public health emergency of international concern** at the end of January 2020. According to the latest available [daily situation reports](#) by the WHO at the time of closing the manuscript, on 7 April 2020, there were close to 1.280.000 confirmed cases worldwide, of which more than 68.700 appearing in the last 24 hours; and global death toll is now over 72.600, of which more than 5.000 deaths happened in the last 24 hours. The **epicentre of the disease, which was in China at the time of the outbreak, has shifted first to the European region and now to the region of the Americas.** (It is to be noted that the UN considers for its statistics the European region in a larger sense, as it includes for example Turkey and the Russian Federation as well.) It is still Europe which has the most case count and the highest death toll, but the rapid increase of new cases and the rising death numbers in America shows how the pandemic spreads further to the West.

Daily confirmed news cases, 5-day moving average - Outbreak evolution for the current 10 most affected countries



Source: [John Hopkins University](#)

It is important to underline that what is included in the statistics is the number of *confirmed cases*. The confirmation of a case is a laboratory tests, therefore the confirmed case number depends on how testing is organised in the given country, i.e. what is their testing policy, what is their testing capacity, and how they report testing data. The *total number of cases* would include also those infected people who are not tested because their symptoms are too mild to go a doctor or have no symptoms at all, or test kits are not available to test them; but they are evidently missing out from the statistics. The total number of cases is therefore not known, but estimated that it might be 10-15 times higher than the number of confirmed cases.

In addition to statistical data on reported cases, a number of [computer models](#) have been developed by researchers to simulate the spread of the infection.

All eyes are on China again, as it has now less than a quarter of the global cases, and after two months of strict containment it started to gradually lift those measures; this is a valuable experience for the rest of the world. It is still too early to declare though that this outbreak is under control in China; all that can be said is one peak has passed now, and the task is to prevent a resurgence. “(T)he next phase of public health response is focused on **mitigating the risk of COVID-19 across the general population over the long term**. This means finding ways to integrate infection prevention and control as a routine part of daily life for everyone across all settings”, [explains](#) Dr Gauden Galea, the WHO Representative to China.

The WHO published its [strategic preparedness and response plan](#) to deal with the crises in the beginning of February 2020. It outlines the public health measures that the international community needs to take to support all countries to prepare for, and respond to the outbreak. “Urgent support is needed to bolster weak health systems to detect, diagnose and care for people with the virus, to prevent further human to human transmission and protect health workers”, said the WHO Director-General. In its assessment, the WHO [estimates](#) that 675m USD is needed for the plan. WHO’s global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics, the [R&D Blueprint](#), is now also [activated](#) in order to accelerate diagnostics, vaccines and therapeutics of the new virus.

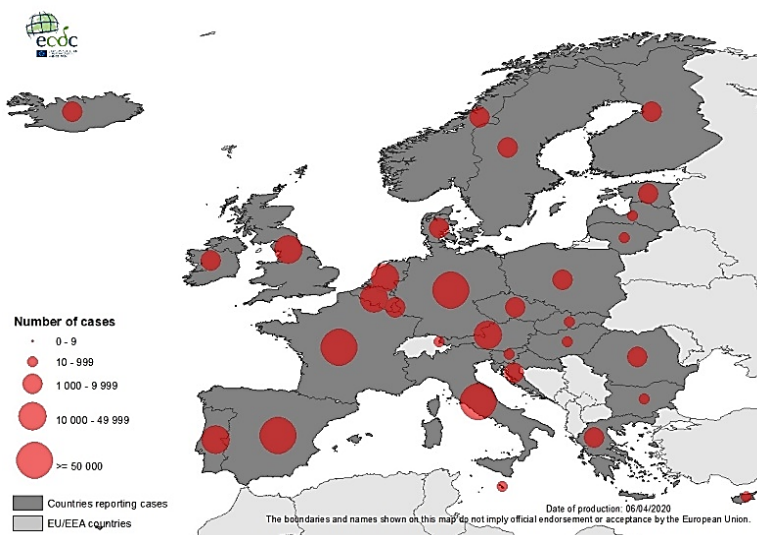
In addition, at the end of March 2020, the UN issued a [2 bn USD appeal](#) to fight coronavirus in the most vulnerable countries, providing laboratory materials for testing, supplies to protect health workers and medical equipment to treat the sick.

To advise public health professionals and the general public, the WHO publishes a number of [technical guidance](#) on infection prevention and control, patient management, surveillance, etc.; and [advises the general public](#) about basic protective measures and clarifies common misconceptions.

## State of play in the EU/EEA and the UK

The European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office request countries to report new cases, including probable and confirmed cases, within 24 hours after identification. On this basis, and after careful screening of some 500 data sources by its team of epidemiologists, the ECDC publishes [daily situation updates for the EU/EEA and the UK](#).

Geographic distribution of COVID-19 in the EU and the UK



Source: [ECDC](#)

Pursuant to the latest update at the time of closing the manuscript, as of 7 April 2020, **608.500 confirmed cases** have been reported in the EU/EEA and the UK. The three most affected Member States, based on the number of confirmed cases, are Spain (in the range of 135.000 cases), Italy (in the range of 132.000 cases), and Germany (in the range of 99.000 cases). The **death toll is now over 51.000** in the EU/EEA and the UK, with Italy (in the range of 16.500 deaths), Spain (in the range of 13.000 deaths), and France (in the range of 8.900 deaths) representing the highest share of fatalities.

In its [updated risk assessment](#) of 25 March 2020, the ECDC estimates that the *risk of severe disease associated with COVID-19* for people in the EU/EEA and

UK is currently *moderate for the general population, and very high for older adults and individuals with chronic underlying conditions*. The ECDC bases its assessment on the case analysis in China and comparative data from the European cases. Case analysis in China revealed that the disease is mild (i.e. not causing pneumonia, or causing only a mild one) in about 80% of cases; most cases recover, 14% develop severe disease, and 6% experience critical illness. Recent data from EU/EEA countries indicate that 30% of cases are hospitalised, and 4% require critical care; the vulnerable population of elderly patients and those with other chronic underlying conditions account for the majority of severe disease and fatalities to date. The mitigation measures that have been introduced at different points in the epidemic and at varying intensities across EU/EEA countries and the UK are slowing the transmission of COVID-19 in the general population more broadly; but it is not yet possible to evaluate it for the vulnerable population groups.

The *risk of occurrence of widespread national community transmission* of COVID-19 in the EU/EEA and the UK in the coming weeks is estimated to be *moderate if effective mitigation measures are in place, and very high if insufficient mitigation measures are in place*. The ECDC warns that the impact of national community transmission would be particularly high if healthcare capacity is exceeded, or if hospitals are affected and a large number of healthcare workers need to be isolated or become infected. It also cautions that a resurgence of cases is likely if mitigation measures are lifted suddenly and too early.

Finally, ECDC concludes that the *risk of healthcare system capacity being exceeded* in the EU/EEA and the UK in the coming weeks is *considered high*. If the pandemic progresses under current trends, without strong countermeasures and surge capacity enacted, many EU/EEA countries will face demands that far exceed the current capacity of intensive care units. Sub-regions in Italy, France, the Netherlands and Spain have already reported that their healthcare systems are saturated due to very high patient admissions requiring intensive care. Healthcare staff is also under pressure, and resources are strained across all EU/EEA countries (ventilator availability, sampling material and laboratory materials affecting diagnostic capacity for COVID-19 testing, contact tracing, surveillance, risk communication, personal protective equipment, shortages of staff and space due to increased needs for triage and isolation of suspected cases). Some healthcare systems may still be under pressure from residual and continued severe seasonal influenza cases.

## Preparedness and response measures taken at EU level

### 1. How the Member States have responded to the public health emergency

Public health is **primarily the competence of the Member States**. It is for them to decide what preparedness and response measures they take, whether and when they introduce containment measures and how stringent those are, when they lift or ease them, and how they proceed with testing and contact tracing. The [Oxford COVID-19 Government Response Tracker](#) and the [COVID-19 Health System Response Monitor](#) gives a comprehensive overview on the national measures.

The positive impact of containment measures on the public health situation is unquestionable. A recent publication by the [Imperial College of London](#) analyses the impact of case isolation, the closure of schools and universities, banning of mass gatherings and/or public events, and widescale social distancing including local and national lockdowns in 11 European countries. They conclude that with current interventions remaining in place until the end of March, 59,000 deaths were avoided; and even more lives could be saved through ensuring that the measures remain in place until transmission drops to low levels.

### 2. What the EU is doing in the field of public health

The Union supports and complements the actions taken at national level, plays a proactive role by issuing guidance and recommendation, and brings Member States together under European solidarity. The Commission is coordinating the common European response through its [Coronavirus Response Team](#), which brings together eight Commissioners and the President of the Commission.



a. Providing scientific advice

The **ECDC monitors closely and assesses regularly the situation**. Through its [dedicated website](#), it issues [daily situation updates](#) and up-to-date [risk assessment](#), and provides technical guidance on a number of issues, e.g. on dealing with patients, cleaning, the use of personal protection equipment, and non-pharmaceutical measures to delay and mitigate the impact of the virus, and testing. Ample information [to the general public](#), in plain and comprehensible language, is also available.

b. Mobilising research for public health

The EU released **48.5 mn euros [emergency research funding](#)** to advance the knowledge for the clinical and public health response to the new coronavirus epidemic. This amount was made available from the Horizon 2020 research framework programme and its annual work programme on health research, which has a standing budget line for emergency research funds.

18 new projects were selected following an open call for expression of interest, related to (i) improving epidemiology and public health, including the EU's preparedness and response to outbreaks; (ii) rapid point-of-care diagnostic tests, enabling first-line health workers to make the diagnosis more quickly and more accurately; (iii) new treatments for COVID-19; and (iv) the development of new vaccines, focussing on developing a prophylactic vaccine and a therapeutic vaccine, which will be used for prevention and treatment respectively.

Further **90 mn euros** in public and private funds will be made available for therapeutics and diagnostics via the **Innovative Medicines Initiative (IMI)**.

c. Protective gears, tests and life-saving medical devices – Ensuring the availability of supply

In the rapidly evolving pandemic, the whole world was caught by surprise by the force and the rapidity of spread of the SARS-CoV-2 virus. That could lead to the situation that even basic personal protective equipment, essential for medical staff and civil protection workers, ran out of stock. The EU therefore decided to create a **first-ever common European reserve of medical equipment**, and help out Member States facing shortages. RescEU is part of the Union Civil Protection Mechanism; originally a reserve of emergency response assets such as firefighting planes and helicopters, it is now proposed to be upgraded to include medical equipment as well. The "[rescEU stockpile](#)" will hold intensive care medical equipment such as ventilators, personal protective equipment such as reusable masks, vaccines when available and therapeutics, and laboratory supplies.

One or several Member States will host the stockpile, and will be responsible for procuring the equipment, with the Commission providing 90% of the financing as a direct grant. The Emergency Response Coordination Centre will manage the distribution of the equipment.

The initial EU budget of the stockpile was planned around 50 mn euros, then it has been recently boosted, up to 80 mn euros. To make this amount available, [the Union's 2020 budget needs to be amended](#), based on the proposal from the Commission, and with the approval of the European Parliament and Council as budgetary authorities.

In addition to the stockpile, Member States are purchasing personal protective equipment, ventilators and items necessary for coronavirus testing in a coordinated way, under the [Joint Procurement Agreement](#). Provisions for the **joint procurement of medical countermeasures** derive from the Serious Cross-Border Threats to Health Decision; in such procurements the Commission has a coordinating role, and Member States buy the goods.

In this case now the Commission launched [four calls for tender](#) for the different categories of medical equipment and supplies. The call seems to be successful, as in response to the first call, the offers match Member States' requests.

Furthermore, the Commission issued a series of [guidance](#) to **increase European production capacities** of protective equipment, hydro-alcoholic gel and 3D printing and 3D printed products. Through this guidance, manufacturers can upgrade production, and manufacturers and market surveillance authorities can ensure that these products are effective, and comply with necessary safety standards.

Also in response to the pandemic, the Commission [proposes to postpone](#) the applicability date of the new [Medical Devices Regulation](#), foreseen for this May, by a year. That it because authorities or conformity assessment bodies might face capacity limitations related to the implementation of the new regulation, and producers of such devices might also have difficulties in adjusting to the new regulatory terms under the unprecedented circumstances. Given, however, the increasing demand for certain vital medical devices, any risk of potential delays or shortages in the availability of such devices must be avoided, hence the proposed postponement. The current Medical Devices Directive remains in force for this additional year, and will continue to guarantee the protection of public health. The Commission has just published the necessary legislative [proposal](#); the [European Parliament](#) and the Council will need to approve it in an accelerated legislative procedure.

#### d. Ensuring the safety and efficacy of COVID-19 treatments and vaccination

Though there are a number of developments underway, the European Medicines Agency, EMA [confirms](#) that on the basis of the preliminary data presented to them, **no medicine has demonstrated yet efficacy in treating COVID-19**.

Several existing drugs which had been authorised for the treatment of other diseases, are now being examined as potential treatment for COVID-19. These include remdesivir (investigational medicinal product, used so far in clinical trials only); lopinavir/ritonavir (currently authorised as an anti-HIV medicine); chloroquine and hydroxychloroquine (currently authorised at national level as treatments for malaria and certain autoimmune diseases); systemic interferons  $\beta$  (currently authorised as treatment for multiple sclerosis); and monoclonal antibodies with activity against components of the immune system.

**Large-scale clinical trials** are now underway to generate robust data and establish evidence on the safety and efficacy of these treatment options.

In particular with regard to **chloroquine and hydroxychloroquine**, which got known to the general public as a promising potential cure for COVID-19, EMA [warns](#) that it is crucial that patients and healthcare professionals only use them for their authorised uses; or if it used off-

#### Medicines and vaccination glossary

*Clinical trial:* a study performed to investigate the safety or efficacy of a medicine. For human medicines, these studies are carried out in human volunteers.

*Phase-I clinical trial:* a type of clinical study where a new medicine is given to humans for the first time, usually in healthy volunteers. It looks at the way the medicine is dealt with by the body, its main effects and main side effects.

*Off-label use:* an authorised medicine is used for an unapproved indication, or in an unapproved age group, dosage, or route of administration.

*Compassionate use:* the use of an unauthorised medicine outside a clinical study in individual patients under strictly controlled conditions. This helps to make medicines that are still under development available to patients. Compassionate use programmes are set up at the level of the Member States.

Source: [European Medicines Agency](#)

label as potential treatment of COVID-19, this can only be done in the context of clinical trials or national protocols. These are vital medicines for patients with autoimmune conditions such as lupus; for the continuity of treatment of those autoimmune patients, it is important that the medicines remain available for them. In some countries the prescribing of the medicines for autoimmune patients has now even been restricted to the usual dose, in order to reduce the risk of shortages and the strain on the supply chain.

Investigating the use of chloroquine and hydroxychloroquine for the treatment of the new coronavirus disease, certain countries like France and the USA have established strict protocols allowing the experimental use of these two medicines in patients with severe forms of COVID-19.

As for **remdesivir**, four Member States (Estonia, Greece, the Netherlands and Romania) requested recommendation from EMA on the compassionate use of the medicine for COVID-19 treatment. EMA, while recalling that clinical trials remain the “gold standard” for gathering data, acknowledged the need for a harmonised approach to compassionate use in the EU and issued recommendations for the Member States that are considering setting up such a programme. The [recommendations](#) describe which patients may benefit from the medicine, explain how to use it, and give preliminary information on its safety.

Several commercial vaccine manufacturers and others are now working on **developing a vaccine** against the SARS-CoV-2 virus. The rapid spread of virus necessitates that vaccine candidates enter swiftly into Phase-I clinical trials, i.e. the first trials can be carried out in humans, in healthy volunteers; regulators authorising those trials will have to strike a balance between the rapid development of vaccines and the need to generate enough robust data to enable decision-making.

At EU-territory, two vaccines have already entered Phase-I clinical trials. EMA [estimates](#) that **it still might take at least one year before a vaccine against COVID-19 is ready** for approval, and available in sufficient quantities for widespread use.

On the global scene, under the umbrella of the [International Coalition of Medicines Regulatory Authorities \(ICMRA\)](#), EMA and other regulators such as the US Food and Drug Administration and Japan's Pharmaceutical and Medical Devices Agency, as well as the Commission and the WHO, are working together on regulatory issues related to [treatment options](#) and [vaccine development](#).

#### e. [Facilitating treatment across the border, and the free movement of healthcare workers](#)

As the pandemic overstretches national health care systems, many Member States fear shortages in their healthcare workforce due to exhaustion and growing number of COVID-19 infections, as well as in their intensive care beds. Recent regional initiatives of hospital cooperation made possible for Italian and French COVID-19 patients to be treated in Germany and Luxembourg; but given the exceptional emergency situation, a more coordinated approach in crossborder healthcare is justified.

The Commission therefore issued [guidelines](#), calling on national, regional and local health authorities to work together to **offer available hospital bed capacity; and enable available health professionals to work across borders**. The Commission would, amongst other, assist health authorities by coordinating the demand and the offer for intensive care places and medical personnel through the Health Security Committee and the Early Warning and Response System (EWRS); and coordinating and co-funding the emergency transport of patients and medical personnel across borders. In addition, **a team of European doctors and nurses are now deployed** to Italy via the Union Civil Protection Mechanism (UCPM), thanks to [Romanian and Norwegian response](#) to Italy's request for help.

#### f. [Bringing people home](#)

The **Union Civil Protection Mechanism** (UCPM) [was activated](#) at the end of January 2020 for the repatriation of EU citizens stranded abroad. More than 2.300 EU citizens [have returned home](#) already, and

further 80 flights are planned. The costs are shared between the Member States and the EU, and the effort is coordinated by national embassies, the European External Action Service and the Emergency response Coordination Centre of the UCPM.

#### g. Working on an exit strategy

Responding to the request of the leaders of the Member States, the Commission has started to work out a roadmap for an exit strategy. **Exit remains in the hands and competence of the Member States, and this roadmap would provide a guidance** to assess whether time has come to start to ease the confinement measures, how a gradual exit could be rolled out, and how Member States should notify each other and the Commission of their intentions.

Though some Member States are now ready to start a gradual exit, others voiced their concern that revealing an exit roadmap at this time, when they are still urging their citizens to stay at home, would send a dangerous signal. The College of Commissioners originally scheduled to adopt the roadmap on 8 April 2020, but now the discussion continues and endorsement could come after the Easter break.

#### h. Providing a framework for coordinated action by the Member States

The Croatian Presidency [activated](#) the **Integrated Political Crises Response arrangements** in relation to

##### EU legal framework

Though public health is primarily the competence of the Member States, the Union supports and complements the actions taken by them ([Article 168 TFEU](#)). [Decision No 1082/2013/EU](#) on **cross-border threats to health** lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health. Under the Decision, a **Health Security Committee** (HSC) was set up, which is composed of the representatives of the Member States, and chaired by the Commission. An **Early Warning and Response System** (EWRS) was established for direct and permanent communication between the Commission and the national authorities.

The **EU Integrated Political Crisis Response arrangements (IPCR)** were established by the [Council Implementing Decision No 2018/1993](#). The ICPR mechanism supports the Council Presidency, the Coreper and the Council, by providing tools and creating a platform for sharing information and coordinating crises responses at political level.

[Decision No 1313/2013/EU](#) established, and in 2019 strengthened further, the **Union Civil Protection Mechanism (UCPM)**. The UCPM plays a role in fostering cooperation in prevention of, preparedness for, and response to disasters. With the 24/7 Emergency Response Coordination Centre, a pool of assets and resources, and a European medical corps, the Mechanism can be activated in case of both natural and man-made disasters.

the outbreak, in information-sharing mode at the end of January 2020; that was in order to facilitate the exchange of information, ensure that there is common understanding of the situation, and allow for the preparation of analytical reports.

In early March 2020 the IPCR was moved to [full activation mode](#). Full activation allows for focussing more on identifying major gaps and elaborating concrete EU response measures, at roundtables led by the Presidency. Representatives of the President of the European Council, the Commission, the European External Action Service, affected member states and other relevant parties attend these roundtables. Their purpose is prepare, develop and update proposals for actions, upon which the Council will decide and act.

The **Health Security Committee** [met several times](#), to exchange information on the situation, and on the preparedness needs and gaps of the Member States. The HSC will now also play an important role in facilitating the coordination of requests for cross-border health care assistance. Requests



for assistance could relate to intensive care places, treatment and transfer of patients and qualified teams of medical personnel.

The **European Union Aviation Safety Agency** issued [recommendations](#) to national aviation authorities, airlines and airports in response to the outbreak.

In an **extraordinary Council meeting** in February 2020, health ministers adopted [conclusions](#) urging the Member States to take measures to protect public health, with particular attention to international travel, and calling for close and enhanced cooperation and sharing of information. The Council also called on the Commission to, inter alia, facilitate the cooperation of the Member State; activate existing funding mechanisms to prepare for and respond to the health threat; promote amongst Member States the alignment of measures efficiently minimising the risk of further infections; and in cooperation with the European Medicines Agency and the national medicines agencies, evaluate the consequences of global health threats for the availability of medicines within the EU and the security of supply chains. Health ministers [discussed further](#) the situation in their meeting in early March 2020.

The **European Council** met via video conference three times in March 2020 on the coronavirus outbreak. Leaders [confirmed](#) the [main priorities](#), such as limiting the spread of the virus and putting citizens' health as a priority; tasking the Commission to coordinate the provision of medical equipment; supporting research for treatment and vaccines; and tackling the socio-economic consequences.

The **European Parliament** held an [extensive debate](#) with the Croatian Presidency and the Commission at the end of January 2020. The Environment, Public Health and Food Safety Committee followed it up by a [discussion](#) with Commissioner Kyriakides in February 2020. During the extraordinary plenary meeting on 26 March 2020, the European Parliament [debated further](#) the crises with, and [adopted](#) a series of legislative proposals in urgency procedure to tackle the coronavirus outbreak. To continue the work on the special measures to fight the pandemic, the [next extraordinary plenary meeting](#) is planned for 16-17 April 2020.

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