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Accompanying the document

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

Introducing the Union prevention, preparedness and response plan for health crises

{COM(2025) 745 final}

European Commission

Union prevention, preparedness and response plan for health crises

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Contents

Abbreviations

Abbreviation	Meaning
ACPHE	Advisory Committee on Public Health Emergencies
AMR	Antimicrobial Resistance
CECIS	Common Emergency Communication and Information System
CBRN	Chemical, biological, radiological and nuclear threats
CVO	Chief Veterinary Officer
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECPP	European Civil Protection Pool
EEA	European Economic Area
EEA	European Environment Agency
EFSA	European Food Safety Authority
EGE	European Group on Ethics in Science and New Technologies
EMA	European Medicines Agency
EMT	Emergency Medical Team
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EUDA	European Union Drugs Agency
ERCC	Emergency Response Coordination Centre
ERVISS	European Respiratory Virus Surveillance Summary
ESI	Emergency Support Instrument
ETF	Emergency Task Force
EU	European Union
EU FAB	Network of ever-warm production capacities for vaccines and therapeutics manufacturing
EUHTF	EU Health Task Force
EUdPLF	EU digital Passenger Locator Form
EURL	European Reference Laboratories
EWRS	Early Warning and Response System
FPI	Foreign Policy Instrument
GDHCN	Global Digital Health Certification Network
GHSI	Global Health Security Initiative
GOARN	Global Outbreak Alert and Response Network
HAI(s)	Healthcare associated infection(s)
HCB	Health Crisis Board
HSC	Health Security Committee
IAEA	International Atomic Energy Agency
IHR	International Health Regulations
IPCR	Integrated Political Crisis Response
ISAA	Integrated Situational Awareness and Analysis Reports
JRC	Joint Research Centre

JPA	Joint Procurement Agreement
LSCO	Large-Scale Combat Operation
MCMs	Medical Countermeasures
MFF	Multiannual Financial Framework
MDSSG	Medical Device Shortages Steering Group
Medevac	Medical Evacuation
MSSG	Medicine Shortages Steering Group
NITAG	National Immunisation Technical Advisory Groups
OECD	Organisation for Economic Co-operation and Development
PHEPA	Public Health Emergency Preparedness Assessment
PIWG+	Pandemic Influenza and other respiratory diseases working group
RRF	Recovery and Resilience Facility
SCBTH	Serious cross-border threats to health
SAM	Scientific Advice Mechanism
SIMEX	Simulation exercise(s)
SoHO	Substances of Human Origin
SoHO-Net	Network for the Microbial Safety of Substances of Human Origin
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TFEU	Treaty on Functioning of the European Union
UCPM	Union Civil Protection Mechanism
UNHRD	United Nations Humanitarian Response Depot
WHA	World Health Assembly
WHO	World Health Organization
WOAH	World Organisation for Animal Health Organisation

1. Introduction

1.1. Why do we need a Union prevention, preparedness and response plan for health crises?

The Union prevention, preparedness and response plan for health crises (**'Union plan'**) is established by the European Commission in accordance with Article 5 of the **EU Regulation on serious cross-border threats to health** ([1]). It is published at a time when multiple threats endanger the lives, health and well-being of people living in the EU/EEA and when crisis preparedness and resilience are high on the EU's political agenda. It is among the actions listed in the action plan accompanying he **EU Preparedness Union Strategy** ([2]), adopted in March 2025, which aims to strengthen Europe's capability to prevent, prepare for and respond to emerging threats and risks, regardless of their nature or origin. The Union plan, which focuses on health crises, promotes an effective and coordinated response and synergies at EU level. Together with the national prevention, preparedness and response plans, it will form a robust planning framework for the EU.

In recent years, the EU has significantly strengthened its health security architecture in order to improve its readiness and response to future health crises. The Commission, Member States and EU agencies took decisive steps toward a stronger, more resilient **European Health Union**, aiming to strengthen the EU's ability to prepare for and respond to health crises. The building blocks of the EU Health Union included the revision of the EU health security legislation in the form of the new EU Regulation on serious cross-border threats to health and strengthened mandates of the European Centre for Disease Prevention and Control (**ECDC**) ([3]) and the European Medicines Agency (**EMA**) ([4]). Moreover, the Health Emergency Preparedness and Response Authority (**HERA**) ([5]) was created to strengthen Europe's ability to prepare for and respond to a health crisis by, among other things, ensuring the swift availability and accessibility of medical countermeasures (MCMs) ([6]). Prevention, preparedness

([1]) Article 5(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

([2]) European Commission, 'Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions', JOIN(2025)130, 26 March 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025JC0130.

([3]) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/851/oj).

([4]) Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

([5]) Commission Decision of 16.9.2021 establishing a Health Emergency Preparedness and Response Authority (HERA), C(2021)6712, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=intcom:C(2021)6712.

([6]) Also supported by the adoption of Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

and response planning for health crises is an essential starting point for an effective and coordinated response. The Regulation on serious cross-border threats to health therefore creates a robust planning framework for the EU where national plans and the Union plan complement each other and operate in coherence ([7]). The Union plan includes provisions on **joint arrangements** for governance, capacities and resources in place at EU level that can be relied upon to effectively prevent, prepare for, respond to and recover from health crises. It is an operational document that navigates the reader through the overall EU health crisis infrastructure and serves as a toolbox for crisis managers to identify and use relevant resources as required.

The Union plan was developed by the Commission in cooperation with Member States (through the Health Security Committee) and the relevant EU agencies and bodies. The public was also consulted during webinars and via a call for evidence. The Union plan therefore brings together a vast amount of current knowledge, best practices and information from different sectors on prevention, preparedness and response planning in the EU. By presenting this information in one practical resource, the Union plan contributes to promoting effective synergies between different governance structures and levels. This approach helps prevent the emergence of health crises and/or facilitate a more effective and coordinated response across the EU if a crisis occurs.

While the Union plan focuses on the joint arrangements within the EU, it is aligned with EU global health priorities ([8]) ([9]) and contributes to the implementation of the recently reinforced global health security framework, as set out in the International Health Regulations (**IHR**) amended in 2024 ([10]) ([11]). These amendments aim to increase global readiness, surveillance and response to public health emergencies ([12]).

The current document is the first version of the first ever Union plan to prevent, prepare for and respond to serious cross-border threats to health. As such, it will be important to test that the Union plan is 'fit for purpose' through simulation exercises, the first of which is planned for 2026. These exercises will test whether the plan promotes an

([7]) Articles 5–9 of Regulation (EU) 2022/2371.

([8]) Communication from the Commission to the European Parliament, the Council, the European economic and Social Committee and the Committee of the Regions: EU Global Health Strategy, COM/2022/675 final, 30.11.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2022:0675:FIN.

([9]) Efforts are also under way under the auspices of the WHO to conclude the negotiations of the WHO Pandemic Agreement, including its Annex on a Pathogen Access and Benefit Sharing (PABS) System. The objective is to submit the outcome of the negotiations to the World Health Assembly in May 2026. The Pandemic Agreement will be open for signature and ratification only once the negotiations on the PABS Annex are concluded. Once implemented, the Agreement is expected to improve global pandemic prevention, preparedness and response.

([10]) World Health Organization, International Health Regulations ('IHR'), 2005 (as amended in 2014, 2022 and 2024), https://apps.who.int/gb/bd/pdf_files/IHR_2014-2022-2024-en.pdf.

([11]) Council Decision (EU) 2025/1129 of 26 May 2025 inviting Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024. (OJ L, 4.6.2025, ELI: http://data.europa.eu/eli/dec/2025/1129/oj).

([12]) Efforts are also under way under the auspices of the World Health Organization to conclude the negotiations on the WHO Pandemic Agreement, including its Annex on a Pathogen Access and Benefit Sharing (PABS) System. The objective is to submit the outcome of the negotiations to the World Health Assembly in May 2026. The Pandemic Agreement will be open for signature and ratification only once the negotiations on the PABS Annex are concluded. Once implemented, the Agreement is expected to improve global pandemic prevention, preparedness and response.

effective and coordinated response in the EU/EEA to a specific threat scenario focusing on the joint arrangements for governance, capacities and resources. It will also be important to adapt it in accordance with EU-level developments in relevant policy areas, in particular following the implementation of relevant actions announced in the Preparedness Union Strategy, the EU Strategy to support medical countermeasures ([13]) against public health threats and the EU Stockpiling Strategy ([14]).

1.2. What types of health crises are covered?

The current threat and risk landscape in the EU is complex and continuously evolving due to megatrends such as climate change, demographic transition, globalisation, urbanisation, migration, habitat destruction and geopolitical power relations ([15]) ([16]). These megatrends, often interlinked, not only increase the likelihood of health threats occurring, but might also make the population more vulnerable to adverse health crises. For example, extreme weather conditions can disrupt ecosystems, increasing the likelihood of infectious diseases emerging, but can contribute to the population being more vulnerable to such diseases by negatively impacting food security.

Considering the current operating environment, the Union plan takes an **all-hazards approach** when it comes to health crises that the EU could face. It addresses life-threatening or otherwise serious threats to public health that spread or entail a significant risk of spreading across Member States' national borders and may necessitate coordination at EU level to ensure a high level of human health protection ([17]). Such events involving serious cross-border threats to health can be natural, accidental or intentional, and can be of biological, chemical, environmental, unknown or other origin (see Table 1). Events of 'other' origin can include any exceptional emergency situation impacting public health that requires a coordinated cross-border response, particularly in situations where the national public health measures prove to be insufficient. In these situations, which can cover also armed conflicts, the coordinated response between the EU institutions and the Member States is needed if it is considered that public health measures taken previously have proven insufficient

([13]) European Commission, 'Medical Countermeasures Strategy', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/preparedness/medical-countermeasures-strategy_en.

([14]) European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions: EU stockpiling strategy: Boosting the EU's material preparedness for crises', COM(2025) 528 final, 9 July 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0528.

([15]) Lentini, A., Eklund, G., Corbane, C., Asikainem, T., Ronco, M. et al., *Analysis of Risks Europe is facing - An analysis of current and emerging risks*, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/0176850, JRC141673.

([16]) European Commission: Secretariat-General, *Strategic Foresight Report 2025. Resilience 2.0: Empowering the EU to thrive amid turbulence and uncertainty*, Publications Office of the European Union, Luxembourg, 2025, https://commission.europa.eu/strategy-and-policy/strategic-foresight/2025-strategic-foresight-report_en.

([17]) Articles 3(1) and 19 of Regulation (EU) 2022/2371.

to ensure a high level of protection of human health ([18]). Serious cross-border threats to health can endanger health either directly – by causing disease or trauma – or indirectly by impacting the health systems' capacities to provide services, as it is the case in armed conflicts.

Table 1. Examples of serious cross-border threats to health covered by the Union plan

 Biological	**Human outbreak of zoonotic influenza**	**Scenario:** A highly pathogenic Avian influenza virus jumps from animals to humans with sustained transmission between people is observed.
 Chemical	**Explosion in a chemical production facility**	**Scenario:** A chemical production facility bordering several countries experiences an explosion in its storage tanks, releasing a large volume of toxic chlorine gas and other volatile chemicals into the atmosphere.
 Environmental	**Extreme weather event**	**Scenario:** Extreme temperatures lead to excess morbidity and mortality in multiple countries, resulting in overburdened healthcare systems.
 Unknown	**Armed conflict involving the use of an unknown toxin**	**Scenario:** A regional armed conflict erupts involving the use of an unknown toxin that spills into rural zones rich in agriculture and freshwater sources, creating an exceptional emergency situation to public health that requires cross-border coordination.
 Other	**Cyber incidents in healthcare**	**Scenario:** A cyberattack results in service disruptions and outages in hospitals in several countries, disrupting the provision of essential services.

Disclaimer: The scenarios are hypothetical situations for illustrative purposes only. They are not presented in any order of priority.

The Union plan also covers events that are of such a serious nature that they are recognised as a public health emergency at Union level by the Commission or as a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO) ([19]).

While EU external action in health contributes to health security in both partner countries and EU Member States, the Union plan describes joint arrangements for governance, capacities and resources to prevent, prepare for and respond to events in the EU/EEA regardless of whether these threats have originated within the EU or outside Europe. The Union plan therefore does not cover EU actions taken to address

([18]) Articles 2(1) and (4) of Regulation (EU) 2022/2371.

([19]) Provided that they fall under one of the categories of threats set out in points (a) to (d) of Article 2(1) of Regulation (EU) 2022/2371.

health crises that occur outside the EU/EEA area and that are unlikely to pose a health threat to people living in the EU/EEA.

1.3. How to use the Union plan?

The Union plan shows how governance for prevention, preparedness and response to health crises across the EU is implemented and includes provisions for joint arrangements for capacities and resources that can be mobilised to prevent the emergence of a health threat and/or to mitigate its impact. Moreover, the Union plan provides details on the procedure for recognising a public health emergency at Union level and related additional measures. Finally, the Union plan describes joint arrangements in place for learning and continuous improvement. These are important for updating national prevention, preparedness and response plans as well as ensuring swift recovery.

The development of the Union plan is founded on four guiding approaches: all-hazards, One Health, whole-of-government and whole-of-society:

Table 2. Approaches considered by the Union plan

- The **all-hazards** approach to preparedness ensures that organisational capabilities, and controls are designed and applied in such a way as to be able to respond to all types of disruptive events, irrespective of their nature or cause.
- The **One Health** approach is an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, and ecosystems. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent, as well as the need for coordination and collaboration between relevant sectors ([20]).
- The **whole-of-government** approach brings together all levels of administration (from local and regional to national and EU level as well as international level) and promotes multisectoral and multidisciplinary collaboration, policy coherence and the sharing of resources.
- The **whole-of-society approach** supports an inclusive culture of preparedness and resilience and is essential for achieving national unity and solidarity for managing the risks and impacts of health crises, as well as the resilience of communities and countries.

The Union plan is relevant to **all EU Member States and EEA countries**, including the outermost regions ([21]). Its main audience is relevant authorities in the Member States responsible for developing and implementing policies for prevention, preparedness and response planning and for crisis management. Other key audiences include EU agencies and bodies, international organisations such as the WHO and neighbouring countries. The general population, private sector, civil society, academia and the media can also benefit from the Union plan.

([20]) One Health High-Level Expert Panel (OHHLEP), Adisasmito W.B., Almuhairi S., Behravesh C.B., et al., 'One Health: A new definition for a sustainable and healthy future'. *PLoS Pathogens*, Vol. 18, Issue 6, 2022, https://doi.org/10.1371/journal.ppat.1010537.

([21]) Article 349 of the Treaty on the Functioning of the European Union (TFEU).

The Union plan complements **national prevention, preparedness and response plans**. When preparing or developing their national plans, Member States must seek coherence with the Union plan to the largest extent possible, in accordance with national responsibility for prevention, preparedness and response to health crises and considering national circumstances ([22]). For example, national plans can include references to the joint arrangements for governance, capacities and resources described in the Union plan. Documenting such linkages can facilitate coordinated action from local, regional and national to EU level and, as appropriate, international level and across sectors.

Throughout the Union plan, special focus is given to **cross-border interregional preparedness elements** for prevention, preparedness and response to health crises (see Table 3). The Union plan illustrates examples of existing cross-border arrangements to ensure seamless, coordinated action and efficient use of resources.

Table 3. Types of cross-border interregional collaboration considered in the Union plan

- Collaboration between regions sharing an EU/EEA internal border
- Collaboration at national level between countries sharing an EU/EEA internal border
- Collaboration at regional or national level between regions or countries not sharing an EU/EEA internal border
- Collaboration across EU external borders, in particular with the countries and regional organisations that border the EU's outermost regions.

Regions refer to any sub-national territorial units as per NUTS classification ([23]).

The Union plan should not be considered an exhaustive blueprint of step-by-step procedures to follow if a certain event arises. Each health crisis would require different types of expertise and response adapted to the type of threat, the socio-demographic characteristics of the population, and the environment in which it occurs. However, the Union plan represents an asset providing an overview of the joint arrangements for governance, capacities and resources currently in place to effectively respond to health crises in the EU/EEA. For this reason, it does not contain references to relevant new actions announced in a number of cross-cutting and sectoral EU strategies, as these activities and arrangements are yet to be implemented.

Furthermore, the Union plan does not refer to time-limited EU-funded projects that are relevant for the prevention of, preparedness for or response to health crises. However, Annex 6 provides an overview of EU funding instruments relevant to strengthening health security, including activities funded under the EU4Health and Horizon Europe programmes.

([22]) Article 6 of Regulation (EU) 2022/2371.

([23]) European Commission: Eurostat, 'NUTS - Nomenclature of territorial units for statistics', European Commission website, accessed 31 October 2025, https://ec.europa.eu/eurostat/web/nuts.

1.4. How will the Union plan be kept up to date?

The current version of the Union plan is its first edition. It should be considered a living document that the Commission in coordination with Member States and relevant EU agencies and bodies will regularly review and, as necessary, revise to address any changes that can occur in its legal basis or in the overall operating environment or based on lessons learned from simulation exercises or from real-life events. To measure the plan's performance, the Commission plans to develop a set of indicators that will enable the assessment of its performance. Moreover, as the Union plan is to complement the national plans and promote synergies between the Member States, the Commission and the relevant EU agencies, the findings and recommendations from the regular reporting and assessment of national prevention, preparedness and response plans can identify needs for further development of the Union plan. Implementation of the Union plan will be monitored and discussed in the HSC.

To ensure that the Union plan continues to meet its aim of promoting an effective and coordinated response to serious cross-border threats to health in the EU, the Commission will regularly organise simulation exercises testing the content of the Union plan against a range of hazards. Based on the lessons identified from these exercises, the Commission will revise the Union plan. Moreover, should a real-life event occur, the Commission will carry out in-action or after-action reviews with Member States to ensure that the Union plan is updated, functional and operational.

Based on the findings of the first simulation exercise planned for 2026, as well as the implementation of the relevant actions of the EU Preparedness Union Strategy, the Commission will assess whether an update is required.

2. Key EU health crisis governance structures, mechanisms and instruments

Effective governance and coordination mechanisms within the EU, its agencies, bodies and Member States, as well as with international organisations such as WHO and other international partners, are crucial for ensuring effective readiness and response to serious cross-border threats to health. Coordinated action enables timely early detection, information sharing, joint risk assessments, prevention and response measures, efficient resource mobilisation, and effective risk and crisis communication. These governance arrangements not only strengthen the EU's collective preparedness and response capacity, but also uphold the principles of solidarity, resilience, equity and trust in times of crisis.

The EU governance structures and support mechanisms for health crises are presented in Annexes 3 and 4. The key joint arrangements to ensure health security in the EU are active in different phases of the health crisis management cycle (see Figure 1). These governance structures, mechanisms and instruments act in coordination, cooperation and complementarity in the prevention of, preparedness for and response to health crises, avoiding any overlaps or duplication of efforts.

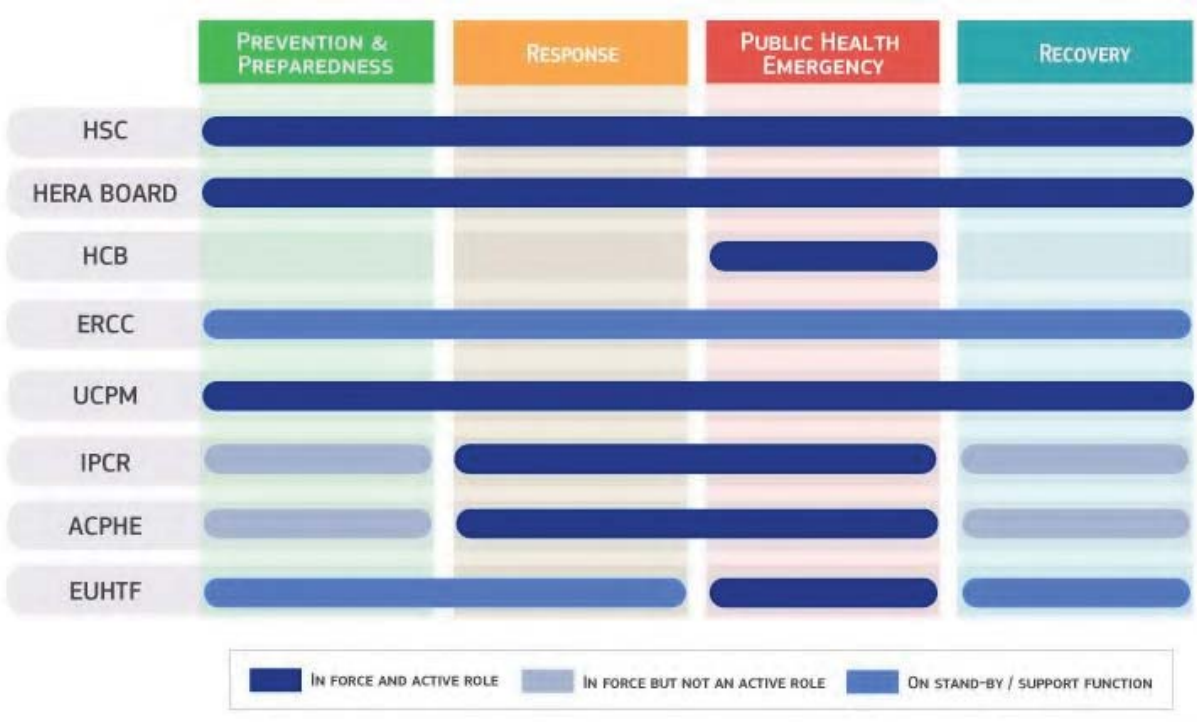


Figure 1. Main EU health crisis governance structures, mechanisms and instruments that can be operational during different phases of the health crisis management cycle. HSC=Health Security Committee; HCB=Health Crisis Board; ERCC= Emergency Response Coordination Centre; UCPM=Union Civil Protection Mechanism; IPCR=Integrated Political Crisis Response; ACPHE=Advisory Committee on Public Health Emergencies; EUHTF=EU Health Task Force.

The Health Security Committee (**HSC**), composed of nominated representatives of EU Member States and EEA countries, plays an important role in coordinating activities related to the prevention, preparedness and response to health crises with cross-border potential at EU level ([24]). The HSC operates throughout the entire crisis management cycle and provides a platform where EU Member States and EEA countries and the Commission meet to discuss and ensure coordination on health security matters. It meets at regular intervals and whenever the situation requires, at the request of the Commission or an EU Member State or an EEA country. The HSC invites relevant EU agencies and bodies, the European Parliament as well as international organisations – such as the WHO – to participate as observers where relevant to the topic.

The HSC is chaired by the Commission and operates at two working levels: the **senior level group** and **technical working groups** dedicated to specific subjects. It allows for rapid information exchange, the sharing of best practices and experiences, discussion on EU support needs and actions required to strengthen prevention, preparedness and response planning, as well as the development and adoption of EU-level guidance and opinions to support the coordination of national measures ensuring a coherent EU-wide response to a health crisis ([25]). By maintaining a strong communication channel and encouraging collaboration, the HSC supports Member States in their preparedness planning (see Section 4.1.1) for emerging health threats and for continuously improving their readiness to mitigate future health crises.

In the area of MCMs, the **HERA Board** is composed of the representatives of the Member States and chaired by the Commission, while EU institutions and agencies may participate as observers ([26]). The task of the HERA Board is to assist and advise the Commission in the formulation of strategic decisions concerning Commission's activities on MCMs, contributing to leveraging Member States' resources and capacities. This entails work on the assessment of health threats and intelligence gathering; promoting advanced research and development; addressing market challenges and boosting the Union's open strategic autonomy in production; swift procurement and distribution; increasing stockpiling capacity; and strengthening knowledge and skills in preparedness and response related to MCMs. In view of the information that is exchanged during meetings of the HERA Board, its work can help decision-making on measures at national level to improve the availability of and access to MCMs.

The HERA Board is supported by the **HERA Advisory Forum** consisting of Member State experts in the area of health security, research and industrial policy ([27]). The Advisory Forum exchanges technical information and pools knowledge on MCMs to

([24]) Articles 4, 10 and 21 of Regulation (EU) 2022/2371.

([25]) European Commission, 'Health security and infectious diseases – Publications. Opinions of the Health Security Committee', European Commission website, accessed 31 October 2025, https://health.ec.europa.eu/health-security-and-infectious-diseases/publications_en?f%5B0%5D=topic_topic%3A224.

([26]) Commission Decision of 16.9.2021 establishing a Health Emergency Preparedness and Response Authority (HERA), C(2021)6712, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=intcom:C(2021)6712.

([27]) European Commission, 'HERA Advisory Forum', European Commission website, accessed 31 October 2025, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/hera-advisory-forum_en.

provide scientific knowledge and advice to the HERA Board. As a subgroup of this Forum, a **Joint Industrial Cooperation Forum** has been set up to link Member States and industry representatives in the whole-of-society approach. It complements the Commission's broader intelligence tools and bodies by focusing specifically on the industrial aspects of preparedness. It aims to identify market failures and supply chain dependencies that could limit the production capabilities of relevant MCMs and their raw materials. The **Civil Society Forum** ensures exchanges with academia and civil society and provides recommendations to the Advisory Forum on specific matters related to health crisis preparedness and response, with a focus on MCMCs, and monitors relevant research, industrial and policy developments.

The **Health Crisis Board** is established when the emergency framework for MCMs is activated following the recognition of a public health emergency at Union level ([28]). The Health Crisis Board ensures the coordination of action by the Council, the Commission and relevant Union agencies and bodies and Member States to ensure the supply of and access to crisis-relevant MCMs. It is composed of the Commission and one high-level representative from each Member State. It meets whenever the situation requires, upon request from the Commission or a Member State and is co-chaired by the Commission and the Member State holding the rotating Presidency of the Council. Relevant EU institutions, agencies and bodies as well as a representative of the European Parliament, the HSC and, where relevant, international organisations – such as WHO, Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH) – to participate as observers where relevant to the topic.

The Health Crisis Board and the HERA Board coordinate on the MCMs response based on their distinct roles. Moreover, they coordinate with the HSC and exchange information to effectively respond to the threat. Given their mutually complementary roles and responsibilities, close coordination, including the exchange of information and the facilitation of discussions, is ensured ([29]).

In terms of EU support mechanisms that are in place in case of natural and human-induced disasters, including health crises, the EU Civil Protection Mechanism (**UCPM**) plays a crucial role. It aims to strengthen civil protection cooperation between the EU Member States and 10 additional UCPM Participating States to improve prevention, preparedness, and response to disasters in Europe and beyond. The Emergency Response Coordination Centre (**ERCC**) of the Commission is at the heart of the UCPM, ensuring 24/7 operational capacity to facilitate rapid coordination and support ([30]).

The Integrated Political Crisis Response (**IPCR**) arrangements of the European Council are the central EU mechanism that support rapid and coordinated decision-

([28]) Article 5 of Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the suppy of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

([29]) Article 5(5) of Regulation (EU) 2022/2372.

([30]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924, ELI: http://data.europa.eu/eli/dec/2013/1313/oj).

making at EU political level for major and complex crises. Chaired by the Presidency of the Council, the IPCR is scalable according to the gravity of the crises ([31]). It can be triggered either by the Presidency of the Council or by a request from a Member State ([32]). During a health crisis, the HSC, and the Health Crisis Board, if established, work closely with the IPCR mechanism to ensure that political coordination at EU level is supported by public health expertise and operational input from Member States, including through information exchange, situational awareness in the form of Integrated Situational Awareness and Analysis (ISAA) reports and sharing opinions or guidance. The Emergency response Coordination Centre (**ERCC**) supports both the EU institutions and the Member States when IPCR arrangements are activated, or the solidarity clause is invoked. Annex 3 contains further examples of important governance structures and instruments for EU health security in the European Council, as well as the Council of the EU and the European Parliament.

The Advisory Committee on Public Health Emergencies (**ACPHE**) is a multidisciplinary expert group whose mission is to provide advice, at the request of the Commission or the HSC, on whether an emerging threat constitutes a public health emergency at Union level. It also provides advice on appropriate response measures for an emergency and the need for termination of a public health emergency at Union level ([33]).

Throughout all phases of the health crisis management cycle, the EU Health Task Force (**EUHTF**), established and operated by the ECDC ([34]), is ready to provide support to Member States where needed. The EUHTF can be mobilised on field missions or for remote support in an EU Member State or an EEA country or outside the EU based on a request for support. Once a public health emergency at Union level has been recognised and following the request of at least two Member States and the Commission, the ECDC must mobilise the EUHTF enhanced emergency capacity and its pools, in coordination with the Commission and the HSC ([35]) ([36]).

The European Centre for Disease Prevention and Control (**ECDC**); European Medicines Agency (**EMA**); European Food Safety Authority (**EFSA**); European Environment Agency (**EEA**); and the European Chemicals Agency (**ECHA**) have established the **Cross-agency task force on One Health** ([37]). This is a collaborative

([31]) Council Decision 2014/415/EU of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (OJ L 192, 1.7.2014, p. 53, ELI: http://data.europa.eu/eli/dec/2014/415/oj).

([32]) European Council, 'How the Council coordinates the EU response to crises', European Council/Council of the European Union website, accessed 31 October 2025, https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/.

([33]) Article 24 of Regulation (EU) 2022/2371.

([34]) European Centre for Disease Prevention and Control (ECDC), EU Health Task Force (EUHTF), ECDC website, accessed 31 October 2025, https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/support-and-services-eueea-countries/health-task-force.

([35]) Article 11a of Regulation (EC) No 851/2004.

([36]) Commission Implementing Regulation (EU) 2025/1536 of 29 July 2025 setting out the procedure concerning the mobilisation of the enhanced emergency capacity of the EU Health Task Force (OJ L, 2025/1536, 30.7.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/1536/oj).

([37]) One Health cross-agency task force: Strengthening EU agencies' scientific advice on One Health, EFSA website, accessed 31 October 2025, https://www.efsa.europa.eu/sites/default/files/documents/news/one-health-cross-agency-task-force.pdf.

framework that brings together these five EU agencies to address health threats at the human-animal-environment interface. The network promotes a holistic, interdisciplinary approach to preventing and managing risks such as zoonotic diseases, antimicrobial resistance (AMR), food safety threats and emerging pandemics.

Additionally, several **EU agencies and bodies** can be tasked with carrying out joint risk assessments of the potential severity of a threat to public health, including possible health measures (see Figure 2) ([38]). Each EU agency and body has a specific mandate and role in the prevention, preparedness and response to health crises (see Annex 4).

Figure 2: EU agencies and bodies tasked with carrying out joint risk assessments on threats to public health

To strengthen evidence-informed crisis prevention, preparedness and response, the Commission's Scientific Advice Mechanism (**SAM**) plays a pivotal role in delivering independent, evidence-based scientific advice and opinions with policy recommendations upon request from the College of Commissioners ([39]). The mechanism collaborates with the European Group on Ethics in Science and New Technologies (**EGE**), which is an independent, multi-disciplinary body advising on all policies where ethical, societal and fundamental rights issues intersect with the development of science and new technologies.

Finally, although the Union plan does not focus on the international level in terms of health crises emerging in and affecting regions outside of the EU, the Union plan is aligned with EU global health priorities, enshrined in the EU Global Health Strategy ([40]). Furthermore, health is a key area of partnership under the EU Global Gateway strategy and the EU collaborates extensively with its international partners by pooling resources and expertise for effectiveness and greater impact through the **Team**

([38]) Article 20 of Regulation (EU) 2022/2371.
([39]) Scientific Advice Mechanism to the European Commission, accessed 3 November 2025, https://scientificadvice.eu/.
([40]) European Commission, 'Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the EU Global Health Strategy', COM(2025) 392 final, 10 July 2025, https://health.ec.europa.eu/latest-updates/report-implementation-eu-global-health-strategy-2025-07-10_en.

Europe approach ([41]) ([42]). For example, at global level the EU supports global health initiatives such as the Pandemic Fund, the Vaccine Alliance Gavi and the Global Fund. At regional level, the EU engages with African regional partners in a Team Europe approach, while EU Delegations manage bilateral health programmes at country level. Annex 5 contains more information on global health security governance.

([41]) European Commission, 'Team Europe Initiatives', European Commission website, accessed 31 October 2025, https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives_en.

([42]) European Commission, 'Global Gateway', European Commission website, accessed 19 November 2025, https://commission.europa.eu/topics/international-partnerships/global-gateway_en.

3. Health crisis management cycle

The Union plan is structured around the different phases of the **health crisis management cycle**, a comprehensive framework that guides preparation for, management of and recovery from health crises in the EU (see Figure 3). The cycle consists of four interconnected phases: Prevention & Preparedness; Detection & Assessment; Response; and Recovery. Each phase builds on the previous one, creating a continuous process that strengthens the EU's ability to protect public health and respond effectively to emerging threats.

Establishing capacities and resources, preparedness planning, training, testing the plans, implementing lessons learned and building resilience take place every day for continuous improvement (inner circle). An effective and coordinated response to a serious cross-border threat to health relies on early threat detection and assessment of risks, taking the necessary steps to manage the situation and to learn from the response through in-action and after-action reviews (middle circle). The recognition of a public health emergency at Union level releases additional capacities and resources (outer circle).

The **Prevention & Preparedness** phase focuses on reducing the risk of health crises before they occur. This involves building response capacities and resources to strengthen the resilience of the health systems by ensuring a skilled health workforce, investing in health infrastructure, ensuring continuous access and availability of medicines and other MCMs, and in developing national prevention, preparedness, and response plans. The Commission and EU agencies and bodies work closely with Member States to assess their readiness, identify gaps, and support improvements in their capacity to manage cross-border health threats. Moreover, the EU joint arrangements provide additional support for the prevention of health threats such as EUHTF support for planning and EU training for the health workforce.

The **Detection & Assessment** phase involves identifying potential health threats early, assessing their risks and determining the appropriate level of response. This phase relies on public health intelligence on health threats performed by the Member States, the Commission and the EU agencies and bodies according to their mandates. Member States and the Commission are responsible for alerting events through early warning systems to trigger a response. Risk assessments and intelligence gathering conducted at national or EU level help us understand the type, likelihood and severity of the threat. This allows the EU and Member States to take informed, necessary and proportionate action.

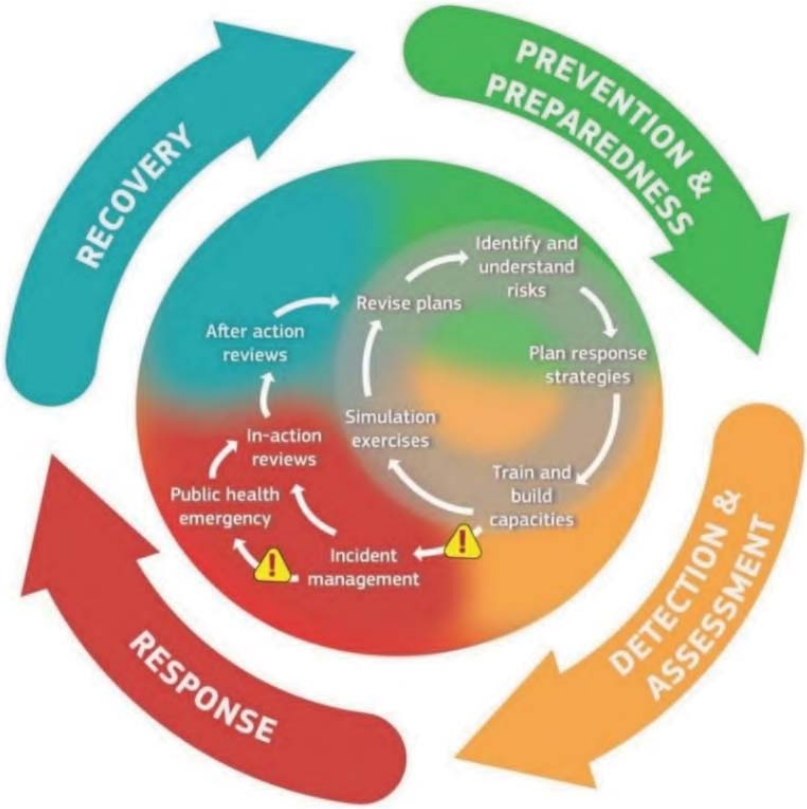


Figure 3. Health crisis management cycle. Adapted from ECDC, 2025 ([43]).

The **Response** phase is vital to prevent an escalation of an event and to mitigate the impacts of a health crisis by coordinating actions across the EU, mobilising capacities and resources, and supporting affected countries. The Member States, relevant EU agencies and bodies and the Commission coordinate their actions, among others, in the Health Security Committee, in the HERA Board and under the Union Civil Protection Mechanism, if activated. In major or complex crises, the Council is responsible for the overall cross-sectoral coordination of responses with the activation of the Integrated Political Crisis Response arrangements. These joint arrangements for governance enable information exchange, consultation, coordination and adoption of advice, guidance and recommendations based on which the stakeholders implement response measures in accordance with their respective mandates. EU joint arrangements for capacities and resources ensure situational awareness, risk and crisis communication, emergency research and innovation, availability and supply of related MCMs and emergency funding. Moreover, these joint arrangements facilitate continuity of care across borders, including contact tracing and medical evacuation. If a situation becomes serious enough, the Commission can formally recognise a public health emergency at Union level. This allows the Council to decide on the activation of measures for ensuring the supply of crisis-relevant MCMs and establishing the Health Crisis Board.

([43]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/Recommendations-for-preparedness-planning-for-public-health-threats.pdf.

The **Recovery** phase focuses on restoring people's health and well-being, rebuilding the health systems' resilience and supporting broader social and economic recovery. As the immediate emergency subsides, efforts turn to helping affected communities recover and restoring essential services. This phase also involves strengthening systems to better withstand future crises, by reviewing the response, identifying lessons learned during and after the health crisis, and using these insights to drive concrete improvements that enhance the health and stability of all. Simulation exercises help to identify areas of improvement in the joint arrangements for governance, capacities and resources outside real-life events.

By following the health crisis management cycle, the EU and its Member States can ensure they are better prepared to prevent, prepare for, respond to and recover from health crises, ultimately protecting the health and well-being of people living in the EU/EEA.

4. PHASE 1: Preventing and preparing for health crises

Ensuring robust prevention and preparedness for potential cross-border health crises is essential for the EU's ability to protect its population and safeguard public health security. In an interconnected Europe, health crises do not respect borders, meaning that an event in one Member State can rapidly escalate into a continent-wide emergency if it is not addressed swiftly and collectively. Building population preparedness for health crises requires involvement of a broad range of stakeholders in a 'whole-of-society' approach.

Prevention, including the resilience of healthcare systems and strong occupational safety and health measures, as well as good working conditions to protect workers on the frontlines of health systems as well as critical infrastructures and services, is the first and most effective line of defence. This is complemented by communicating clear and science-based preventive messages to the public and other actions to build health literacy especially among vulnerable groups. Training of healthcare and public health staff and the presence of coordinated research capabilities enable the EU to identify emerging health threats swiftly and prevent them from spiralling into full-blown crises. Preparedness complements prevention by ensuring that, when crises do occur, the EU can respond rapidly and efficiently. This involves robust coordination between national health authorities, the development of national and EU plans, the development of joint response capacities including strategic stockpiling of MCMs, and clear lines of communication and decision-making between EU institutions, its agencies and bodies and EU Member States as well as social partners and international stakeholders.

Health crises can have a significant impact on the mental health and well-being. This is especially the case for vulnerable populations (elderly, children and young people) and socioeconomic disadvantaged population groups, who are disproportionately affected, deepening health inequalities. Ensuring that prevention, preparedness and response measures are designed and implemented in a way that is inclusive and accessible to all people is essential for strengthening trust, equity and resilience of the Union's public health systems.

Ultimately, preventing cross-border health crises reflects core EU values of solidarity and cooperation. By embracing an all-hazards, whole-of-society, whole-of-government and One Health approach, the EU can more effectively anticipate, mitigate, and respond to complex crises that transcend borders and sectors.

4.1. Prevention, preparedness and response planning

Prevention, preparedness and response plans are the starting point for an effective and coordinated action. The development of these plans provides an opportunity to engage individuals from across relevant sectors and neighbouring regions, promoting learning and building connections that will support the implementation of the plan.

Ensuring political commitment and sufficient financial and human resources for the planning process is essential. The Health Security Committee (**HSC**) plays a crucial role in the coordination of prevention, preparedness and response planning, and in the discussions on the overall state of preparedness in the EU/EEA ([44]).

In the EU/EEA, national prevention, preparedness and response planning for health crises is enhanced through interlocking reporting and assessment cycles taking place every three years and starting in 2023 and 2024 respectively (see Figure 4). Based on the information submitted by the Member States while reporting on national prevention, preparedness and response planning, the Commission prepares a report to initiate discussions in the HSC. In parallel, the ECDC assesses national planning through Public Health Emergency Preparedness Assessments (PHEPA), while also providing recommendations for improvement. Afterwards, the Commission summarises the findings from the reporting and assessment cycles in a report on the state of play and progress on prevention, preparedness and response planning at Union level. This is then submitted to the European Parliament and the Council, to ensure transparency and accountability in the EU's health security efforts ([45]).

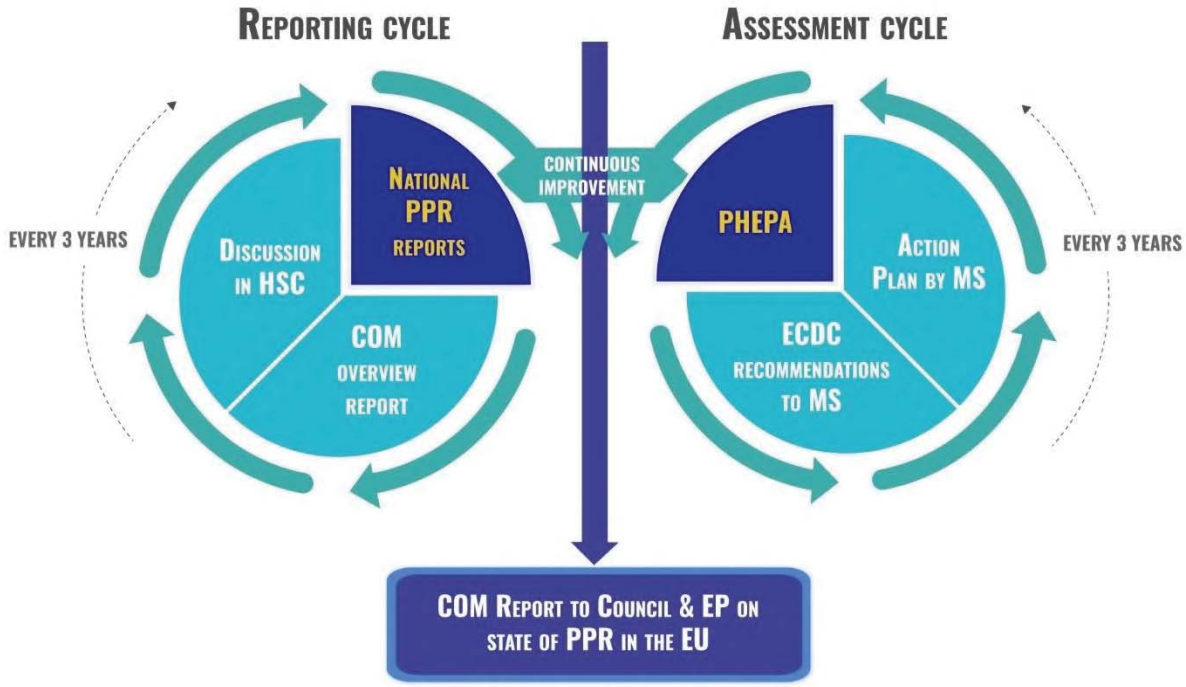


Figure 4. The interlocking reporting and assessment cycles of Member States' prevention, preparedness and response planning taking place every three years under Regulation (EU) 2022/2371. PPR=prevention, preparedness and response. COM=Commission. ECDC=European Centre for Disease Prevention and Control. HSC=Health Security Committee. MS=Member State. PHEPA=Public Health Emergency Preparedness Assessment.

([44]) Article 10 of Regulation (EU) 2022/2371.
([45]) Articles 6-9 of Regulation (EU) 2022/2371.

4.1.1. Development of prevention, preparedness and response plans

Member States develop their national prevention, preparedness and response plans for health crises, which are tailored to their respective health systems, preparedness and response structures, protocols, capacities, resources and circumstances. National prevention, preparedness and response plans can include elements relating to governance, capacities and resources, as well as cross-border interregional preparedness elements laid down in this plan. When preparing their national plans, Member States are to liaise with each other within the HSC and coordinate with the Commission in order to seek coherence with the Union plan to the largest extent possible. Moreover, they must inform the Commission and the HSC of any substantial revisions of their plans ([46]). Through the Early Warning and Response System (EWRS), the Member States can share information on their national prevention, preparedness and response plans securely.

The template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health provides benchmarks to support Member States in preparing their national prevention, preparedness and response plans for health crises ([47]). The WHO has developed guidance and tools for the development and implementation of national plans ([48]) ([49]). The **EUHTF** can support countries in the preparation of their national plans following a country's request.

At EU level, the general plan for crisis management in the field of food and feed safety established by the Commission specifies the procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy. The scope of the plan covers emergency situations that involve risks to human health arising from food and feed, which are not likely to be prevented, eliminated or reduced to an acceptable level by legal provisions already in place or cannot adequately be managed solely by way of the application of usual protective measures (suspension of

([46]) Article 6 of Regulation (EU) 2022/2371.

([47]) Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council (OJ L 234, 22.9.2023, p. 105, ELI: http://data.europa.eu/eli/reg_impl/2023/1808/oj).

([48]) WHO, *WHO benchmarks for strengthening health emergency capacities*, Geneva, 2023, Licence: CC BY-NC-SA 3.0 IGO, https://iris.who.int/server/api/core/bitstreams/8883ae92-ecbe-4cc6-8ad4-500297ef1df9/content.

([49]) WHO, *WHO guidance on preparing for national response to health emergencies and disasters*, Geneva, 2021, Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/9789240037182.

placing on the market, special conditions or any other appropriate interim measures) ([50]) ([51]).

On medicines, the EMA has established plans for dealing with incident and crisis-level issues related to the quality, efficacy, or safety of medicines (European medicines regulatory network incident management plan for medicines for human use) ([52]) and for addressing the medicine-related aspects of the response to health threats (EMA Health Threats Plan) ([53]).

4.1.2. Reporting on prevention, preparedness and response planning

By December 2023, and every three years after that, Member States report to the Commission and relevant EU agencies and bodies on national prevention, preparedness and response planning. They provide an overview of the national arrangements for governance, capacities and resources in place to ensure their countries' readiness and response to cross-border health crises ([54]). This self-assessment is structured based on a template built around 16 capacities and aligned with the reporting requirements for Members to WHO under the International Health Regulations (IHR) ([55]) ([56]).

Based on the information on national planning submitted by the Member States, the Commission prepares an **overview report** in cooperation with the ECDC and other relevant EU agencies and bodies, which is discussed within the HSC. The overview report allows for the monitoring of progress and the identification of gaps in

([50]) Article 55 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/2024-07-01).

([51]) Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55, http://data.europa.eu/eli/dec_impl/2019/300/oj).

([52]) European Medicines Agency (EMA), *The European Medicines Regulatory Network Incident Management Plan for Medicines for Human Use*, 2009 (revised in 2017 and 2025), https://www.ema.europa.eu/en/documents/other/eu-regulatory-system-incident-management-plan-medicines-human-use_en.pdf.

([53]) EMA, 'EMA's work on public health emergencies', EMA website, accessed 31 October 2025, https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/emas-work-public-health-emergencies#:~:text=The%20European%20Medicines%20Agency%20%28EMA%29%20has%20developed%20a,threat.%20This%20enables%20a%20rapid%20and%20efficient%20response.

([54]) Article 7 of Regulation (EU) 2022/2371.

([55]) Commission Implementing Regulation (EU) 2023/1808.

([56]) 11 of the 16 capacities are also IHR core capacities reported annually in February to the WHO as part of the IHR States Parties Self-Assessment Annual Report (SPAR). For more information, see International Health Regulations (2005) GUIDANCE DOCUMENT FOR STATE PARTY SELF-ASSESSMENT ANNUAL REPORTING TOOL. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/WHO-WHE-CPI-2018.17.

preparedness at national and EU levels ([57]). Recommendations stemming from the findings of the report are published online by the Commission and the ECDC ([58]).

In addition, the Commission prepares a report every three years on the **state of play and progress on prevention, preparedness and response planning at Union level**, which is submitted to the European Parliament and Council ([59]). The first report outlining the EU's comprehensive efforts to improve health preparedness, disease surveillance, and antimicrobial resistance management through integrated One Health strategies, legislation and funding initiatives across human, animal and environmental health sectors was published in December 2023 ([60]).

4.1.3. Assessment of national prevention, preparedness and response planning

Every three years, the ECDC assesses the state of implementation each EU Member State's or EEA country's national prevention, preparedness and response plans as part of the **Public Health Emergency Preparedness Assessments (PHEPA)** ([61]) ([62]). Based on the findings and taking into consideration the context and national circumstances, the ECDC provides **country-specific recommendations** on how to improve prevention, preparedness and response planning as well as implementation. Member States can opt to have their country reports published on the ECDC website ([63]).

Within nine months of receiving the recommendations, each country develops an **Action plan** addressing the ECDC's recommendations. Action plans provide a detailed breakdown of steps to be taken within a specific timeline to achieve the strategic priorities. Furthermore, the National Action Plans for Health Security involve a country owned, multi-year planning process developed by the WHO that can be used by the Member States as a guide in preparing their action plans after the PHEPAs ([64]).

([57]) This report is not publicly available.
([58]) European Commission, 'Recommendations for health security preparedness', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/publications/recommendations-health-security-preparedness_en.
([59]) Article 9 of Regulation (EU) 2022/2371.
([60]) European Commission, 'State of Health Preparedness Report', 15 December 2023, https://health.ec.europa.eu/publications/state-health-preparedness-report-2023_en.
([61]) Article 8 of Regulation (EU) 2022/2371.
([62]) Delegated Regulation (EU) 2024/1232 of 5 March 2024 supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan (OJ L 2024/1232, 8.5.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1232/oj).
([63]) ECDC, 'Public Health Emergency Preparedness Assessments', ECDC website, accessed 31 October 2025, https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/public-health-emergency-preparedness-assessments.
([64]) WHO, 'National Action Plan for Health Security (NAPHS)', WHO website, accessed 31 October 2025, https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/national-action-plan-for-health-security.

The One Health national action plans on antimicrobial resistance also include key components on prevention and surveillance actions ([65]).

In addition to the PHEPAs, Member States may also request to be evaluated by a WHO team of experts. The Joint External Evaluation is a voluntary, collaborative, multisectoral process to assess country capacities to prevent, detect and rapidly respond to public health threats, whether they occur naturally or due to deliberate or accidental events ([66]). Based on a Member State's preference, a PHEPA can be conducted jointly with a Joint External Action and/or a **One Health fact-finding mission** using a modified methodology that enables both assessments to fulfil their objectives. In addition, WHO's Universal Health and Preparedness Review is a voluntary, transparent, Member State-led peer review mechanism, that aims to establish regular intergovernmental dialogue between Member States on their respective national capacities for health emergency preparedness ([67]).

4.2. Ensuring healthcare system preparedness and resilience

Ensuring healthcare system preparedness and resilience is a cornerstone of health security. A strong and adaptable healthcare system with well-equipped and trained workers, with good working conditions, enables the early detection, rapid response and sustained delivery of essential services. By investing in system-wide readiness and infrastructure resilience as well as health workforce capacity, working conditions and skills, governments and institutions can mitigate risks, protect persons in vulnerable situations and maintain trust in health services.

Cross-cutting EU legislation that addresses the cyber and physical resilience of critical sectors applies to the healthcare sector. The NIS2 Directive ([68]) sets out requirements on the cybersecurity of essential and important entities in sectors including health, while the Critical Entities Resilience Directive ([69]) lays down rules for critical entities on their physical resilience. Furthermore, the European action plan on the cybersecurity

([65]) WHO, 'Country-specific template for a national One Health action plan', WHO website, 26 September 2023, accessed 31 October 2025, https://www.who.int/publications/m/item/country-specific-template-for-a-national-one-health-action-plan.

([66]) WHO, 'Joint External Evaluation (JEE)', WHO website, accessed 31 October 2025, https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations.

([67]) WHO, 'Universal Health and Preparedness Review', WHO website, accessed 3 November 2025, https://www.who.int/emergencies/operations/universal-health---preparedness-review.

([68]) Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 ('NIS 2 Directive') (OJ L 333, 27.12.2022, p. 80, ELI: https://eur-lex.europa.eu/eli/dir/2022/2555/oj/eng).

([69]) Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: https://eur-lex.europa.eu/eli/dir/2022/2557/oj/eng).

of hospitals and healthcare providers ([70]) is a non-legislative initiative that sets out actions to improve prevention, detection, response, recovery and deterrence against cybersecurity threats. The action plan indicates activities for the Commission, the European Union Agency for Cybersecurity and Member States. Furthermore, the Cyber Solidarity Act ([71]) as one of the initiatives provides for the coordinated preparedness testing of entities operating in sectors of high criticality. The health sector has been chosen as one of the first sectors where this exercise will be conducted.

Moreover, Council Recommendation of 6 June 2025 on an EU blueprint for cyber crisis management ([72]) recalls that, in a large-scale cybersecurity incident with cross-sectoral impact requiring an EU-level response, the Commission should facilitate the information flow between points of contact of relevant EU-level crisis mechanisms.

4.2.1. Health system capacities

An essential element of improving the resilience of health systems is targeted investment in health infrastructure and equipment, for example in hospitals, primary healthcare centres and laboratories. IT technology and the secondary use of health data contribute to the efficiency and resilience of health systems. The **Recovery and Resilience Facility (RRF),** within its lifetime of 2021–2026, is offering significant financing to Member States for investments that strengthen the resilience of their health systems, in response to the COVID-19 pandemic and for enhancing their preparedness for future health crises ([73]) (see Annex 6). **Cohesion policy funding** and the **InvestEU** programme offer additional financing possibilities for Member States to invest in health infrastructure, to strengthen the resilience of their health systems and promote interregional cross-border healthcare both along internal and external EU borders (see Annex 6). Member States participating in the **European Partnership on Pandemic Preparedness** seek to establish a European research and innovation ecosystem to avoid uncoordinated research efforts during future health crises.

Each year, country-specific analysis in the **European Semester** points to the need for reforms and investments, where macroeconomically relevant, in the health systems of several Member States. These Member States then receive **country-specific recommendations (CSRs)** to strengthen their health systems. In 2020, at the onset

([70]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European action plan on the cybersecurity of hospitals and healthcare providers, COM/2025/10 final, 15.1.2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0010.

([71]) Regulation (EU) 2025/38 of the European Parliament and of the Council of 19 December 2024 laying down measures to strengthen solidarity and capacities in the Union to detect, prepare for and respond to cyber threats and incidents and amending Regulation (EU) 2021/694 (Cyber Solidarity Act) (OJ L, 2025/38, 15.1.2025, ELI: http://data.europa.eu/eli/reg/2025/38/2025-01-15).

([72]) Council Recommendation of 6 June 2025 on an EU blueprint for cyber crisis management (OJ C, C/2025/3445, 20.6.2025, ELI: http://data.europa.eu/eli/C/2025/3445/oj).

([73]) For example, the Slovenian Recovery and Resilience Plan includes investments to tackle emerging health threats such as new communicable diseases and to increase the efficiency of the management and functioning of the health system in crisis situations. Similarly, the Latvian Recovery and Resilience Plan includes investments in the infrastructure of health institutions to adapt to crisis situations and to improve the preparedness of the health system to deliver services during epidemiological crises.

of the COVID-19 pandemic, all 27 Members States received CSRs related to health and some Member States have received additional health CSRs since 2020 ([74]). The national **recovery and resilience plans under the RRF** help address these CSRs effectively. The Commission monitors the progress that Member States make in addressing the CSRs on an annual basis.

The recent **2025 European Semester Spring Package communication** advocated that several Member States need to build resilient health systems, including by shifting towards a preventive and primary healthcare model. Investments to **strengthen primary healthcare** are essential, given that a strong primary healthcare forms the foundation of emergency responses and is central to addressing public health crises ([75]). The **EU4Health** Programme (see Annex 6), among others, is supporting the transfer of good practices in primary healthcare among Member States and building an improved coordination of e.g. laboratory capacities ([76]).

Complementary to investments, regular testing of the resilience of health systems under various shock scenarios is required to identify weaknesses and areas for remedial action. With funding from EU4Health, a **handbook for resilience testing of health systems** has been developed and made available to health authorities ([77]).

4.2.2. Health workforce

Healthcare and public health workers are critical as they are in strong demand at every level of the health system. Health professionals – from doctors, nurses, to pharmacists and other health professions and workers – are the backbone of crisis preparedness, ensuring timely care, safe access to care and medicines, and the resilience of health systems when it matters most. However, in 2022, EU countries were facing an estimated shortage of 1.2 million doctors, nurses and midwives ([78]). The military sector faces the same shortage of medical professionals as the civilian one. Only half of EU Member States and EEA countries have a strategy for workforce planning in the field of prevention and control of infectious diseases, and many countries experience difficulties in recruiting and retention of staff ([79]). Addressing health crises in One Health approach requires human resources also outside the health sector.

([74]) European Commission, 'The European Semester', European Commission website, accessed 4 November 2025. https://commission.europa.eu/business-economy-euro/european-semester_en.

([75]) European Commission, 'Organisation of resilient health and social care following the COVID-19 pandemic', European Commission website, 7 December 2020, accessed 31 October 2025, https://health.ec.europa.eu/publications/organisation-resilient-health-and-social-care-following-covid-19-pandemic_en.

([76]) See for example CIRCE-JA, 'JA Transfer of best practices in primary care', CIRCE-JA website, accessed 21 November 2025 https://circeja.nfz.gov.pl/.

([77]) Zimmerman J, McKee C., Karanikolos M., Cylus J. and members of the OCD Health Division, *Strengthening Health Systems: A Practical Handbook for Resilience Testing,* WHO Regional Office for Europe and OECD Publishing, Paris, 2024, https://iris.who.int/server/api/core/bitstreams/7d611fde-18cc-46dd-9740-1afb50489802/content.

([78]) OECD and the European Commission, *Health at a Glance: Europe 2024: State of Health in the EU Cycle*, OECD Publishing, Paris, 2024, https://doi.org/10.1787/b3704e14-en.

([79]) ECDC, *ECDC assessment of public health workforce capacity in prevention and control of infectious diseases in the EU/EEA*, Stockholm, 2025, https://www.ecdc.europa.eu/en/publications-data/ecdc-assessment-public-health-workforce-capacity-prevention-and-control.

Attractiveness and staff retention as well as good working conditions are crucial for improving the resilience of the health workforce. For that reason, the Commission supports Member States in addressing systematic challenges. For example, the Expert Group on Health Systems Performance Assessment, collects practices on minimum staffing levels. It provides an opportunity to exchange knowledge between Member States. The Commission also supports Member States through various actions and projects (see Annex 6) which aim at addressing structural challenges with shortages of health professionals and the development of relevant skills. Member States also benefit from financial support provided by the RRF within its 2021–2026 lifetime and cohesion policy funding to address their country-specific needs.

The development of **staffing plans** for health emergencies is crucial to ensure Member States are prepared to manage any serious health threat ([80]). These should include defining essential public health functions, recruitment, good working conditions, retention, repositioning, and capacity building. Information on the availability, skills, and location of staff is necessary for the management of human resources ([81]). The EUHTF can provide support to Member States in strengthening the preparedness of their health workforce.

Training and exercises strengthen the knowledge, skills and collaboration of staff in relation to health crisis management. The Commission can organise training for healthcare staff, social service staff and public health staff together with Member States and the ECDC and in particular the EUHTF ([82]). To this end, the Commission has already organised in-person training courses, national workshops and exchange visits under the **EU Health Preparedness Training Programme** on the development and implementation of the national prevention, preparedness and response plans, together with activities to strengthen crisis preparedness and surveillance capacities ([83]).

Joint civil-military trainings and exercises on health crises can significantly contribute to enhance civil-military cooperation in health security preparedness. They are important in both cases of military support provided to the civil health sector in case of e.g. natural disasters and for support provided by the civilian health sector to the military in case of an armed conflict.

Furthermore, the **ECDC** provides a wide range of training activities for public health professionals in the areas of epidemiology, communicable diseases and public health ([84]). For example, mid-career professionals, who have roles in preparing for and

([80]) As per Article 5(6) of Regulation (EU) 2022/2371 and at the Member States' request, the Commission can provide technical assistance to countries for the development of their staffing plans to address specific healthcare needs and facilitate the exchange of staff between Member States in the event of a serious cross-border threat to health.

([81]) WHO, *National workforce capacity for essential public health functions: operational handbook for country-led contextualization and implementation*, Geneva, 2024, Licence: CC BY-NC-S, https://www.who.int/publications/i/item/9789240091412.

([82]) Article 11 of Regulation (EU) 2022/2371.

([83]) Service contract 'EU preparedness: analysis, planning, reporting and training programmes for health specialists' (HaDEA/2022/OP/0017).

([84]) ECDC, 'Training programmes', ECDC website, accessed 31 October 2025, https://www.ecdc.europa.eu/en/training.

responding to public health emergencies, are offered a four-month **Preparedness and Response Executive Training Programme** in coordination with neighbouring countries. Moreover, the **ECDC Learning Portal** offers free online courses on various disease-specific and public health topics ([85]). The **ECDC Fellowship Programme** hosts a learning-by-doing programme – the European Programme for Intervention Epidemiology Training – and the European Public Health Microbiology Training Programme path – to strengthen the prevention, preparedness, surveillance and control of infectious diseases and other cross-border health threats in the Member States and at EU level ([86]).

The Commission also organises **training courses related to the management of MCMs** from development to manufacturing, procurement, stockpiling, and distribution as part of of crisis management ([87]). Under the Union Civil Protection Mechanism, the Commission also supports training ([88]) and simulation exercises ([89]), that often involve **emergency health professionals** due to the health impacts of disasters and crises.

Example of cross-border interregional collaboration: Emergency medicine training on the Polish-Ukrainian border

The EMERGENCY project under the Interreg Poland-Ukraine programme organises joint training courses, workshops and exchanges of experience in cardiology, vascular surgery and emergency medical care for medical staff from Poland and Ukraine. The project aims to develop and introduce modern clinical procedures, tailored to the realities of both countries.

4.2.3. Vaccination

Vaccination is one of the most effective public health measures for preventing communicable diseases and also often the most effective tool to respond to outbreaks limiting the spread of infectious agents avoiding overwhelming health systems' capacity. While the design and implementation of national vaccination programmes is a Member State competence, the EU has an important role to play in the provision of guidance. Furthermore, EU-level coordination helps Member States align their strategies and allows for faster information sharing. Through funding and initiatives, the EU supports national efforts to increase vaccination coverage, to promote sustainable vaccination programmes, and to secure vaccine supply. In times of crises, the role of the EU may become more prominent in ensuring the supply of certain vaccines for example through central purchases, or in providing guidance to the Member States.

([85]) ECDC, *Learning Portal*, accessed 31 October 2025, https://learning.ecdc.europa.eu/.
([86]) ECDC, 'Fellowship programme: EPIET/EUPHEM', ECDC website, accessed 31 October 2025, https://www.ecdc.europa.eu/en/epiet-euphem.
([87]) Article 2(2)(f) of the Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority.
([88]) UCP Knowledge Network, 'Union Civil Protection Mechanism training', accessed 31 October 2025, https://civil-protection-knowledge-network.europa.eu/UCPM-training-programme.
([89]) UCP Knowledge Network, 'Civil protection exercises', accessed 31 October 2025, https://civil-protection-knowledge-network.europa.eu/civil-protection-exercises.

The Commission, together with the **ECDC** and the **EMA,** in helping Member States develop national vaccination programmes and strategies (see Table 4). Strategic discussions on purchasing, monitoring and stockpiling vaccines are also coordinated at EU level together with other MCMs (see section 4.3).

Evidence-based vaccination policies are a key pillar of public health systems in the EU. The ECDC provides the Member States with technical knowledge to strengthen and support vaccination policies. EU Member States and EEA countries base their decisions on vaccines and their use on evidence-based recommendations from their **National Immunisation Technical Advisory Groups (NITAGs).** These are independent expert committees that help shape national immunisation strategies by evaluating scientific evidence and assessing data on vaccine safety and effectiveness. The ECDC manages the EU/EEA NITAG collaboration – a network for sharing information, best practices and scientific evidence as well as facilitating the joint collection of evidence. It provides a structured forum for regular dialogue among NITAGs and the ECDC, to assess vaccination needs and provide advice to national governments on vaccination strategies supporting their continuous updates.

Table 4. Roles played by the Commission, the ECDC and the EMA in relation to authorisation and vaccination programme monitoring and implementation	
Commission	- Grants marketing authorisations for new centrally authorised vaccines - Ensures exchanges on vaccination strategies in the HSC - Supports EU Member States in coordinating vaccination policies and programmes and in maintaining or increasing vaccination rates - Helps raise awareness of the importance of immunisation - Runs communication campaigns designed to support informed vaccination decision-making - Collects intelligence on vaccine development and manufacturing - Analyses supply chain vulnerabilities - Funds the development of novel vaccines - Supports the procurement of vaccines at EU level, including through advance purchase agreements and reservation contracts - Supports the reservation of vaccine manufacturing capacities to allow swift scale-up in times of crisis - Coordinates the work of the HERA Board and ensures the secretariat of the Health Crisis Board in case of activation of the emergency framework for MCMs during a public health emergency at Union level
ECDC	- Responsible for EU surveillance and data collection that allows for the monitoring of vaccination coverage, the impact of vaccination programmes and gaps - Assesses and monitors vaccine effectiveness (i.e. from the point vaccines are deployed to the population) - Provides scientific advice and guidance on vaccination strategies and target groups - Supports the coordination of vaccination strategies devised by the Member States - Supports the strengthening of national immunisation systems - Addresses vaccine hesitancy and carries out communication campaigns
EMA	- Assesses the safety, efficacy, quality and benefit-risk balance of centrally authorised vaccines - Develops guidelines and sets standards on the non-clinical and clinical development of vaccines - Facilitates the development and access to vaccines - Provides information to healthcare professionals and patients, e.g. in the European public assessment reports that also include the summary of product characteristics

The EMA and the ECDC jointly coordinate independent vaccine studies through the **Vaccine Monitoring Platform.** It generates real-word evidence on the safety, effectiveness and use of vaccines in the EU Member States and EEA countries. Its principal aim is to enable and coordinate large vaccine post-authorisation studies at the European level, following the identification and prioritisation of evidence gaps. The studies are independent and use the EMA and the ECDC scientific/operational infrastructures and procurement ([90]).

The ECDC developed the **Vaccine Scheduler** – an interactive tool that shows up-to-date information on national vaccination schedules across EU Member States and EEA

([90]) ECDC, 'Vaccine Monitoring Platform', ECDC website, accessed 31 October 2025, https://www.ecdc.europa.eu/en/about-ecdc/partners-and-networks/eu-institutions-and-agencies/vaccine-monitoring-platform.

countries. This enables comparisons to be made between countries and by disease ([91]). The ECDC also helps monitor the impact of vaccination programmes through the regular surveillance of vaccine-preventable diseases.

Vaccine hesitancy and vaccine fatigue can result in an upsurge in vaccine-preventable diseases such as measles. Vaccine hesitancy remains a significant challenge, driven by mis- and dis-information, which the EU is fighting via the promotion of science-based information through platforms like the **European Vaccination Information Portal** and campaigns like #UnitedInProtection, and ECDC tools available in all EU languages based on social and behavioural science ([92]). It is also promoting increased transparency over the authorisation of vaccines and post-marketing monitoring.

4.3. Medical countermeasures

4.3.1. Development and innovation

Advanced research, innovation and development of MCMs are promoted by the Horizon Europe and EU4Health programmes as well as innovative technologies for existing and emerging threats, including those related to climate change and chemical, biological, radiological, and nuclear threats (CBRN) ([93]). The scope of EU support extends from vaccines to therapeutics, diagnostics, medical devices, and protective equipment. Building on the work done during the preparedness phase, the objective during the response phase is to swiftly identify the most relevant and promising technologies and products in the pipeline and support their development from proof-of-concept to market in a timely manner.

The **Clinical Trial Coordination Mechanism** is an expert group under the HERA Board that advises the Commission on the prioritisation and funding of clinical studies for public health emergencies. If the emergency framework for MCMs is activated, the Health Crisis Board ensures coordination of action by the Council, the Commission, the relevant Union bodies, offices and agencies and Member States in the area of research to ensure the supply and access to crisis-relevant MCMs. One of the specific emergency measures that the Council can activate is the emergency research measure (see 6.4) ([94]).

([91]) ECDC, 'ECDC Vaccine Scheduler', ECDC website, 26 August 2024, accessed 31 October 2025, https://www.ecdc.europa.eu/en/publications-data/ecdc-vaccine-scheduler.

([92]) ECDC, *Tools and methods for promoting vaccination acceptance and uptake: a social and behavioural science approach*, Stockholm, April 2025, https://www.ecdc.europa.eu/en/publications-data/tools-and-methods-promoting-vaccination-acceptance-and-uptake.

([93]) Articles 2(2)b and 6(4)a of the Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority.

([94]) Article 9 of the Regulation (EU) 2022/2372.

To ensure access to MCMs for priority health threats, the Commission mobilises financing and other actions for the procurement, stockpiling, and research and development of novel MCMs.

4.3.2. Authorisation and certification

In the EU, the Commission is responsible for granting marketing authorisations of medicinal products under the centralised procedure, which are valid in all EU Member States and EEA countries. Under this procedure, a single marketing authorisation application for a human medicinal product is submitted to **EMA**, where it is assessed by the Committee for Medicinal Products for Human Use.

For medicinal products addressing a public health emergency, this assessment is supported by EMA's Emergency Task Force. It provides scientific advice to the developers on the development of medicinal products with the potential to treat, prevent, or diagnose and that can be used in a public health emergency. It involves representatives of Member States with clinical trial expertise in the preparation of the scientific advice, in particular in cases where an application for authorisation of a clinical trial is submitted or is intended to be submitted to harmonise requirements between clinical trials and medicine authorisations.

The pharmaceutical legislation provides for several regulatory mechanisms for facilitating the development and access to medicines. These include issuing regulatory guidance for developers, providing scientific support to facilitate larger multinational clinical trials and encouraging new approaches by organising scientific workshops and publishing reflection papers.

During public health emergencies, faster timelines and exceptional accelerated procedures for the rapid assessment and approval of medicines targeting the emergency can be implemented where warranted – while fully respecting the standards of quality, safety and efficacy of medicines.

For medical devices and *in vitro* diagnostic medical devices, while self-certification is allowed for low-risk devices, for medium- and high-risk devices their placing on the EU market requires an EU certificate to be issued by a notified body – an independent third party – after the relevant conformity assessment procedure against the relevant requirements of the Medical Device Regulation and the *In Vitro* Diagnostic Medical Device Regulation, and for auditing manufacturers. Member States competent authorities are responsible for designating notified bodies and for monitoring their activities, as well as for carrying out appropriate market surveillance.

The Medical Device Regulation and *in vitro* Diagnostic Medical Device Regulation allow authorities to make exceptions to the usual approval process for certain medical devices when this is necessary to protect public health or patient safety. The Commission, in exceptional cases relating to public health or patient safety or health, may extend the validity of an authorisation granted by a Member State to the territory

of the EU for a limited period and set the conditions under which the device may be placed on the market or put into service.

Other MCMs such as personal protective equipment or substances of human origin follow their specific regulation and procedures including accelerated processes that can be used in emergency situations.

4.3.3. Manufacturing

During crises, the demand for MCMs can increase substantially in a very short period. While the use of existing stockpiles and emergency procurement often serves as the first option to ensure the availability of MCMs, in prolonged crises the manufacturing capacity needs to be scaled up.

To strengthen MCM manufacturing preparedness, it is essential to monitor the access and availability of MCMs and identify vulnerabilities across the supply chain. The Commission is implementing targeted actions to improve supply chain resilience. These actions complement the Critical Medicines Act by extending mapping efforts to broader categories of MCMs and preparedness-related products, beyond critical medicines and active pharmaceutical ingredients.

As a risk mitigation measure in the event of future health emergencies, the Commission has put in place the **EU** Factory for EU-based Vaccines **framework contract** (EU FAB) to reserve vaccine manufacturing capacity for up to 325 million vaccines in three different vaccine technologies. The Commission is also funding innovative manufacturing to stimulate innovation and support improved manufacturing process of MCMs that are more efficient, greener, easier to scale up, and support EU production of MCMs. The **European Vaccines Hub for Pandemic Readiness** is a consortium of leading European organisations in charge of advancing vaccine development and manufacturing for public health threats (see Annex 6). Additionally, the Commission and Member States can gather information on strategic production sites for crisis-relevant MCMs to enable scaling up at the EU level during health crises.

4.3.4. Stockpiling

Member States have the primary responsibility of ensuring the availability of MCMs for the needs of their population during crises. Several Member States maintain strategic national stockpiles and/or have provisions in national legislation that mandate the different operators in the supply chain to maintain a contingency stock in order to have a buffer when short-term shortages occur. Stocks in Member States can therefore exist at national, subnational and service provider levels. MCMs serve both civilian and military settings.

At EU level, stockpiles of MCMs are an additional preparedness measure to support the Member States and act as insurance to gain time in the event of a crisis affecting

the health of the population. They aim to complement Member States' efforts and focus on critical gaps where national response capabilities are insufficient, inadequate, or unavailable. This requires a strategic approach as stockpiling may impact market availability, be costly and potentially wasteful ([95]).

The Commission has built stockpiles of MCMs as part of the rescEU strategic reserves within the Union Civil Protection Mechanism (UCPM). These stockpiles are meant for the EU but can be deployed outside the Union if there is an EU interest at stake. The rescEU stockpiles are procured, hosted and managed by several Member States in strategic locations. The stocks encompass MCMs with a significant risk of rapid depletion or increased demand during crises. Items in rescEU stockpiles include medicines (e.g. intensive care medicines, antibiotics, vaccines, and antidotes), medical devices, personal protective equipment and equipment to respond to CBRN threats ([96]). Under the UCPM framework, the Commission can in duly justified cases of urgency also directly purchase necessary materials and enable support services for emergency response, including MCMs ([97]). Strategically located across the EU, these stockpiles ensure immediate access to life-saving treatments also in case of security-related events.

4.3.5. Procurement of MCMs

The Commission has different procurement mechanisms at its disposal to secure MCMs for Member States and beyond, including central purchasing ([98]). The Commission can also purchase directly. The third procurement tool is the joint procurement at EU level, which can be used both in times of crisis but also during preparedness phase ([99]).

In joint procurement, as contracting parties, Member States and the Commission can engage in a voluntary joint procurement procedure with a view to purchase MCMs against serious cross-border threats to health ([100]). This mechanism aims to ensure equitable access to and increase the availability of MCMs in participating countries, as

([95]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions addressing medicine shortages in the EU, COM/2023/672 final, 24.10.2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0672.

([96]) Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41, ELI: http://data.europa.eu/eli/dec_impl/2019/570/oj).

([97]) Article 12(3b) of Decision No 1313/2013/EU.

([98]) As per: Financial Regulation (Regulation 2024/2509, article 168), Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health

([99]) Article 12 of Regulation (EU) 2022/2371.

([100]) European Commission, 'Public procurement of medical and protective equipment', European Commission website, accessed 31 October 2025, https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/ensuring-availability-supplies-and-equipment_en#public-procurement-of-medical-and-protective-equipment.

well as improve the security of supply, together with fair prices and better purchasing conditions. As example, the reservation contracts for pandemic influenza vaccines ([101]) and zoonotic influenza vaccines ([102]) have been used to prepare for a potential influenza pandemic.

Practical arrangements governing the procedure and the decision-making process for joint procurement are set out in the Joint Procurement Agreement involving EU Member States and EEA countries and EU candidate countries ([103]) ([104]). Representatives of the participating countries in the Joint Procurement Agreement Steering Committee decide which MCMs should be purchased. The Commission involves the participating countries in the procurement processes of individual MCMs through the respective Specific Procurement Procedure Steering Committees. Such procurement procedures result in the signature of contracts that set the terms and conditions applicable to all contracting authorities. Countries use their national budgets to purchase the products contracted. The Commission is also a contracting party and can benefit from the joint procurement contracts for its own needs or for further donations.

([101]) European Commission, 'Commission offers 17 countries the possibility to purchase over 27 million influenza vaccine doses', European Commission website, 29 April 2025, accessed 31 October 2025, https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1096.

([102]) European Commission "Commission secures access for Member States to 665,000 doses of zoonotic influenza vaccines", European Commission website, 11 June 2024, accessed 12 November 2025, https://ec.europa.eu/commission/presscorner/detail/en/ip_24_3168

([103]) European Commission, *Joint procurement agreement to procure medical countermeasures*, https://health.ec.europa.eu/document/download/1926f539-98d3-44ef-b16d-373be1202623_en.

([104]) European Commission, 'Signing ceremonies for Joint Procurement Agreement', European Commission website, accessed 20 November 2025, https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response-planning/signing-ceremonies-joint-procurement-agreement_en.

5. PHASE 2: Detecting and assessing health threats

5.1. Public health intelligence

Public health intelligence, which is the integration, interpretation, and communication of health data collected through surveillance and monitoring, forms the backbone of the EU's approach to health security, underpinning both preparedness and response. Member States play a key role in this as EU surveillance and public health intelligence rely on the data gathered and shared by countries. In addition to joint arrangements for the surveillance and monitoring of communicable diseases, public health intelligence also collects information on other threats (Table 5).

Table 5. Different surveillance approaches

Description	Focus	Type of integration
Integrated surveillance is a strategy that brings together different streams of data and surveillance activities within the human health system. This holistic approach streamlines processes like data collection, reporting, analysis and interpretation to more effectively monitor health threats, from individual patient symptoms to widespread outbreaks.	Cross-disease, cross-data or cross-level integration	Cross-system
The concept of **One Health surveillance** is cross-sectoral and therefore broader than integrated surveillance as it aims to link data and surveillance systems across humans, animals and the environment in order to capture and monitor the full ecosystem range of health risks (e.g. zoonotic influenza).	Cross-sectoral (human, animal, environmental)	Cross-domain
Collaborative surveillance, a concept used by the WHO, is a multi-sectoral approach to public health that strengthens information systems by coordinating collaboration between diverse stakeholders to improve decision-making for public health emergencies and routine health needs.	Cross-institutional and cross-border cooperation	Cross-actor

In the preparedness phase, public health intelligence provides an early warning of emerging threats and disease severity from different data sources, informs risk assessments and guides planning and capacity building. During a response, public health intelligence delivers real-time situational awareness, monitors the effectiveness of interventions, analyses of MCM needs and enables the rapid adaptation of strategies. It also supports cross-border coordination by ensuring a shared evidence base across countries. In essence, surveillance ensures preparedness is proactive and the response is targeted.

The integration and interoperability of digital technologies and surveillance data reporting platforms enable authorities to track health threats faster and more accurately. They can, therefore, also respond more efficiently. Surveillance systems ensure that policymakers, healthcare providers, and laboratories can coordinate responses and mobilise resources where they are most needed. Strong, integrated surveillance and monitoring systems supported by rapid digital data sharing platforms,

are essential not only for crisis response but also for building preparedness and resilience against future health emergencies. A number of tools and platforms contribute to surveillance at EU level (see Annex 7).

Surveillance systems have evolved into several distinct but complementary approaches as no single method can fully capture the complexity of today's interconnected health threats. As outbreaks require rapid, coordinated responses across different sectors and governance levels, health security relies on frameworks that address different aspects of detection and preparedness. Together, these different approaches build a comprehensive, resilient understanding of health risks.

Example of integrated surveillance in action

The ECDC is taking an integrated surveillance approach when it comes to monitoring communicable diseases in the EU. Through the implementation of its new mandate, it defines surveillance standards starting from intended public health objectives. For diseases that are prone to developing into pandemics, vector- and food-borne diseases as well as zoonoses and antimicrobial resistance, this entails integrated surveillance systems across sectors, with timely joint analyses and the sharing of actionable data.

For example, the ECDC, together with the WHO, has published operational considerations for the **surveillance of respiratory viruses** in the EU, integrating information on relevant diseases such as COVID-19, influenza and respiratory syncytial virus (RSV) ([105]). The ECDC is now developing updated guidance with action-oriented surveillance objectives that will support national systems for respiratory virus surveillance in the EU.

Example of One Health action

The ECDC has adopted a One Health Framework ([106]), set up a One Health working group, and joined the cross-agency task force on One Health to strengthen transdisciplinary cooperation among five EU agencies in order to better address challenges to human, animal, plant and environmental health and contribute to the implementation of the One Health approach in Europe ([107]).

The Commission has conducted **One Health fact-finding visits** to Member States to identify both good practices and critical gaps in multisectoral coordination, guidance and policy actions aimed at reducing, for example, zoonotic risks that pose a serious threat to public health. These visits facilitate the exchange of knowledge and practices across EU, national, and local levels, while identifying policy gaps to be overcome for strengthening multidisciplinary prevention, preparedness and response mechanisms in order to prevent and prepare for spillover events. The outcomes of the visits are documented in reports that are made publicly available subject to the agreement of the Member State concerned ([108]) ([109]). While the reports do not issue recommendations, they present factual observations on practices, gaps, and risks, including on joint surveillance efforts ([110]).

([105]) ECDC and WHO, *Operational considerations for respiratory virus surveillance in Europe*, Copenhagen: WHO Regional Office for Europe and Stockholm: European Centre for Disease Prevention and Control, 2022, https://www.ecdc.europa.eu/en/publications-data/operational-considerations-respiratory-virus-surveillance-europe.

([106]) ECDC, 'ECDC One Health Framework', ECDC website, 7 May 2024, accessed 3 November 2025, https://www.ecdc.europa.eu/en/publications-data/ecdc-one-health-framework.

([107]) ECDC, 'Cross-agency One Healthtask force framework for action', ECDC website, 7 May 2024, accessed 3 November 2025, https://www.ecdc.europa.eu/en/publications-data/cross-agency-one-health-task-force-framework-action.

([108]) European Commission, 'Finland 2024-7983', European Commission website, accessed 3 November 2025, https://ec.europa.eu/food/audits-analysis/audit-report/details/4813.

([109]) European Commission, 'Belgium 2024-7986', European Commission website, accessed 3 November 2025, https://ec.europa.eu/food/audits-analysis/audit-report/details/4884.

([110]) Article 116 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of

5.1.1. Epidemiological surveillance

The ECDC serves as the EU's central hub for global epidemic intelligence from open sources and EU-level epidemiological surveillance. It aims to monitor communicable diseases, detect outbreaks and inform relevant public health interventions and policies in the EU. Within this scope, the ECDC collects, validates, analyses and disseminates routine surveillance data on notifiable infectious diseases ([111]) from 30 EU Member States and EEA countries.

Table 6. Examples of routine EU/EEA integrated surveillance outputs

- Surveillance Atlas of Infectious Diseases ([112])
- Annual Epidemiological Reports ([113])
- Daily and weekly communicable disease threat reports ([114])
- Enhanced surveillance reports produced jointly with other EU agencies or the WHO ([115])
- Weekly bulletins focusing on specific diseases ([116])
- Online surveillance maps for certain diseases or indicators ([117])

The ECDC works closely with the Member States and coordinates **disease or health-issue-specific networks** for infectious disease surveillance in the EU/EEA ([118]). These networks involve nominated national disease experts and experts in public health functions with cross-cutting roles in different areas. The ECDC's **network of National Focal Points (NFPs) for Surveillance** ([119]) is a structured system of designated experts in each EU Member State and EEA country. They ensure continuous dialogue between the Commission, the ECDC and the relevant national competent authorities on matters of epidemiological surveillance. The NFPs are officially nominated by their countries and play a crucial role in providing expertise, ensuring smooth communication, sharing data sharing, and coordinating relevant

the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ('Official Controls Regulation') (OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj).

([111]) Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions (OJ L 170, 6.7.2018, p. 1, ELI: http://data.europa.eu/eli/dec_impl/2018/945/oj).

([112]) ECDC, 'Surveillance Atlas of Infectious Diseases', ECDC website, 23 April 2023, accessed 3 November 2025, https://www.ecdc.europa.eu/en/surveillance-atlas-infectious-diseases.

([113]) ECDC, 'Annual Epidemiological Reports (AERs)', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/annual-epidemiological-reports.

([114]) ECDC, 'Weekly threats reports (CDTR): Communicable disease threats reports', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/publications-and-data/monitoring/weekly-threats-reports.

([115]) See for example WHO, 'Epidemic Intelligence from Open Sources (EIOS)', WHO website, accessed 3 November 2025, https://www.who.int/initiatives/eios.

([116]) For example, weekly surveillance bulletins on West Nile virus infections in humans in Europe, see ECDC, 'Surveillance of West Nile virus infections in humans in Europe, weekly report', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/west-nile-fever/surveillance-and-disease-data/disease-data-ecdc.

([117]) For example, map on polio cases worldwide, updated on a monthly basis, see ECDC, 'Polio dashboard', ECDC website, 26 May 2025, accessed 3 November 2025, https://www.ecdc.europa.eu/en/publications-data/polio-dashboard.

([118]) ECDC, 'Disease and laboratory networks', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/about-ecdc/partners-and-networks/disease-and-laboratory-networks.

([119]) Article 13 of Regulation (EU) 2022/2371.

activities across the EU. NFPs in other areas exist as well. These also make a significant contribution to overall EU surveillance, including the NFPs for microbiology, NFPs for Threat Detection, EWRS and IHR.

As epidemiological surveillance in the EU therefore depends on data collection and transmission by Member States, it is crucial to ensure that harmonised case definitions are developed for accurate and comparable EU surveillance. This, together with agreed standards for data transmission for relevant diseases and events, will be agreed in the future as part of the implementation of Articles 13 and 14 of Regulation (EU) 2022/2371.

The ECDC works closely with the WHO Regional Office for Europe (WHO/Europe) to produce the Joint **European region surveillance reports** for specific communicable diseases, such as HIV/AIDS and tuberculosis ([120]).

The Network for Substances of Human Origin (**SoHo-Net**) ([121]) is a cooperative network established by the ECDC. It aims to ensure the microbial safety of human-derived substances like blood, tissues and cells, and including transfusion and transplantation. SoHo-Net facilitates strategic and operational collaboration, data collection, and surveillance among EU Member States and EEA countries to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. The existence of the network is critical for maintaining the high standards of quality and safety for substances of human origin, which are vital for various medical treatments.

Furthermore, through the EU4Health Programme funds several actions to improve surveillance systems at EUand national level (see Annex 6).

Finally, WHO also plays a key role in epidemiological surveillance in the European region. One key example is the Epidemic Intelligence from Open Sources tool (EIOS) ([122]), which is an initiative led by the WHO that uses open-source information to detect and assess public health threats in near real time. It uses cutting-edge technology to gather and analyse data from sources like websites and social media to provide public health officials with evidence for quick decision-making. The initiative is built on a global community of practice and collaboration with various organisations, including the Commission ([123]).

([120]) For example, ECDC and WHO, 'HIV/AIDS Surveillance in Europe 2024 – 2023 data', ECDC website, 28 November 2024, accessed 21 November 2025, https://www.ecdc.europa.eu/en/publications-data/hiv-aids-surveillance-europe-2024-2023-data; and ECDC and WHO, 'Tuberculosis surveillance and monitoring in Europe 2025 – 2023 data', ECDC website, 24 March 2025, accessed 21 November 2025, https://www.ecdc.europa.eu/en/publications-data/tuberculosis-surveillance-and-monitoring-europe-2025-2023-data and

([121]) Article 16 of Regulation (EU) 2022/2371.

([122]) WHO, 'Epidemic Intelligence from Open Sources', Who website, accessed 3 November 2025, https://www.who.int/initiatives/eios.

([123]) WHO, 'Epidemic Intelligence from Open Sources', both portal and processing chain have been developed by the European Commission.

5.1.2. Laboratory-based surveillance and diagnostics

Laboratories serve as the backbone of EU surveillance systems because of their crucial role in monitoring, detecting and confirming health threats. Their diagnostic capacities allow for the timely identification of pathogens, support outbreak investigations and provide the scientific evidence necessary for risk assessments and decision-making at both national and EU level. Beyond diagnostics, laboratories contribute to enabling early warning, strengthening situational awareness and supporting coordinated response measures. Investments in laboratory capacity, biosafety and biosecurity standards, and cross-border collaboration are therefore critical for sustaining resilient EU-wide surveillance.

5.1.2.1. Laboratory networks and capacities

The ECDC does not operate its own laboratories but relies instead on laboratory information provided at national level. Since 2010, ithas coordinated **12 EU-wide networks of public health microbiology laboratories** embedded in disease-specific networks([124]). Within these networks, the ECDC supports microbiology activities via EU-wide laboratory network coordination, capability building and external quality assessments, laboratory staff training, outbreak investigations, risk assessments, method harmonisation and the development of standard procedures, and the integration of molecular typing into surveillance programmes.

The ECDC also operates the EU laboratory capability (**EULabCap**) system for monitoring the capacities and capabilities of microbiology laboratories in EU Member States. National laboratory capacities are also among the elements that are being assessed as part of the prevention, preparedness and response reporting and PHEPAs. In the future, such capacities and capabilities will be assessed through the compliance monitoring of surveillance standards.

The Commission is developing detection tools – such as novel assays and reference materials – to contribute to the standardisation and harmonisation of data across laboratories ([125]) ([126]).

The European Civil Protection Pool currently includes two quality-assured rapid response mobile laboratories, ready for deployment under the Union Civil Protection Mechanism.

([124]) For more information about the ECDC microbiology networks and their activities, see Albiger, B., Revez, R., Leitmeyer, K. C., Struelens, M. J., 'Networking of Public Health Microbiology Laboratories Bolsters Europe's Defenses against Infectious Diseases', *Frontiers in Public Health*, Vol. 6, 2018, p. 46, https://doi.org/10.3389/fpubh.2018.00046.

([125]) Buttinger, G., Petrillo, M., Valastro, V., et al., 'Novel (d)PCR assays for influenza A(H5Nx) viruses clade 2.3.4.4b surveillance', *Eurosurveillance*, Vol. 30, Issue 33, 2025, https://doi.org/10.2807/1560-7917.ES.2025.30.33.2500183.

([126]) Marchini, A., Toth, K., Buttinger, G., et al., *Certification of the identity and the copy number concentration of synthetic single-stranded RNA including fragments of the SARS-CoV-2 genome and part of the human RNAse P gene: EURM®-014k*, Publications Office of the European Union, Luxembourg, 2024, https://op.europa.eu/en/publication-detail/-/publication/d5857267-b12a-11ef-acb1-01aa75ed71a1/language-en.

Recently, with the adoption of the new mandate of the European Union Drugs Agency (EUDA) in 2024, an EU-wide network of forensic and toxicological laboratories active in investigations into drugs and drug-related harm was set up, as required by Article 15 of Regulation No 2023/1322.

5.1.2.2. EU reference laboratories

EU reference laboratories (EURLs) for public health have been designated by the Commission, bringing together consortia of specialised laboratories, based in EU Member States and EEA countries, to provide scientific and technical expertise in specific fields (see Table 7). They play a crucial role in strengthening laboratory-based surveillance by guaranteeing the reliability and comparability of data generated across the EU; strengthening capacities and capabilities of laboratories throughout the EU; and by enabling the timely detection of cross-border health threats. The ECDC is responsible for running the network of EURLs for public health. These EURLs are supporting national reference laboratories and coordinate the networks managed by the ECDC that are relevant to the scope of their work.

Table 7. EU reference laboratories relevant for prevention, preparedness and response to cross-border health threats

EURLs for public health aim to support national reference laboratories to promote good practice and alignment by Member States on a voluntary basis regarding diagnostics, testing methods and use of certain tests for the uniform surveillance, notification and reporting of serious cross-border health threats.	Article 15 of Regulation (EU) 2022/2371
EURLs for in vitro diagnostic medical devices (IVDs) provide scientific and technical expertise for high-risk (class D) IVDs. Their tasks include verifying the performance and compliance of class D devices, performing batch testing on behalf of notified bodies, and assisting the Commission and other authorities. They also contribute to developing common specifications and harmonising testing methods across the EU.	Article 100 of Regulation (EU) 2017/746
EURLs for animal health, food and feed, and plant health support the Commission and Member States by harmonising diagnostic methods, ensuring laboratory quality, providing expert advice, and coordinating the network of National Reference Laboratories. They also offer technical support during outbreaks.	Regulation (EU) No 2017/625

5.1.3. Wastewater surveillance

Wastewater-based surveillance has emerged as a **potential complement to traditional public health surveillance** within the EU's health security framework. It can provide a community-wide overview of circulating pathogens as it captures information independent of clinical testing or healthcare seeking behaviour. Since pathogens such as SARS-CoV-2, poliovirus and influenza viruses are excreted in human waste, analysing sewage wastewater can provide insights into the presence and trends of infections across populations as well as the sequencing of pathogen

genomes. In addition, wastewater-based surveillance could serve as an additional cost-effective tool as a single wastewater sample can represent thousands of people and is scalable, making it useful for both urban centres and smaller communities. On the other hand, methodologies used to detect and analyse wastewater samples vary, and site-specific factors can influence the measured results. This makes direct comparison of absolute values between locations challenging.

The new **Urban Wastewater Treatment Directive**([127]) requires Member States to coordinate between public health and wastewater treatment authorities and to identify health parameters for monitoring, for example SARS-CoV-2, poliovirus, influenza and emerging pathogens. In a public health emergency, relevant parameters must be monitored. Additionally, Member States must establish antimicrobial resistance surveillance in urban wastewater for areas with populations of 100,000 or more. The Commission will set a minimum sampling frequencies and a harmonised methodology for monitoring antimicrobial resistance in urban wastewater by July 2026 and ensure results are communicated to the relevant authorities and reported annually to the European Environment Agency. The Commission will define the reporting format through implementing acts.

The Joint Research Centre has built and maintains the EU Wastewater Observatory for Public Health([128]).

Since the COVID-19 pandemic, the Commission has significantly invested in scaling up capacities for wastewater surveillance at national and global levels, including via the creation of the **Global Consortium for Wastewater and Environmental Surveillance for Public Health**. Annex 6 contains more examples of EU initiatives that promote wastewater-based surveillance.

The ECDC concept paper to guide the integration of wastewater-based surveillance into EU-level infectious disease surveillance provides insights on its potential uses for public health decision making ([129]). The document describes the status of EU/EEA support to wastewater-based surveillance implementation for infectious disease surveillance. It also highlights the role of wastewater-based surveillance in public health as well as the challenges and considerations for implementation to support Member States in developing national wastewater-based surveillance systems.

([127]) Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (recast) (OJ L 2024/3019, 12.12.2024, ELI: http://data.europa.eu/eli/dir/2024/3019/oj).

([128]) European Commission, 'EU Wastewater Observatory for Public Health', European Commission website, accessed 3 November 2025, https://wastewater-observatory.jrc.ec.europa.eu/.

([129]) ECDC, *ECDC concept for integration of wastewater data in surveillance of infectious diseases at EU/EEA level*, Stockholm, 2025, https://www.ecdc.europa.eu/en/publications-data/ecdc-concept-paper-guide-integration-wastewater-data-infectious-disease.

5.1.4. Vector surveillance and control

Vector surveillance and control are key in the prevention of vector-borne disease transmission, and their organisation can be complex due to the many stakeholders involved. EU-level collaboration and coordination on vectors and vector-borne diseases enable the pooling of expertise, developing joint guidance and strategies and advocating for research and innovation ([130]). The European network for medical and veterinary entomology (VectorNet) started in 2014 and coordinated jointly by the ECDC and the EFSA. It supports the collection of data on vectors related to both animal and human health ([131]).

The Commission is supporting Member States to strengthen national vector surveillance and control capacities (see Annex 6). This includes assessing the ability of vectors to transmit and spread emerging diseases across Europe and strengthen laboratory capabilities for monitoring insecticide resistance and One Health fact-finding missions.

5.1.5. Serious drug-related risks

Serious risks related to illegal drugs are captured via event-based surveillance, aggregated routine reporting and other complementary methods implemented by the EUDA. Where relevant, signals and alerts are shared with the Commission and Member States and, when cross-border criteria are met, an alert can be pushed by the Commission to the Early Wardning and Response System to enable coordinated assessment and response.

5.1.6. Anticipation and forecasting

Strategic foresight and anticipation are structural forward-looking approaches for identifying emerging risks early and preparing effectively for alternative futures. The Commission provides systematic risk analysis and develops tools and techniques, such as epidemiological modelling and other outbreak analytics, for public health risk

([130]) ECDC, *Organisation of vector surveillance and control in Europe*, Stockholm, 2021, https://www.ecdc.europa.eu/sites/default/files/documents/Organisation-vector-surveillance-control-Europe_0.pdf.

([131]) ECDC, 'European network for medical and veterinary entomology (VectorNet)', ECDC website, accessed 11 November 2025, https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/vector-net.

assessment and forecasting of emerging infectious disease threats ([132]) ([133]) ([134]). The Commission also works on threat assessment modelling and forecasts of MCMs ([135]).

The ECDC is tasked to provide analyses and advice on prevention and control of communicable diseases and related special health issues through epidemiological modelling, anticipation and forecasting, and to coordinate such effort across the EU and with international partners ([136]). The ECDC Foresight Programme aims to inform strategic decisions and policy in the area of infectious disease prevention and control ([137]).

5.2. Threat assessment and early warning

Once a signal of a potential serious cross-border threat to health is detected through public health intelligence, it will be assessed to determine whether specific actions should be taken (see Figure 5).

The threat will first be evaluated by Member States and/or the Commission against the following three criteria to determine whether it constitutes a serious cross-border threat to health:

a) it is unusual or unexpected for the given place and time, or it causes significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and
b) it affects or may affect more than one Member State; and
c) it requires or may require a coordinated response at EU level ([138]).

If a threat of biological, chemical, environmental or unknown origin meets all of the above criteria or is notifiable in accordance with the International Health Regulations, it must be notified, without delay, in the **Early Warning and Response System (EWRS)**. If a threat does not (yet) fulfil all the criteria but is deemed to be of significance, national competent bodies and/or the Commission can submit a

([132]) Lentini, A., Eklund, G., Corbane, C., Asikainen, T., Ronco, M. et al., *Analysis of Risks Europe is facing - An analysis of current and emerging risks*, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/0176850.
([133]) Corbane, C., Eklund, G., Gyenes, Z., et al., *Cross-border and emerging risks in Europe*, Publications Office of the European Union, Luxembourg, 2024, https://op.europa.eu/en/publication-detail/-/publication/e7ccf960-1ef7-11ef-a251-01aa75ed71a1/language-en.
([134]) Angelou, A., Pappa, A., Markov, P.V. et al., 'Early warning system of the seasonal West Nile virus infection risk in humans in Northern Greece, 2020–2024', Scientific Reports, Vol. 15, Issue 1, 2025, https://doi.org/10.1038/s41598-025-91996-9.
([135]) Article 6 of the Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority.
([136]) Articles 3 and 5 of Regulation (EC) No 851/2004.
([137]) ECDC, 'ECDC Foresight Programme', ECDC website, accessed 20 November 2025, https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/ecdc-foresight-programme.
([138]) Article 19(1) of Regulation (EU) 2022/2371.

notification in EWRS. Information on the alert notification must be updated as soon as new information becomes available ([139]).

When a Member State notifies a serious cross-border threat to health that can also constitute a Public Health Emergency of International Concern (PHEIC), the national authority can fulfil their notification obligation to WHO through a push-notification from EWRS ([140]).

Apart from an alert being notified directly in EWRS, a threat can also initially be notified though and picked up from another alert information system (AIS) or platform for public health intelligence of the Commission or EU agencies (see Annexes 7 and 8). This can occur when the event does not meet all the criteria of a serious cross-border threat to health or does not seem to cause health impacts in the first instance. However, as the threat evolves, it may become relevant to also submit a notification in EWRS.

([139]) Article 19(5) of Regulation (EU) 2022/2371.
([140]) Article 6 and Annex 2 of WHO IHR 2005 (amended in 2014, 2022 and 2024).

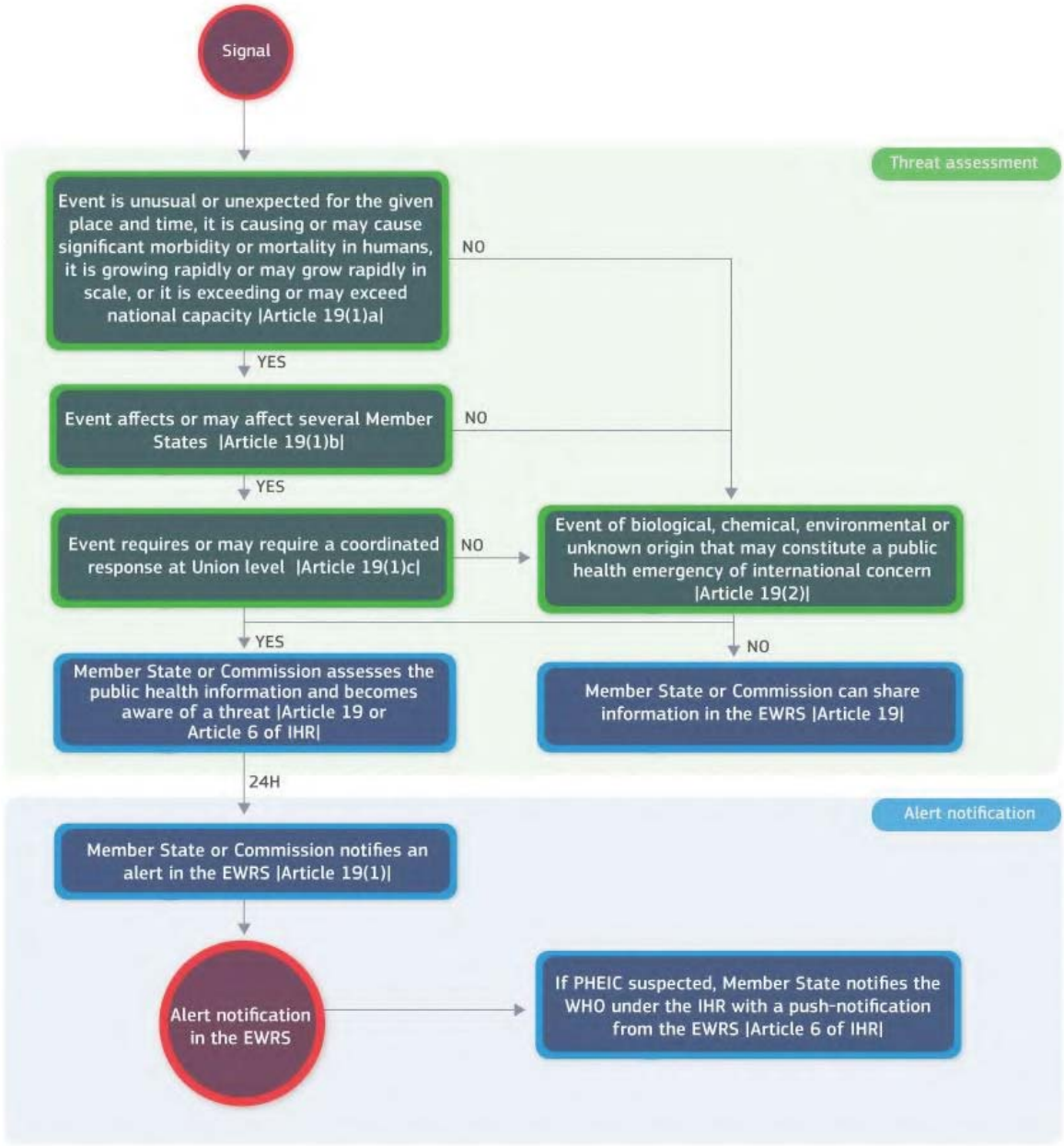


Figure 5. Process of threat assessment and early warning in the EU/EEA

5.3. Risk assessments

Risk assessment and vulnerability analyses are crucial for evidence-based decision-making for health crises. The objectives of a risk assessment depend on the phase of the health crisis management cycle in which it is conducted. During the prevention and preparedness phase, risk assessments help identify, analyse and evaluate the risks and can be used for decision-making on preventive measures and to prioritise resources. During the response phase, they support evidence-based decision-making, including on what measures to take. To ensure transparency of governance, the risk

assessment should be conducted independently of the decision-making process even though it includes options or recommendations for measures.

Risk assessments improve awareness and understanding of the risks among stakeholders, foster inclusive debate and decision-making about the relative priority of areas of work and the use of resources, and helps engage relevant groups in society. Whereas single-risk assessments determine a singular risk from a particular threat, multi-risk assessments determine the overall risk from several threats occurring simultaneously or threatening the same at-risk entities. Geographical risk maps provide information on risks for a specific geographical area ([141]).

5.3.1. National risk assessments

In the prevention and preparedness phase, risk assessment and prioritisation exercises conducted at national or regional level make it possible to pan and prioritise health emergency preparedness and disaster risk management activities. The WHO has developed a toolkit for this ([142]).

Member States carry out all-hazards risk and vulnerability assessments in the critical sectors and subsectors. On the basis of the outcome of those risk assessments, Member States identify critical entities and inform the Commission of the types of risks identified ([143]) ([144]).

Every three years, Member States report to the Commission on their national all-hazards risk assessments ([145]). The Commission has developed specific reporting guidelines for this ([146]) ([147]). Member States identify key risks that could have significant adverse human, economic, environmental and political/social impacts and assess their probability and impact. From among these risks, Member States are asked to identify high-impact low probability risks, emerging risks and climate-related risks and risks that could have a cross-border impact. The Commission summarises the Member

([141]) Commission staff working paper, Risk Assessment and Mapping Guidelines for Disaster Management, SEC(2010) 1626 final of 21 December 2010, https://ec.europa.eu/echo/files/about/COMM_PDF_SEC_2010_1626_F_staff_working_document_en.pdf.

([142]) WHO, *Strategic Toolkit for Assessing Risks – A comprehensive toolkit for all-hazards emergency risk assessment*, Geneva, 2021, Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/9789240036086.

([143]) Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: http://data.europa.eu/eli/dir/2022/2557/oj).

([144]) Communication from the Commission, Commission Guidelines and reporting template developed pursuant to Articles 5(5), 6(6) and 7(3) of Directive (EU) 2022/2557 on the resilience of critical entities (OJ C, C/2025/4990, 12.9.2025, ELI: http://data.europa.eu/eli/C/2025/4990/oj).

([145]) Article 6 of Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924, ELI: http://data.europa.eu/eli/dec/2013/1313/oj).

([146]) Commission Notice, Reporting Guidelines on Disaster Risk Management, Art. 6(1)d of Decision No 1313/2013/EU, C/2019/8929 (OJ C 428, 20.12.2019, p. 8, ELI: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2019.428.01.0008.01.ENG).

([147]) Commission staff working paper, Risk Assessment and Mapping Guidelines for Disaster Management, SEC(2010) 1626 final of 21 December 2010, https://ec.europa.eu/echo/files/about/COMM_PDF_SEC_2010_1626_F_staff_working_document_en.pdf.

States' reports for the European Parliament and the Council to give an indication of the progress made towards implementing risk assessments at EU level. In 2025, risks to human health were among the most frequently reported risks ([148]).

Similarly, every three years, when reporting on national prevention, preparedness and response planning, Member States report to the Commission on their plans to assess serious cross-border threats to health. The ECDC then assesses Member States' capacities for health emergency risk assessment as part of the PHEPAs ([149]). The ECDC can support Member States improve both their risk assessment and risk prioritisation capacities for infectious diseases ([150]).

Starting in 2025, Member States in the Network and Information Systems (NIS) Cooperation Group, in cooperation with the Commission and the European Union Agency for Cybersecurity (ENISA), can conduct cybersecurity risk assessments on medical devices starting in 2025 ([151]).

Member States also conduct climate change and vulnerability analyses to provide a basis for their national climate adaptation strategies and plans. These strategies and plans are guided by the best available scientific evidence and take account of the particular vulnerabilities of the sectors concerned including the health sector. ([152]) Moreover, every six years, Member States assess and manage the risks to human health posed by the drinking water supply chain including risks related to urban wastewater discharges ([153]) ([154]).

5.3.2. Public health risk assessment at EU level

After receiving an alert about a serious cross-border threat to health, the Commission or the HSC can request a public health risk assessment. These assessments are conducted by the relevant EU agencies and bodies and/or by the Commission to ensure that the EU's response to serious cross-border threats to health is data-driven, evidence-based and supported by expert advice ([155]). In urgent situations, the first rapid

([148]) 'Report from the Commission to the European Parliament and the Council, Advancing risk management and resilience-building in Europe: First report on the implementation of the union disaster resilience goals and Second update on preventing and managing disaster risk in Europe', COM(2025) 561 final of 25 September 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0561.

([149]) Articles 7 and 8 of Regulation (EU) 2022/2371.

([150]) Article 8a of Regulation (EC) No 851/2004.

([151]) Article 22 of the NIS 2 Directive. In line with this Article, the Cooperation Group, in cooperation with the Commission and ENISA, may carry out coordinated security risk assessments of specific critical ICT services, ICT systems or ICT products supply chains.

([152]) Article 5 of Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1119/oj).

([153]) Article 18 of Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (recast) (OJ L 2024/3019, 12.12.2024, ELI: http://data.europa.eu/eli/dir/2024/3019/oj).

([154]) Articles 7, 8, 9 and 10 of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1, ELI: https://eur-lex.europa.eu/eli/dir/2020/2184/oj).

([155]) Article 20 of Regulation (EU) 2022/2371.

risk assessment should be delivered within 48 hours and can be updated later as more information becomes available. Public health risk assessments are shared through EWRS and, if relevant, through other Alert Information Systems (AIS).

ECDC, EMA, EFSA, ECHA, EEA, EUDA, and Europol each contribute to public health risk assessments on the basis of their respective mandates and expertise. If an event of a serious cross-border threat to health is caused by communicable diseases or of unknown origin, the ECDC is responsible for carrying out the risk assessment ([156]). When the event, its impact or its management requires expertise from several sectors, the agencies conduct the risk assessment jointly. If the risk assessment falls outside the mandates of the EU agencies and is considered necessary for coordinating a response at EU level, it is carried out by the Commission, either at the request of the HSC or on its own initiative.

The EU agencies assess the potential severity of the threat to public health, its impact on public health and the effectiveness of possible social measures. They take into account the information provided by other entities, such as the Member States and the WHO. Public health risk assessments can: provide information on risk factors for disease and the associated disease burden, including social, economic and environmental determinants; include forecasts of the evolution of the event and the pressure on the capacity of the health system as well as other types of modelling; assess the risk for different population groups; and recommend general and targeted science-based response options, including public health and social measures ([157]). These recommendations and response options are comprehensively discussed and considered in the relevant governance structures where Member States, the Commission and EU agencies convene to manage the response as well as present it to the ACPHE if called to formulate advice and response measures.

However, given its mandate, the ECDC is tasked with providing (rapid) risk assessments on disease threats and related special health issues, on its own initiative or at the request of a Member State or the Commission ([158]) ([159]). These risk assessments are based on a standardised approach and contain clear and actionable recommendations for mitigating the risks at EU and Member States level. The ECDC prepares these risk assessments independently, although there is an internal quality control process in place. These risk assessments are published on the ECDC's website.

([156]) Article 8a of Regulation (EC) No 851/2004.
([157]) Article 8a of Regulation (EC) No 851/2004.
([158]) Articles 3 and 8a of Regulation (EC) No 851/2004.
([159]) ECDC, *Operational tool on rapid risk assessment methodology*, Stockholm, 2019, https://www.ecdc.europa.eu/en/publications-data/operational-tool-rapid-risk-assessment-methodology-ecdc-2019.

5.3.3. Other EU risk assessments

Using information provided by Member States in their national risk assessments, the Commission updates the cross-sectoral overview and the map of natural and man-made disaster risks that can have multi-country transboundary effects ([160]). An overview of 16 key hazards and transboundary cross-sectoral scenarios shapes the subsequent prevention, preparedness, disaster anticipation and risk management planning and the response activities, including disaster risk reduction strategies, at EU and Member State level ([161]).

Risk assessments on climate-related risks are performed by the EEA and the European Climate and Health Observatory ([162]) ([163]). Based on risk assessments, the EEA also develops guidance on various topics, including on mobile measuring technology regarding air quality and air pollution.

5.3.4. Threat assessment and prioritisation in the area of medical countermeasures

The Commission assesses health threats and gathers intelligence relevant to MCMs. It does this using the Advanced Technology for Health Intelligence and Action IT System (ATHINA) ([164]).

Firstly, this anticipatory threat assessment involves identifying and prioritising health threats in relation to the availability of relevant MCMs. When prioritising health threats, the Commission takes into account existing scientific and epidemiological assessments and refers to global and EU-level frameworks, including from the WHO and the ECDC. The Commission aims to assess the pandemic potential, the likelihood of a public health emergency at Union level, the availability of MCMs, and the impact of climate change on the spread and severity of viral threats. Threat prioritisation is a dynamic, consultative, and iterative process that is continuously evolving. This assessment serves as a basis for outreach and engaging with stakeholders, including Member States, other EU institutions and the professional and scientific MCM

([160]) Article 5(1)(c) of Decision No 1313/2013/EU.

([161]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, European Union Disaster Resilience Goals: Acting together to deal with future emergencies, COM(2023) 61 final of 8 February 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0061.

([162]) European Environment Agency, *European climate risk assessment*., Publications Office of the European Union, 2024, https://op.europa.eu/publication-detail/-/publication/8e234e44-7bb5-11ef-bbbe-01aa75ed71a1.

([163]) European Climate and Health Observatory, 'Climate risk exposure of vulnerable groups - map viewer', European Climate and Health Observatory website, 22 October 2025, accessed 3 November 2025, https://climate-adapt.eea.europa.eu/en/observatory/publications-data/analysis-data/copy_of_exposure-of-vulnerable-groups-to-climate-risks.

([164]) Commission Decision of 16.9.2021 establishing a Health Emergency Preparedness and Response Authority (HERA), C(2021) 6712 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=intcom:C(2021)6712.

community. It will make it easier to mount a coordinated and effective response to emerging threats ([165]).

On the basis of the threat assessment and prioritisation, the Commission works closely with EU agencies to maintain a list of priority threats against which the EU needs to improve its MCM preparedness and response.

The current priority health threats for MCM preparedness are listed below:

i. Respiratory or contact-based viruses with pandemic potential. These are highly transmissible viruses that have a history or likelihood of causing large-scale outbreaks and are influenced by environmental factors such as biodiversity loss.

ii. Vector-borne or animal-reservoir viruses with epidemic potential. These are viruses whose spread is accelerated by climate change and other environmental factors, and which are categorised as a specific threat due to their growing relevance for the EU, given that Europe is the fastest-warming continent.

iii. Antimicrobial resistance (AMR). This is a rising global concern that threatens the efficacy of existing treatments and increases the burden of infectious diseases.

iv. Armed conflict-related threats and chemical, biological, radiological and nuclear (CBRN) threats.

Secondly, the Commission has put in place processes for systematic threat assessment to review signals and events that might call for action to be taken as regards MCM preparedness or response. This builds on the public health risk assessment delivered by EU agencies to assess: the relevance of events for MCM preparedness, including whether a MCM response is considered effective and desirable; and the potential gaps identified in terms of innovation, availability or access to the required MCMs.

([165]) European Commission, 'Medical Countermeasures Strategy', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/preparedness/medical-countermeasures-strategy_en.

6. PHASE 3: Responding in an EU coordinated manner

6.1. Coordination of response

Coordination is crucial to respond effectively to a health crisis. EU coordination entails exchanging information and coordinating measures between national and EU-level governance structures. Joint arrangements for governance – including the HSC, the Health Crisis Board, if the emergency framework for MCMs is activated, and the UCPM – all have the primary objective of coordinating action within their respective mandates ([166]). When activated, the Integrated Political Crisis Response (IPCR) has an important coordination role as well. Moreover, the Council of the European Union, through its Employment, Social Policy, Health and Consumer Affairs Council (**EPSCO**), and the European Parliament, specifically through its **SANT and ENVI committees,** can provide further leadership and strategic guidance on health crisis management in the EU/EEA ([167]) ([168]).

Coordination takes place within and between these governance structures, and involves the Commission, EU agencies and Member States. The EU agencies and bodies have an important role in providing the evidence base for coordination, including through their public health risk assessments.

To ensure consistent and timely crisis management, it is essential that there is a clear division of powers and responsibilities across the EU's crisis coordination structures. While the EU governance structures each operate within distinct mandates, health crises often have a multidimensional impact that requires them to act simultaneously, coordinate closely and exchange information, with a view to maximising synergies, efficiency and effectiveness and avoiding overlaps. Joint meetings between different governance structures are an asset in bringing a wide range of expertise to the same table and ensuring a joint situational awareness. The EU's matrixed approach to health crisis governance improves consistency, speeds up decision-making and ensures that all stakeholders work within a shared situational picture during complex emergencies.

Coordination is escalated to EU level only where EU-level coordination brings added value. Most early responses to serious cross-border threats to health are managed at national level or in collaboration with neighbouring regions.

([166]) The HERA Board provides support to the work of the Commission in the area of MCM as per C(2021) 6712 final.

([167]) European Council / Council of the European Union, 'Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO)', European Council/Council of the European Union website, accessed 3 November 2025, https://www.consilium.europa.eu/en/council-eu/configurations/epsco/.

([168]) European Parliament, 'Committee on Public Health', European Parliament website, accessed 3 November 2025, https://www.europarl.europa.eu/committees/en/sant/home/highlights.

6.1.1. Coordination of response within the HSC

After notification of a serious cross-border threat to health in EWRS, the Member States and the Commission will assess whether there is a need for consultation and coordination of response within the HSC. If a need is identified, a Member State or the Commission will make **a request for coordination of response within the HSC** (Figure 6) ([169]). A request for coordination can also be made in an exceptional emergency situation caused by a threat that is not biological, chemical, environmental or unknown origin ([170]).

Following a request for consultation for the purposes of coordination of response within the HSC, the Commission must in principle organise such a consultation within 48 hours of the request depending on the urgency. During the consultation, and on the basis of the available information, the HSC can: (i) consult the Member States affected; (ii) draw on the expertise of the Commission, EU agencies and bodies, international partners, and subject-matter experts, (iii) exchange information; (iv) coordinate national response measures, research needs, and risk and crisis communication; (v) adopt opinions and guidance; and (vi) support the IPCR arrangements if activated ([171]) ([172]).

Upon adoption of **public health measures** in response to a serious cross-border threat to health, Member States must promptly inform the other Member States and the Commission of the nature, purpose and scope of those measures, especially in cross-border regions. Similarly, they must coordinate within the HSC before terminating measures. Only in urgent situations, can this be done immediately after adopting or terminating the measures ([173]).

To coordinate the response, the HSC collaborates with other structures and coordinates with the UCPM and, where activated, the Health Crisis Board. When it comes to requesting, offering and delivering cross-border medical assistance, including medical evacuation, the HSC coordinates with the **UCPM.** On matters relating to MCMs, the **HERA Board** collaborates with the HSC. In case of a recognition of a public health emergency at Union level and an activation of the emergency framework for MCMs, the **Health Crisis Board** acts in close coordination with the HSC and ensures timely and efficient exchange of information.

([169]) Article 21 of Regulation (EU) 2022/2371.
([170]) Article 2(4) of Regulation (EU) 2022/2371.
([171]) Article 4 of Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council (OJ L 37, 14.2.2017, p. 23, ELI: http://data.europa.eu/eli/dec_impl/2017/253/oj).
([172]) Article 21 of Regulation (EU) 2022/2371.
([173]) Article 21 of Regulation (EU) 2022/2371.

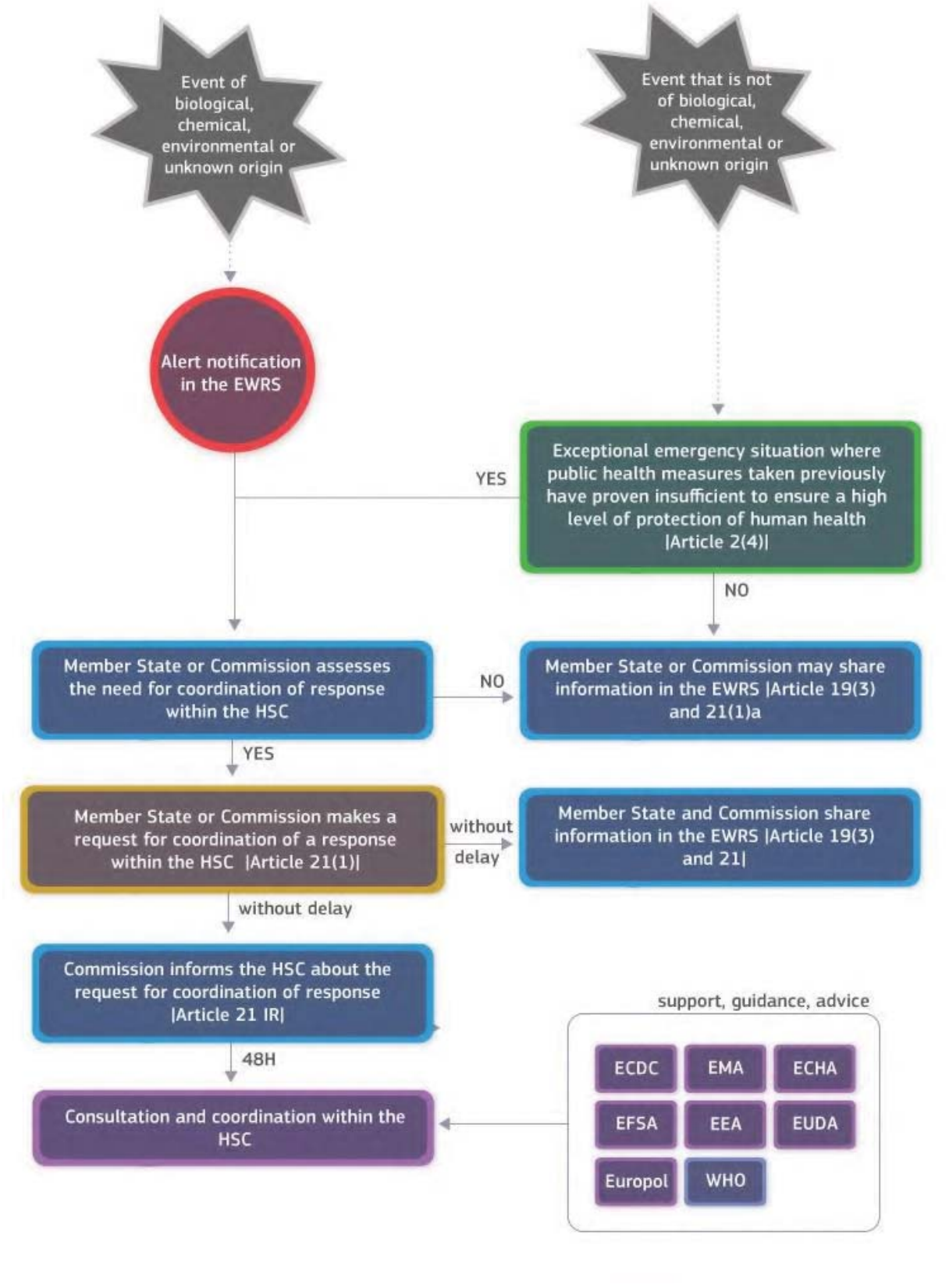


Figure 6. Process for the initial coordination of response within the HSC.

6.1.2. Coordination of MCM response

When an event constituting a serious cross-border threat to health is notified in the EWRS, the Commission will assess the need to coordinate the MCM response at EU level. If EU-level action on MCMs is needed, the Commission will open a response case and seek advice of the HERA Board, where relevant. Depending on the event and availability of MCMs, an ad hoc meeting of the HERA Board can be convened to assess the demand for and availability of crisis-relevant MCMs and to discuss the actions (e.g. joint procurement) that the Commission could take to support the availability of and equitable access to MCMs. This could include possible support through the UCPM (joint or centralised procurement) and the deployment of rescEU capacities. Where appropriate, the results of the set of options identified by the HERA Board will be shared with the HSC.

An event or likely imminent event may also lead to a notification in the Common Emergency Communication and Information System (CECIS) of a possible upcoming or actual request for assistance to the UCPM. In such cases, the ERCC is responsible for coordinating the response including the deployment of rescEU stocks.

6.1.3. Coordination of response within the IPCR

In the event of activation of the **Integrated Political Crisis Response (IPCR) arrangements**, the HSC coordinates support for the IPCR to ensure that political coordination at EU level is supported by public health expertise and operational input from Member States. This may also include exchanging information or sharing of opinions or guidance ([174]). The **IPCR** is the EU mechanism designed to support a rapid and coordinated political response for major and complex crises ([175]). It is under the leadership of the Presidency of the Council, which can activate it, has political control over it and determines its strategic direction ([176]). The IPCR provides a flexible framework that can be scaled depending on the severity and characteristics of the crisis. Once activated, the IPCR has three operational modes, namely: a monitoring mode (for situational awareness); an information sharing mode (for collecting and analysing data); and a full activation mode (for active coordination of the preparation of response measures).

The Commission's Emergency Response Coordination Centre (**ERCC**) operates on a 24/7 basis and supports both the EU institutions and the Member States in its capacity of single point of contact for IPCR. It provides assistance to Member States and the EU when IPCR arrangements are activated, or the solidarity clause is invoked.

([174]) Article 21 of Regulation (EU) 2022/2371.
([175]) Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response Arrangements (OJ L 320, 17.12.2018, p. 28, ELI: https://eur-lex.europa.eu/eli/dec_impl/2018/1993/oj).
([176]) Article 222 of the TFEU.

The Committee of Permanent Representatives of the Governments of the Member States to the European Union (**Coreper**) oversees the implementation of the IPCR arrangements.

6.1.4. Response coordination under the Union Civil Protection Mechanism

When any country in the world is hit by a disaster or faces an imminent threat of disaster – such as a health crisis – it can request emergency assistance from the Union Civil Protection Mechanism (UCPM) (see Figure 7). Requests for assistance can also be made by the United Nations and its agencies (e.g. the WHO) and certain other relevant international organisations in coordination with and on behalf of the affected country([177]).

The **request for assistance** is sent via the Common Emergency Communication and Information System (CECIS 2.0) ([178]) to the Commission's Emergency Response Coordination Centre (ERCC). The ERCC operates on a 24/7 basis to be ready to coordinate and deploy emergency support.

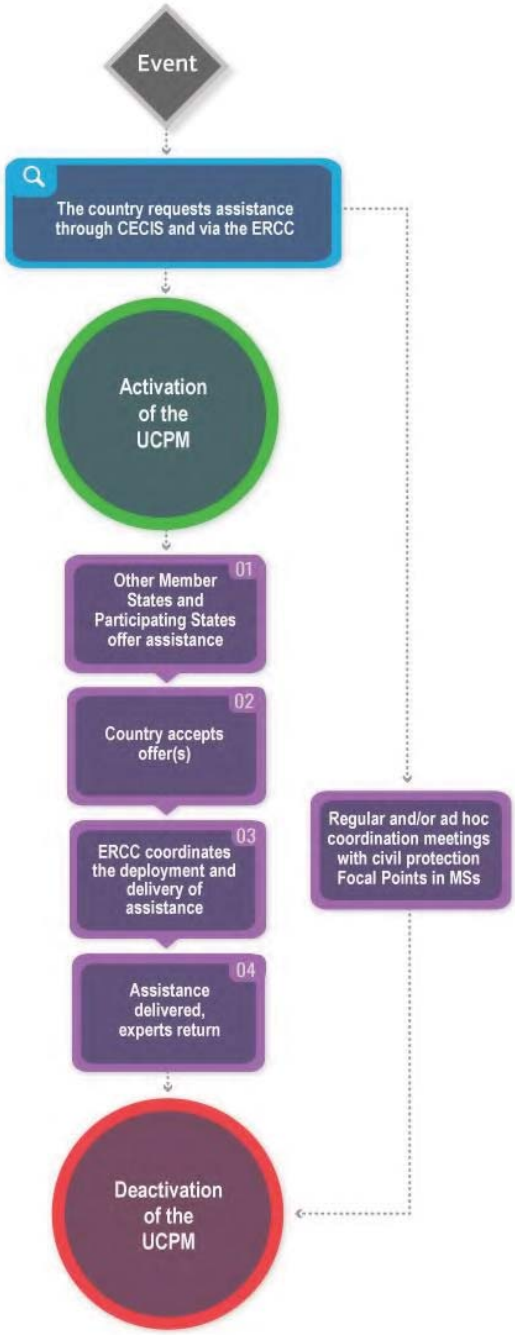
After the ERCC has validated a request for assistance, EU Member States and states participating in the UCPM may offer assistance via CECIS 2.0.

In addition to **experts**, capacities may be mobilised under the UCPM from **national response capacities** ('ad hoc' offers of assistance by Member States or participating states), the European Civil Protection Pool (**ECPP**, pre-committed national capacities that meet certain UCPM requirements) and/or **rescEU** (the 'last resort' EU strategic reserve of capacities) ([179]). The UCPM can also involve the EUHTF. Where an effective response cannot be ensured through national 'ad hoc' offers of assistance and/or capacities available as part of the ECPP, the Commission may decide, through the ERCC, to deploy rescEU capacities, in consultation with the requesting Member State or participating state and the state hosting the rescEU capacity.

The ERCC coordinates the operational response between all 27 EU Member States, the 10 additional participating states, the affected country, and civil protection and humanitarian aid experts. It can help with the transport and effective deployment of the assistance once it has been **accepted by the requesting country**. It can also help

([177]) Including the International Federation of Red Cross and Red Crescent Societies (IFRC).
([178]) Non-EU countries have no access to CECIS; their requests are sent to the ERCC, which enters them in CECIS.
([179]) Report from the Commission to the European Parliament and the Council, Capacity Progress Report on the Response Capacities of the Union Civil Protection Mechanism, COM(2025) 286 final of 6 June 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0286; and the accompanying Union Civil Protection Mechanism Capacity Development and Gaps Overview, SWD(2025) 146 final of 6 June 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025SC0146#:~:text=This%20Staff%20Working%20Document%20represents%20the%20descriptive%20portion,foreseen%20under%20Article%2034.2%20of%20Decision%20No%201313%2F2013%2FEU.

with the production of satellite maps ([180]), and scientific emergency reports ([181]) (e.g. in the event of major natural disasters, or chemical, radiological or nuclear incidents).



([180]) Produced by the Copernicus Emergency Management Service in support of civil protection operations; see 'Copernicus Emergency Management Service – Mapping', Copernicus website, accessed 3 November 2025, https://mapping.emergency.copernicus.eu/#zoom=4&lat=41.92304&lon=17.89688&layers=0BT00.

([181]) Prepared under the Scientific and Technical Advisory Facility ('STAF') of the UCPM.

Figure 7. Process for responding to a request for assistance under the Union Civil Protection Mechanism as per Decision No 1313/2013/EU. CECIS = Common Emergency Communication and Information System. ERCC = Emergency Response Coordination Centre.

During **health crises**, where health systems are overwhelmed, damaged or unable to provide adequate care, the UCPM can provide support by offering, for example:

1. MCMs and in-kind assistance: addressing shortages of essential medicines, personal protective equipment, and medical equipment;
2. reinforcement of medical staff and services: deploying health experts and emergency medical teams (EMTs) (see also Section 6.7.3);
3. medical evacuation (Medevac): facilitating patient evacuation and transport to hospitals across EU Member States and UCPM participating states (see also Section 6.6.3);
4. help with the transport and/or operational costs of deployments.

When to end of a UCPM operational response depends on the evolving needs of the emergency and the situation. The requesting country informs the ERCC when assistance is no longer required. Disengagement is coordinated by the requesting country together with the assisting EU Member State(s) or UCPM participating state(s), in close consultation with the ERCC. Decisions to withdraw the rescEU capacity are taken by the Commission, through the ERCC, in close coordination with both the host state of the rescEU capacity and the requesting country.

In parallel to the UCPM's response to requests for assistance and coordination for individual requests, the ERCC and national civil protection focal points hold regular coordination meetings on the ongoing emergencies and related general UCPM response coordination matters. For health emergencies to which response is coordinated in the HSC, the ERCC participates in the relevant meetings to ensure appropriate information exchange and coordination with the UCPM operational response. Similarly, if the framework of measures for ensuring the supply of crisis-relevant MCMs is activated in the event of a public health emergency at Union level, coordination is ensured with the Health Crisis Board.

Finally, the ERCC uses **ReliefEU** ([182]), to extend EU assistance to humanitarian settings worldwide. It coordinates the provision of ReliefEU assistance to disaster- and crisis-stricken areas outside the EU, either in addition to or as a humanitarian alternative to UCPM support. ReliefEU capacities ([183]) and funding help bridge the gap between the urgent needs of the affected population in those areas and the resources available from European humanitarian partners.

([182]) European Civil Protection and Humanitarian Aid Operations, 'ReliefEU', European Commission website, accessed 3 November 2025, https://civil-protection-humanitarian-aid.ec.europa.eu/what/humanitarian-aid/reliefeu_en.

([183]) Logistic services, warehousing, stockpiling and deployment of expertise.

6.2. Situational awareness

Situational awareness builds on the information exchanged between Member States, the relevant EU agencies and the Commission, and is crucial for an effective response. Following a request for consultation and coordination of a response within the HSC, the Member States and the Commission exchange the available relevant information in the Early Warning and Response System (EWRS) to build a situational picture and awareness ([184]). Information on MCMs is primarily communicated through ATHINA, while requests and offers for cross-border emergency assistance are communicated via CECIS. The Commission coordinates the information exchange to avoid duplication of efforts and ensures the transfer of relevant information between different Commission alert information systems (Annex 8).

To consult on and coordinate national public health measures, Member States must inform the HSC of their intention to adopt or terminate such measures. In urgent cases, the HSC must be informed and consulted promptly after the adoption or termination of the public health measures concerned ([185]).

Integrated situational awareness and analysis (**ISAA**) reports, part of IPCR arrangements, facilitate a common understanding of the crisis and make it possible to identify urgent needs and gaps and promote solidarity measures in the IPCR. The ERCC as well as EU agencies such as ECDC and EMA assist with the production of ISAA reports, which are developed by the Commission or EEAS depending on the centre of gravity of the crisis.

Secure exchange of information within the EU is facilitated by the various digital platforms for public health intelligence and alert notification (Annexes 7 and 8) and for communication ([186]). EU classified information means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or one or more Member States. Where Member States enter classified information bearing a national security classification marking into the Commission's structures or networks, the Commission must protect that information in accordance with the requirements applicable to EU classified information of the equivalent level ([187]). Sensitive non-classified information, on the other hand, is information or material that the Commission must protect because of legal obligations and/or because of its sensitivity ([188]).

([184]) Article 19(3) to (5) of Regulation (EU) 2022/2371.
([185]) Article 21 of Regulation (EU) 2022/2371.
([186]) Secure Union Environment (SUE) system for the Member States, EU agencies and the Commission, and the HCI system for the Council.
([187]) Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53, ELI: http://data.europa.eu/eli/dec/2015/444/oj).
([188]) Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41 ELI: http://data.europa.eu/eli/dec/2015/443/oj).

Example of cross-border interregional collaboration: Nordic mechanism for sharing situational awareness

The Nordic public health agreement between the governments of Denmark, Finland, Iceland, Norway, and Sweden has been in place since 2002 and serves as a basis for cooperation between the Nordic countries in the development of public health preparedness to address crises and disasters. This group, which is also known as the 'Svalbard Group', has established a common framework and common situational awareness data for preparedness for and management of crisis situations in health and social services in the Nordic countries ([189]).

6.3. Risk and crisis communication

Risk and crisis communication is one of the core capacities for the successful management of a health crisis ([190]). Communicating science-based, accurate and clear information adapted to the target audience, early and often, and through the channels used by the target audience, improves health literacy and enables people to make informed choices to protect themselves and others from hazards. Communicating science-based, accurate and clear information adapted to the target audience, early and often, and through the channels used by the target audience, improves health literacy and enables people to make informed choices to protect themselves and others from hazards. Open, timely and consistent communication can increase public trust and prevent misinformation and disinformation from taking root. From a preparedness perspective, efforts to build trust in science, MCMs and institutions more broadly, lay the foundations for a successful crisis response.

Risk and crisis communication is comprised of several interconnected areas. These include: the timely flow of accurate and relevant information; intelligence gathering and monitoring perceptions; infodemic management, including countering harmful misinformation and disinformation ([191]); and coordination of messages. Managing public perception and addressing false or misleading narratives during a health crisis is pivotal, as panic or distrust can undermine the effectiveness of public health responses.

Member States provide the public with information on the prevention of and preparedness for cross-border threats to their health. Given the increasingly global nature of information and the need to strive for consistency of messaging across the EU, the Commission works together with EU agencies and bodies to ensure: EU-wide public recommendations, warnings and risk communication, and accessible and inclusive crisis communication, which reaches all those concerned regardless of possible social and cultural barriers ([192]).

([189]) Nordic Group for Public Health Preparedness ('Svalbard Group'), 'Nordic Public Health Preparedness Agreement', Nordic Health Preparedness website, accessed 3 November 2025, https://nordichealthpreparedness.org/.
([190]) Capacity 8 in Commission Implementing Regulation (EU) 2023/1808.
([191]) WHO, 'Infodemic', WHO website, accessed 3 November 2025, https://www.who.int/health-topics/infodemic.
([192]) Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, on the European Preparedness Union Strategy, JOIN(2025) 130 final of 26 March 2025, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025JC0130.

The Commission and EU agencies support Member States in ensuring that timely and accurate information on a health crisis reaches the public and the media. Both digital and more traditional communication channels are used. Media representatives pay close attention to EU-level announcements and approach EU bodies for reactions to or comments on the latest developments. This requires a rapid and coordinated response at all levels. Close collaboration with the relevant EU agencies ensures that messaging is rooted in the latest scientific evidence. Moreover, local healthcare professionals and members of the community often enjoy high levels of trust. They can play a pivotal role during a crisis by communicating risk, providing insights and supporting the roll-out of response measures. These partners, however, rely on expert public health advice from national and EU bodies during public health emergencies.

The ECDC is tasked with communicating information on current and emerging threats to public health in the EU/EEA and has provided guidance on the best way to involve members of the community in crisis preparedness and response ([193]) ([194]). The ECDC operates a public health network for communicating with representatives from Member States ([195]).

Information manipulation, including foreign interference, is a major challenge for coherent health emergency response. With the Digital Services Act, the Code of Conduct on Disinformation and the European Democracy Shield, the Commission has policies in place that make it more difficult for threat actors to misuse online platforms, while simultaneously protecting freedom of speech and media pluralism. The Commission also has the capability to support situational awareness across the Union through monitoring, detection and analysis of open-source information. There is close cooperation with other EU institutions, national authorities, fact-checkers, civil society organisations, media, academia and other organisations.

Awareness-raising programmes provide tools for the Commission to support risk and crisis communication in the Member States. Such programmes include citizens' panels, the EUvsDisinfo portal for detecting, analysing, and raising awareness about disinformation ([196]), online campaigns, and toolkits for strategic communication and countering information manipulation.

In the event of a serious cross-border threat to health or a public health emergency at Union level, EU information, communication and coordination structures enable systematic and consistent crisis communication. The HSC is the forum where Member States coordinate risk and crisis communication messages ([197]). The Commission can

([193]) ECDC, *Community engagement for public health events caused by communicable disease threats in the EU/EEA*, Stockholm, 2020, https://www.ecdc.europa.eu/en/publications-data/guidance-community-engagement-public-health-events-caused-communicable-disease.

([194]) Article 2c of Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1, ELI : http://data.europa.eu/eli/reg/2022/2370/oj).

([195]) ECDC, 'Public Health Networks', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/about-us/what-we-do/partners-and-networks/public-health-networks.

([196]) EUvsDisinfo, accessed 3 November 2025, https://euvsdisinfo.eu/.

([197]) Article 21 of Regulation (EU) 2022/2371.

provide suggested messaging, templates or communication assets; but each Member State develops its own communication strategy, in line with its national, regional and cross-border context ([198]). The Commission works with EU representations in the Member States and fact-checking networks to respond to false narratives before they take hold. Public health risk assessments can also be used for crisis communication at national, EU and international level.

The Presidency of the Council takes the lead on public communication from the IPCR. It is supported in this by the informal **Crisis Communicators' Network** which is made up of communication experts from Members States and relevant EU bodies.

6.4. Emergency research and innovation

Scientific evidence is crucial for taking decisions on preventing, preparing, and responding to serious cross-border threats to health ([199]). When an event is unusual or unknown and growing rapidly in scale, emergency research is needed to better understand the threat and to guide the development and implementation of response measures and the use of resources.

Emergency research in the EU/EEA covers a broad range of study settings, grounded in continuous research preparedness efforts. Examples include basic biomedical research, pre-clinical and clinical research, behavioural science, observational studies, implementation, and public health research. Such research and innovation may be publicly funded at national level or at European level, the latter mainly through the European research and innovation framework programmes.

Coordinating emergency research priorities and resources at EU level ensures efficiency and underpins evidence-based policymaking. Key players include the HSC, the HERA Board and the Health Crisis Board (when activated), along with the Horizon Europe and EU4Health Programme committees. Each body plays an important role, within their respective remits, in facilitating research and innovation and its funding, ultimately strengthening the EU's resilience in preparing for and responding to serious cross-border threats to health. The **Clinical Trial Coordination Mechanism** advises the Commission on prioritising clinical studies and their funding.

The **ECDC** is mandated to collect data and provide concrete analyses and independent science-based recommendations to prevent and control communicable diseases and other serious cross-border threats to health and multinational outbreaks to rapidly generate evidence on epidemiological parameters such as transmissibility, routes of transmission and risk factors for disease. The ECDC develops its scientific studies and opinions on its own initiative or at the request of the Commission or the HSC ([200]). The

([198]) Article 21 of Regulation (EU) 2022/2371.
([199]) European Commission, 'EU preparedness union strategy', European Commission website, accessed 3 November 2025, https://commission.europa.eu/topics/preparedness_en.
([200]) Articles 6 and 11 of Regulation (EC) No 851/2004.

HSC is also consulted on the planning and priority setting of the ECDC's research and public health studies ([201]). The **EMA** collaborates with ECDC to conduct vaccine effectiveness and safety studies through the agencies' Vaccine Monitoring Platform. The EMA also gives scientific advice on data generation for medicines.

Research during health crises can benefit from existing research and innovation networks and infrastructure and build on the investments made during prevention and preparedness stages. The **European partnership on pandemic preparedness** helps create the required research and innovation ecosystem to respond to health crises quickly and effectively ([202]). The partnership's strategic research and innovation agenda provides a solid foundation for rapidly responding to serious cross-border threats to health. The **ever-warm clinical research networks** under the partnership have the built-in ability to adapt quickly in emergency situations and are an essential component of this preparedness ecosystem. Other networks in the partnership cover basic fundamental and pre-clinical research, as well as clinical and public health research ([203]).

When a public health emergency at Union level is recognised and the emergency research measure of the emergency framework for MCMs is activated, the Commission and Member States must, after consulting the Health Crisis Board, activate the Union plan's emergency research and innovation mechanisms ([204]). This is to be done in coordination with the ECDC and with the involvement of the EMA Emergency Task Force (Annex 4) and the European Clinical Research Infrastructure Network.

The Commission and the Member States can activate several emergency research and innovation mechanisms (Table 8).

([201]) Article 6 of Regulation (EC) No 851/2004.

([202]) European partnership on pandemic preparedness (BE READY 4 PANDEMICS), accessed 3 November 2025, https://beready4pandemics.eu/.

([203]) The Horizon 2020 funded project EU RESPONSE provides an example for ever-warm clinical trials networks. Similar networks are envisaged by the Horizon Europe partnership on pandemic preparedness; see EU Response website, accessed 3 November 2025, https://eu-response.eu/.

([204]) Articles 5 and 9 of Regulation (EU) 2022/2372.

Table 8. Emergency research and innovation mechanisms in the EU/EEA.

- EU research and innovation funding;
- European partnership for pandemic preparedness;
- The Commission's Scientific Advice Mechanism (SAM);
  - identifying emerging risks and providing anticipatory advice to inform proactive measures;
  - rapid evidence synthesis: mobilising expert networks to deliver timely scientific input in an emergency;
  - strategic policy guidance: making recommendations to ensure EU action is grounded in robust scientific evidence;
  - stakeholder engagement and communication: facilitating dialogue between the scientific community, policymakers and the public to build trust and increase transparency;
- European Group on Ethics in Science and New Technologies;
- Information exchange on national emergency research and coordination of national research needs within the HSC in response to a cross-border threat to health;
- Coordination of clinical studies related to the cross-border threat to health as part of the Clinical Trial Coordination Mechanism under the HERA Board.

6.5. Emergency funding

The EU's long-term budget (the multiannual financial framework or 'MFF') sets out rules with which the EU's annual budget must comply. The MFF can include funding instruments for preventing, preparing for and responding to health crises ([205]) ([206]). Member States also benefit from financial support from the Recovery and Resilience Facility for the period 2021–2026 and cohesion policy funding to meet their specific needs ([207]) ([208]) ([209]).

The Emergency Support Instrument (ESI) enables the EU to provide financial assistance, logistical support, technical expertise and resources to Member States facing crises in exceptional circumstances where other available resources are insufficient. It is a flexible tool designed to respond rapidly to different types of evolving needs. Member States can use it when they require immediate support in managing a crisis, preventing a crisis, and during recovery. The ESI can be activated by the Council based on a proposal by the Commission where such assistance is appropriate to the economic situation and the exceptional scale and impact of the disaster is such that it gives rise to severe wide-ranging humanitarian consequences in one or more Member

([205]) European Commission, 'EU4Health programme 2021–2027 – a vision for a healthier European Union', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en.

([206]) European Commission, 'Horizon Europe', European Commission website, accessed 3 November 2025, https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en.

([207]) European Commission, 'New Cohesion Policy', European Commission website, accessed 3 November 2025, https://ec.europa.eu/regional_policy/2021-2027_en.

([208]) European Commission, 'Recovery and Resilience Facility (RRF)', European Commission website, accessed 3 November 2025, https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility_en.

([209]) European Commission, 'Technical Support Instrument (TSI)', European Commission website, accessed 3 November 2025, https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/technical-support-instrument/technical-support-instrument-tsi_en.

States including in a public health emergency at Union level ([210]) ([211]). The ESI aims to create synergies and consistency with existing EU programmes and instruments, such as the Union Civil Protection Mechanism (UCPM). The support provided under ESI is intended to complement ongoing efforts of the affected Member State(s).

6.6. Continuity of care across borders

The design and organisation of national health systems and health services fall within the competence of Member States. The EU plays a complementary role to ensure continuity of care when patients or healthcare personnel cross borders and move freely in the EU. Many Member States have put in place cross-border interregional arrangements for surge capacity and specialised services. These arrangements can include agreements, service procurement, projects or other initiatives. Guidance from the WHO ensure continuity of operations and services ([212]) ([213]).

The Commission can deploy coordinated crisis response measures by the **customs authorities** of the Member States at the external borders facilitated by the Customs Risk Management System (CRMS2) ([214]). These measures can include **export control mechanisms** in which customs authorities help secure the supply of critical MCMs by facilitating their import and, where necessary, restricting their export during a crisis. The Commission can issue crisis alerts, provide guidance and to prioritise customs controls for critical goods (vaccines, medical equipment, personal protective euipment, disinfectants) while maintaining trade flow facilitation. Customs role is also important in curbing illicit and dangerous imports of medicines and medical equipment.

6.6.1. Cross-border healthcare

Cross-border interregional cooperation in healthcare can optimise resources and give access to care during health emergencies when there is available healthcare capacity across the border ([215]). Operating arrangements in border regions can help tackle emergency situations while preserving the continuity of care for the many people living in these regions (about 30% of the EU population).

([210]) Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/369/oj).

([211]) Article 13 of Regulation (EU) 2022/2372.

([212]) WHO, *WHO Guidance for Contingency Planning*, Geneva, 2018. Licence: CC BY-NC-SA 3.0 IGO., https://www.who.int/publications/i/item/WHO-WHE-CPI-2018.13.

([213]) WHO, *Hospital safety index: guide for evaluators*, 2nd edition, 2017, Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/9789241548984.

([214]) European Commission, 'Customs risk management', European Commission website, accessed 21 November 2025, https://taxation-customs.ec.europa.eu/customs/customs-risk-management_en.

([215]) European Commission: Directorate-General for Health and Food Safety, Asterisk Research and Analysis, Empirica, Tetra Tech International Development Sp. z o.o, Dates, M. et al., *Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare : Final report*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2875/88566.

Interregional cooperation under the Interreg programme (a cohesion policy pillar) covers multiple types of projects, initiatives and strategies. These aim to promote the development of cross-border public healthcare services; share resources, staff and knowledge; build up administrative capacities; upgrade technologies; and support innovation. Long-term cooperation helps structure local networks of professionals and institutions who know one another and regularly work together. As a result, these networks can be mobilised more effectively to implement coordinated prevention, preparedness and response measures in a health crisis ([216]).

EU citizens and nationals of EEA countries have the right to access medical treatment with the same terms as local patients in any other EU Member State or EEA country subject to certain conditions. The citizen's country of affiliation (country where the patient is insured) will cover part or all the medical costs, up to the amount their home system would have paid for the same treatment locally (or the actual cost of the treatment, whichever is lower). However, patients usually pay all costs upfront and then apply for reimbursement, based on their home country's fee and reimbursement schedule. For unplanned treatment while temporarily abroad, EU citizens and nationals of EEA countries must have a European Health Insurance Card. There are national contact points in each EU Member State and EEA country that can advise the public on cross-border healthcare procedures ([217]) ([218]) ([219]).

MyHealth@EU is a cross-border digital infrastructure connecting EU Member States and EEA countries' contact points for digital health, enabling patients to share their health data in a standardised European format ([220]). MyHealth@EU can facilitate and support the interoperable exchange of electronic health data with public health applications. This can be of help in a health crisis, for example, to issue and check health certificates or to support contact tracing ([221]).

The European Reference Networks can support the care of patients with rare, low prevalence and complex diseases also during health crises. These cross-border networks bring together European hospital centres of expertise and reference to tackle rare, low-prevalence and complex diseases and conditions. The collaboration is facilitated by the Clinical Patient Management System.

([216]) Interreg, accessed 3 November 2025, https://interreg.eu/.

([217]) Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/883/oj).

([218]) Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems (OJ L 284, 30.10.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/987/oj).

([219]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45, ELI: http://data.europa.eu/eli/dir/2011/24/oj).

([220]) European Commission, 'Electronic cross-border health services', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/electronic-cross-border-health-services_en.

([221]) Article 24 of Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj).

Example of cross-border interregional collaboration: emergency medical services at the French–Spanish border

The Catalan Health Service (SCS) and the French Agence Régionale de Santé Occitanie have an administrative agreement in place to coordinate emergency medical services. This serves to foster cooperation across the entire border region, especially in Cerdanya, where both services already share facilities at the cross-border hospital in Puigcerdà. The agreement sets out communication protocols, leadership roles in emergencies and shared tools such as for transmitting coordinates instead of map names.

Example of cross-border interregional collaboration: cross-border ambulance services at the Austrian-Hungarian border

Austria and Hungary signed an agreement in 2024 on joint ambulance operations across the border. Rescue dispatchers in Burgenland (Austria) and western Hungary can request assistance from one another so that patients can reach the closest emergency site faster. The cooperation also extends to air rescue services, ensuring that severe cases, including accidents and critical illnesses, receive timely and effective treatment. The collaboration improves safety and healthcare access for patients in border regions.

6.6.2. Cross-border contact tracing

Health authorities need to collaborate across borders when trying to limit the spread of diseases from cross-border movement. This can include contact tracing between an EU Member State and a non-EU country. Cross-border contact tracing is a responsibility of national, subnational or local authorities, depending on the Member States.

Cross-border contact tracing involves the secure exchange of personal data, including personal health data, between Member State competent authorities to identify contacts at risk of infection or contamination. The EWRS contact tracing module provides for the secure exchange of information between the competent authorities in Member States and participating countries.

Digital contact tracing can complement conventional contact tracing especially when the demand for contact tracing threatens to exceed the health system's capacity. By measuring signal strength between personal mobile devices, these digital tools can determine proximity between users, identify contacts at risk and then send alerts. The effectiveness of these digital tools in limiting the spread of disease depends on the specific situation and on their users. The interoperability of tools between countries enables individuals to use a single application when travelling in different countries. When implemented effectively, digital contact tracing tools can free up healthcare resources for other purposes ([222]).

Member States can request information from incoming travellers, carry out non-invasive medical examinations and inspect physical items for public health purposes

([222]) European Commission, *Digital Contact Tracing Study: Study on lessons learned, best practices and epidemiological impact of the common European approach on digital contact tracing to combat and exit the COVID-19 pandemic*, Publications Office of the European Union, Luxembourg, 2022, https://commission.europa.eu/system/files/2023-02/DigitalContactTracingStudy.pdf.

([223]). Public health measures for travellers are free of charge ([224]). The EU Digital Passenger Locator Form (**EUdPLF**) is a digital tool and platform that the Commission developed to help collect essential travel information from passengers entering or travelling within the EU ([225]). Passengers can use the online EUdPLF tool to fill in their travel history, contact details and seat assignments. On submission, the data is stored temporarily and is only made available to the national public health authorities of the relevant Member States involved in the journey. Public health authorities can use the tool to share information across borders for contact tracing. The EUdPLF code is publicly available under the European Union Public Licence, allowing for reuse, modification and distribution, provided that any derivative use remains under the same licence ([226]) ([227]).

6.6.3. Medical evacuation of patients

The EU's medical evacuation programme (**Medevac**) is funded and run under the Union Civil Protection Mechanism (UCPM). Medevac involves the organised transfer of patients, who require treatment, that cannot be given in the affected country, to healthcare facilities in EU Member States and UCPM participating states where such treatment is available. For patient safety and logistical reasons, it may be sometimes beneficial to set up Medevac Hubs as stopover points along the treatment route. Medevac is coordinated by the ERCC using the CECIS and the EWRS.

Example:support to Ukraine and medical evacuation of patients
In response to the deteriorating humanitarian situation in Ukraine, all 27 EU Member States and 6 participating states (Iceland, North Macedonia, Norway, Serbia, Moldova and Türkiye) have made help available to Ukraine via the UCPM. The assistance includes millions of items such as first aid kits, medical and shelter equipment, water pumps, power generators and firefighting equipment. The EU is also coordinating the medical evacuation of Ukrainian patients in need of urgent care to hospitals across Europe through the UCPM and the medical evacuation hub set up in Poland. As of November 2025, over 4600 patients had received treatment in 22 EU Member States and EEA countries, as part of the medical evacuations

([223]) Article 23 'Health measures on arrival and departure' of IHR 2005 (amended in 2014, 2022 and 2024). As far as persons enjoying the right of free movement under EU law are concerned, such requirements must comply with Article 29 of Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77, ELI: http://data.europa.eu/eli/dir/2004/38/oj).

([224]) Article 40 'Charges for health measures regarding travellers' of IHR 2005 (amended in 2014, 2022 and 2024).

([225]) Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council (OJ L 37, 14.2.2017, p. 23, ELI: http://data.europa.eu/eli/dec_impl/2017/253/oj).

([226]) Commission Decision of 8 December 2021 on the open source licencing and reuse of Commission software 2021/C 495 I/01 (OJ C 495I, 9.12.2021, p. 1, ELI: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D1209%2801%29).

([227]) Code development platform for open source projects from the European Institutions, 'European Digital Passenger Locator Form', accessed 3 November 2025, https://code.europa.eu/sante/eudplf.

6.6.4. Health documents

EU Member States and EEA countries may require specific health documents for international travel in digital or non-digital formats ([228]). The WHO oversees developing and updating, in consultation with IHR States Parties, technical guidance on issuing and verifying the authenticity of these documents in both formats ([229]) ([230]). It has developed the Global Digital Health Certification Network (**GDHCN**), which is an open-source platform that provides standards for a range of digital products ([231]) building on the EU Digital COVID Certificate framework for issuing and verifying vaccination, test and recovery certificates, while preserving privacy ([232]) ([233]).

6.7. Recognising a public health emergency at Union level

A public health emergency at Union level can be recognised by the Commission where the serious cross-border threat to health endangers public health at EU level ([234]). This recognition extends the legal mandates of some authorities, enhances coordination at EU level and releases resources (Table 9).

To recognise a public health emergency at Union level, the Commission needs to assess whether the event endangers public health at EU level and whether the legal effects of recognising it are necessary and proportionate. For this assessment, the Commission must consider any expert opinions from relevant EU agencies or bodies or the ACPHE (Figure 8) ([235]). The public health risk assessment conducted by one or more of the agencies or bodies at the request of the HSC, or the Commission, can be considered as an expert opinion of the EU agencies and bodies involved ([236]). ACPHE gives its advice in response to requests of the HSC or the Commission ([237]). Moreover, information shared by Member States in the EWRS, as well as in consultation and

([228]) Article 35 of the IHR 2005 (amended in 2014, 2022 and 2024). As far as persons enjoying the right of free movement under EU law are concerned, such requirements must comply with Article 29 of Directive 2004/38/EC.
([229]) Part VI 'Health documents' of the IHR 2005 (amended in 2014, 2022 and 2024).
([230]) WHO, *Digital Documentation of COVID-19 Certificates: Vaccination Status – Technical Specifications and Implementation Guidance, 27 August 2021*, Geneva, 2021, Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/WHO-2019-nCoV-Digital_certificates-vaccination-2021.1.
([231]) WHO, 'Global Digital Health Certification Network', WHO website, accessed 3 November 2025, https://www.who.int/initiatives/global-digital-health-certification-network.
([232]) European Commission, 'Administrative arrangement between the WHO and the European Commission on technical cooperation related to the global digital health certification network', 17 May 2023, https://commission.europa.eu/document/d1fb7b2e-0966-4496-a56a-5ab4a35ab15f_en.
([233]) European Commission, 'Report from the Commission to the European Parliament and the Council pursuant to Article 16(3) of Regulation (EU) 2021/953 of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic', COM(2022)753 final, 22 December 2022, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52022DC0753.
([234]) Article 23 of Regulation (EU) 2022/2371.
([235]) Article 23 of Regulation (EU) 2022/2371.
([236]) Article 20 of Regulation (EU) 2022/2371.
([237]) Article 24 of Regulation (EU) 2022/2371.

coordination with the HSC, and any possible opinions or guidance adopted by the HSC or the HERA Board can contribute to decision-making in the Commission.

Table 9. Legal effects of recognising a public health emergency at Union level.	
Measures	**Legal effects**
Measures related to medicinal products and medical devices in Regulation (EU) 2022/123	EMA activities are expanded by: • adopting the lists of critical medicines and critical medical devices; • monitoring demand and supply of critical medicines and critical medical devices; • reporting on actual or potential shortages of critical medicines and critical medical devices; recommending measures to prevent or mitigate these shortages;Fully activatingof the EMA's Emergency Task Force (ETF) activities, including free scientific advice with shorter timelines and the possibility to use a dedicated procedure to issue formal opinions on the use and distribution of unauthorised medicinal products.
Measures to ensure the availability of MCMs in Regulations (EU) 2022/123, 2022/2371 and 2022/2372	• Possibility for the Council to activate the emergency framework for ensuring the supply of crisis-relevant MCMs under Regulation 2022/2372. • If the emergency framework is activated, the Health Crisis Board is established. • Depending on the emergency framework measures activated, there is the possibility to: monitor the supply and demand of crisis-relevant MCMs; facilitate the procurement, purchase or manufacturing of MCMs and raw materials; activate emergency research and innovation on MCMs; monitor a production inventory of relevant MCMs, materials, equipment and infrastructure; ensure the availability and supply of crisis-relevant MCMs; activate the EU FAB facilities; and release emergency funding for MCMs
Activation of the EU Health Task Force Enhanced Emergency Capacity in Regulation (EC) 851/2004	• Possibility to activate ECDC support to mobilise and deploy the EUHTF Enhanced Emergency Capacity. • The EUHTF can help with prevention, preparedness and response planning, training, and responses to outbreaks, including operational research and after-action reviews. • Activation of all EUHTF Expert Pools.
Activation of the IPCR arrangements	• Activation of the IPCR arrangements to ensure political level coordination the EU'sresponse to the solidarity clause being invoked.
Mobilisation of research funds under Horizon Europe	• Option to mobilise Horizon Europe research funds allowing for procedures tailored to a particular emergency.
Temporary restrictions on travel to the EU in line with Article 21a of Regulation (EU) 2016/399	• Possibility for the Council to impose temporary travel restrictions, including measures such as testing, quarantine and self-isolation.

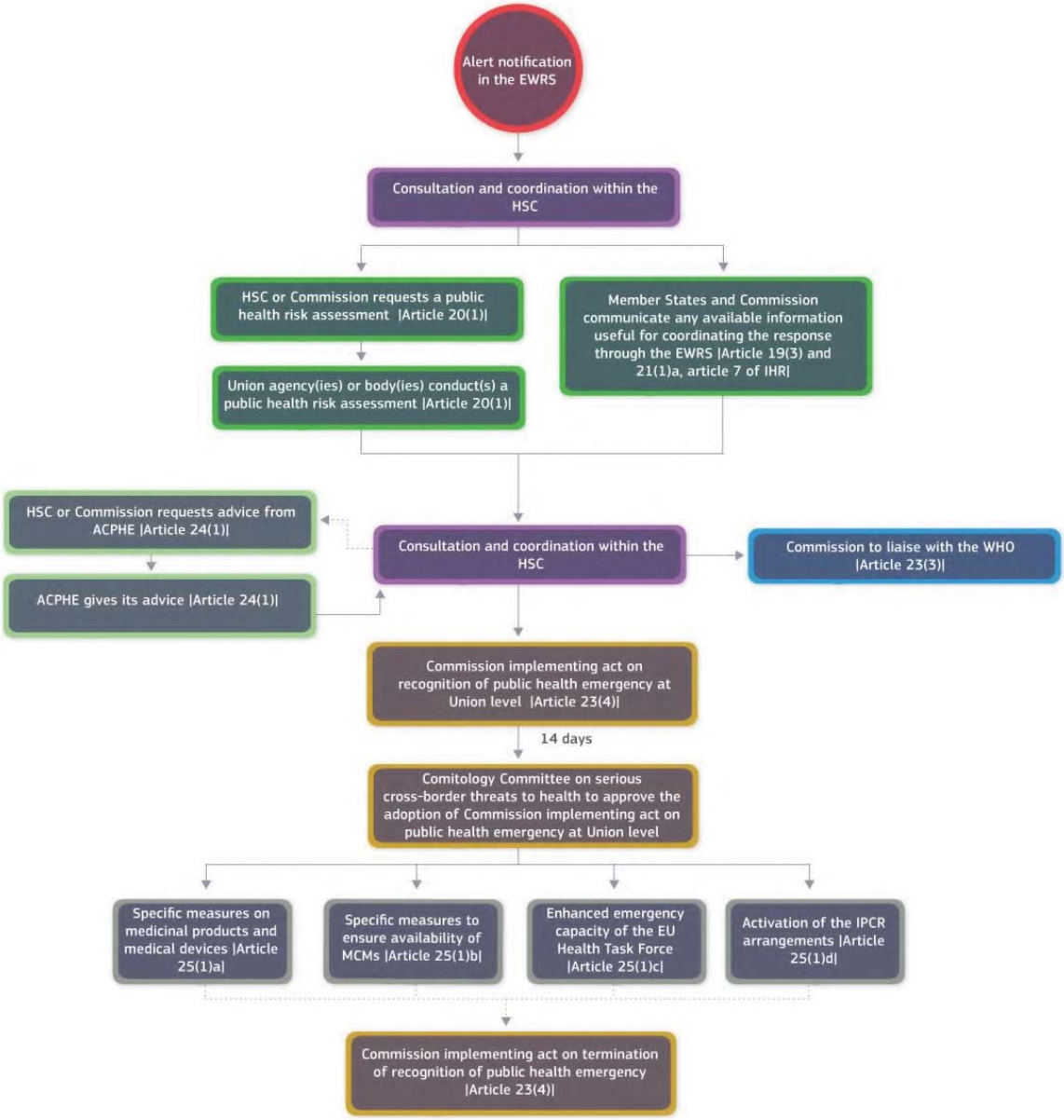


Figure 8. Process to recognise a public health emergency at Union level.

A public health emergency at Union level is formally recognised through the adoption of a Commission implementing act. In urgent and severe situations, the Commission can decide that the implementing act applies immediately and proceed with a Comitology Committee procedure only after the act's adoption.

Recognising a public health emergency at Union level is independent of the decision of WHO's Director-General to determine, based on the views of the IHR Emergency Committee, that an event constitutes a Public Health Emergency of International Concern (PHEIC) ([238]). However, before recognising a public health emergency at

([238]) Article 12 of the IHR 2005 (amended in 2014, 2022 and 2024).

Union level, the Commission must liaise with the WHO to share the Commission's analysis of the situation and to inform it that it intends to adopt such a decision ([239]).

6.7.1. Medicinal products and medical devices

Once a public health emergency is recognised in the EU, the EMA Emergency Task Force (**ETF**) reviews all available data on medicines that could help tackle the situation. The EFT provides scientific advice to developers (including free clinical studies) and supports the organisation of clinical trials in the EU for the most promising medicines, including via discussions on protocols and interactions with the clinital trial coordination mechanism.

Additionally, the ETF supports the authorisation procedures for relevant medicines and can provide scientific recommendations on the use of medicines before they are authorised. This is done in liaison with **EMA's scientific committees, working parties and scientific advisory groups**. The EFT also considers the best use of real-world evidence and cooperates closely with various stakeholders and partners. The EMA may apply accelerated regulatory procedures to approve manufacturing changes that could increase the supply of critical medicines in a crisis.

In a public health emergency at Union level, EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (**MSSG**) draws up a list of critical medicines that need to be monitored for supply issues. This monitoring involves collecting demand and supply forecasts to identify any potential or actual shortages. The group also coordinates activities to prevent shortages or mitigate the effects of such shortages. It also makes recommendations on actions to be taken at EU level to tackle shortages and vulnerabilities in the critical medicines supply chain and issues related to the quality, safety and effectiveness of critical medicines.

To deal with shortages of medical devices, similar activities are carried out by EMA's Executive Steering Group on Shortages of Medical Devices (**MDSSG**).

6.7.2. Activation of the emergency framework for ensuring the supply of crisis-relevant medical countermeasures

When a public health emergency at Union level is recognised and if it is deemed appropriate given the economic situation, the Commission may propose a **draft proposal for a Council regulation** activating the Regulation to ensure the supply of crisis-relevant MCMs ([240]) (Figure 9). The Commission's proposal can take into account advice from the relevant EU governance structures, including EU agencies.

([239]) Article 23(3) of Regulation (EU) 2022/2371.

([240]) Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

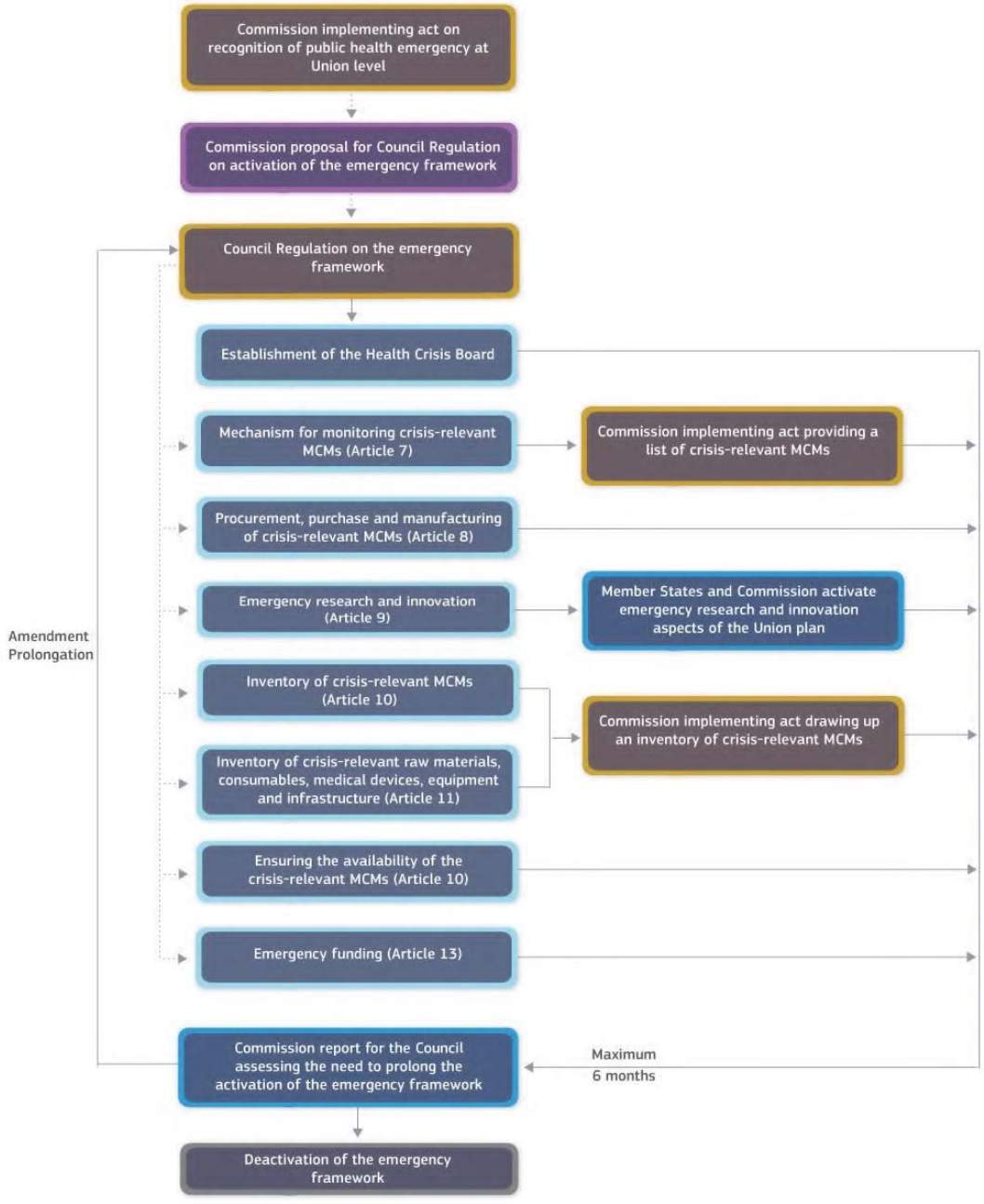


Figure 9. Process to activate the emergency framework for ensuring the supply of crisis-relevant MCMs.

The adoption of a Council regulation activating the emergency framework requires an assessment of the economic situation and the economic implications of the measures to be adopted. This assessment outlines how the public health emergency at Union level is likely to affect the economy, and how the proposed measures can alleviate those effects.

If the emergency framework is activated, the Health Crisis Board will be established (Figure 9). The Health Crisis Board coordinates efforts by the Council, the Commission, the relevant EU bodies, offices and agencies and Member States to ensure the supply of and access to crisis-relevant MCMs.

The Health Crisis Board is co-chaired by the Commission and the Member State holding the rotating presidency of the Council. It is composed of the Commission and one representative from each Member State. The Health Crisis Board will invite an HSC Member State representative, the European Parliament, the relevant EU institutions, bodies or agencies (e.g. the EMA and the ECDC) and a representative from the ACPHE as observers. To improve coordination and information exchange, the Health Crisis Board co-chairs may invite experts with specific expertise to take part as observers in meetings of the Health Crisis Board or its subgroups on an ad hoc basis, based on the agenda. The Health Crisis Board ensures coordination and information exchange with the IPCR, the HSC and the Emergency Response Coordination Centre (ERCC).

Additional measures under the emergency framework for MCMs can be activated at any time through the same procedure as the framework's activation. The activation of the emergency framework for MCMs can be extended for up to six months. To do so, the Commission must submit a report to the Council, analysing, in particular, the public health situation, the economic consequences of the emergency in the EU as a whole and in Member States, and the impact of the measures already put in place. The report must be submitted no later at least three weeks before the date on which the activation of the framework is set to expire. The Council can, upon a proposal from the Commission, decide to prolong the activation of the emergency framework if deemed necessary given the economic situation and the need to ensure a high level of protection of human health.

The emergency framework for MCMs is deactivated either when the Council Regulation activating the framework expires or when the recognition of a public health emergency at Union level is ended.

Depending on which measures of the emergency framework are activated, various outcomes are possible. These include strengthening coordination of MCMs, improving monitoring of MCMs and potentially increasing reporting requirements for those in the supply chain (Table 10).

Table 10. Measures of the emergency framework for ensuring the supply of crisis-relevant MCMs in line with Regulation (EU) 2022/2372	
Emergency framework measure	**Legal effects**
Monitoring crisis-relevant MCMs (Article 7)	• The Commission adops an implementing act setting out a list of crisis-relevant MCMs and raw materials and a template for monitoring their supply and demand. • The Commission gathers additional information on the supply and demand of crisis-relevant MCMs and raw materials.
Procurement, purchase and manufacturing of crisis-relevant MCMs and raw materials (Article 8)	• The Commission, with advice from the Health Crisis Board, proposes an appropriate mechanism to purchase crisis-relevant MCMs and raw materials. • The Commission leads the procurement process. • Participating Member States negotiate the purchasing agreements (opt-out mechanism, simplified procedures, EU-FAB activation).
Emergency research and innovation aspects of the preparedness and response plans and the use of clinical trial networks and data-sharing platforms (Article 9)	• The Commission and Member States activate the emergency research and innovation aspects of the Union plan related to MCMs. • To set up clinical trials, the Commission involves the Emergency Task Force, the Clinical Trial Coordination Mechanism, the European partnership on pandemic preparedness and its research networks and the ECDC.
Inventory of crisis-relevant MCM production and production facilities (Article 10)	• The Commission adopts an implementing act drawing up an inventory and template for monitoring the production capacity and stocks of MCMs. • Producers inform the Commission about production capacity. • The Commission informs Parliament and the Council about production capacity in EU and in non-EU countries.
Inventory of crisis-relevant raw materials, consumables, medical devices, equipment, and infrastructure (Article 11)	• The Commission adopts an implementing act to extend the inventory and template provided for in Article 10 to crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure.
Measures to ensure the availability and supply of crisis-relevant MCMs (Article 12)	• The Commission decides on the reorganisation of supply chains and production lines and the use of existing stocks. • The Commission provides timely financial incentive mechanisms, if feasible.
Emergency funding (Article 13)	• The ESI is activated to finance the required spending to manage the public health emergency.

EU-FAB=Network of ever-warm production capacities for vaccines and therapeutics manufacturing facilities.

6.7.3. Global and EU support for national healthcare systems

In response to local outbreaks of communicable diseases, the **EUHTF,** managed by the ECDC**,** supports Member States and non-EU countries. Support can include field epidemiology, data management, operational research support, infection prevention

and control and logistics expertise ([241]). In a public health emergency at Union level, the Commission, along with at least two Member States, can mobilise the **EUHTF Enhanced Emergency Capacity.** This brings the coordination of the EUHTF under the ECDC and the Commission's control in order to assist the HSC([242]). The mobilisation of the EUHTF can be funded by the EU depending on the situation.

The emergency medical teams (**EMTs**) are a reserve of response teams provided by Member States as part of the European Civil Protection Pool (ECPP), which enable mutual assistance under the UCPM. The EMTs include modules classified on the basis of WHO standards such as specialised care teams.

In addition to the EMTs under the ECPP, the **rescEU EMT** serves as the first pan-European field hospital under the UCPM. It consists of three emergency medical team type 2 (EMT2-type) units and 18 specialised care teams. These teams cover a wide range of services, including intensive care, burn treatment, patient transport, advanced diagnostics, mother and child support, rehabilitation, mental health support, orthopaedic treatment, laboratory services, oxygen supply, telecommunications support, and dialysis. The modular structure of the rescEU EMT makes it flexibile in response to the different needs of local healthcare facilities.

The Global Health Emergency Corps (**GHEC**) coordinated by the WHO is a framework for increasing health emergency workforce capacity in health emergency prevention, preparedness, response and resilience work and a collaborative platform for countries and health emergency networks. The GHEC framework includes several initiatives such as the Global Outbreak Alert and Response Network (GOARN) ([243]). On request, the GOARN can deploy staff and resources to support affected countries in preventing and controlling infectious disease outbreaks and public health emergencies. Several universities, research institutes and public health agencies in Member States and the ECDC are partners of the GOARN ([244]).

([241]) Article 11a of Regulation (EC) No 851/2004.
([242]) Commission Implementing Regulation (EU) 2025/1536 of 29 July 2025 setting out the procedure concerning the mobilisation of the enhanced emergency capacity of the EU Health Task Force (OJ L 2025/1536, 30.7.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/1536/oj).
([243]) WHO, 'Global Health Emergency Corps', WHO website, accessed 3 November 2025, https://www.who.int/emergencies/partners/global-health-emergency-corps.
([244]) Global outbreak alert and response network (GOARN), accessed 3 November 2025, https://goarn.who.int/.

7. PHASE 4: Recovering and learning lessons

Recovering from health crises is essential for restoring health, livelihoods, the economy, the physical, social and cultural environments and assets of disaster-affected communities. Effective recovery helps avoid or minimise the impact of future crises and it is an integral part of health system resilience.

De-escalation of the EU health crisis response occurs when crisis mechanisms or structures are no longer considered necessary and proportionate for effective management and protection of public health. If a public health emergency at Union level was recognised, the de-escalation process would begin as soon as the serious cross-border threat to health no longer endangers public health at EU level and the activated measures are no longer required. After considering any expert opinion from EU agencies or bodies or the ACPHE, the Commission can adopt an implementing act that ends the recognition of the public health emergency.

The Council decision on activating the emergency framework regulation on MCMs expires after the defined timeframe for its activation unless it is prolonged. If the Commission ends the public health emergency at Union level, the emergency framework is also deactivated. The Council can decide to de-escalate the IPCR arrangements to monitoring mode or deactivate them, if they are no longer deemed necessary.

The UCPM is deactivated when there is no longer need for assistance regarding the specific event. The UCPM is deactivated when there is no longer a need for assistance related to the specific event. To follow-up, the Commission draws, manages and disseminates lessons and best practices from UCPM activations through the Lessons Learnt Programme within the Union Civil Protection Knowledge Network ([245]).

In-action and after-action reviews or evaluations can be conducted to capture lessons learned from real-life response to health crises. At EU level, the Commission conducts in-action and after-action reviews to revise the current Union plan based on the lessons learned ([246]). Findings from in-action and after-action reviews can also lead to changes in response strategies and legal frameworks. Moreover, the Commission regularly evaluates Regulation (EU) 2022/2371 on serious cross-border threats and, on the basis of the findings, can adopt proposals to improve the EU legal framework.

After-action reviews or evaluations also play a crucial rule in informing the public on the effectiveness and impact of the crisis response. This process improves accountability and transparency and results in increased trust. To evaluate the EU's crisis response and recovery policy, the Commission can ask for the scientific advice

([245]) Article 13(1)(b) of Decision No 1313/2013/EU.
([246]) Article 5(5) of Regulation (EU) 2022/2371.

of the Scientific Advise Mechanism (SAM) during or after a crisis ([247]). Moreover, the European Court of Auditors is responsible for evaluating how the EU uses its funds and implements its policies, including in a crisis ([248]).

Example of cross-border interregional collaboration: after-action study to assess cross-border cooperation at the Belgian-Dutch-German border

Since its creation in 1976, the Meuse-Rhine Euroregion has built on long-term cross-border cooperation to develop integrated public healthcare schemes, including hospitals and ambulance services (EMRIC: Euregio Meuse-Rhine Incident control and Crisis management). After the COVID-19 pandemic, the region supported the PANDEMRIC study to examine the benefits of regional cooperation in a pandemic or the large-scale outbreak of an infectious disease. Detailed analysis of obstacles to cross-border cooperation on ambulance and intensive care transport was provided and concrete recommendations to tackle the main challenges were made.

Simulation exercises test joint arrangements for governance, capacities and resources using hypothetical scenarios. The Commission is responsible for facilitating these exercises, most notably, to ensure the implementation of the current Union plan with the first exercise scheduled for 2026 ([249]). These exercises aim to assess how effectively the Union plan helps to coordinate responses to cross-border health threats in the EU/EEA. In addition to testing the joint arrangements, the exercises will test and assess the implementation of the One Health, whole-of-government and whole-of-society approaches, along with the cross-border interregional preparedness elements of the Union plan. Based on the lessons learned from these exercises, the Commission reviews the Union plan and amend it as required.

([247]) Scientific Advice Mechanism to the European Commission, 'Strategic crisis management in the EU', SAM website, accessed 3 November 2025, https://scientificadvice.eu/advice/strategic-crisis-management-in-the-eu/.

([248]) European Court of Auditors, *The EU's response to the COVID-19 pandemic – The EU medical agencies generally managed well in unprecedented circumstances*, Special report 12/24, Publications Office of the European Union, Luxembourg, 2024, https://www.eca.europa.eu/en/publications/SR-2024-12.

([249]) Article 5(5) of Regulation (EU) 2022/2371.

ANNEXES

ANNEX 1: Glossary

Term	Definition
All-hazards approach	A comprehensive approach to preparedness and response planning that addresses a wide range of potential emergencies and disasters, where different hazards (outbreaks, cyberattacks, extreme weather events, etc.) could be managed by similar responses from the health system ([250]).
Biosafety	The principles, practices, and containment measures implemented to prevent unintentional exposure to, or release of, biological agents and toxins that may pose risks to human health, agriculture, animals, or the environment ([251]).
Biosecurity	The policies, practices and measures implemented to prevent the loss, theft, misuse, diversion, release or even weaponisation of biological materials, technology or equipment, as well as methods, skills and data related to their handling that may pose risks to human health, agriculture, animals, or the environment ([252]).
Civil protection	Protection of people, the environment and property against all kinds of natural and human-induced disasters. Along with the deployment of forces and equipment in response to an emergency, it also involves the planning and preparation for such events. This includes carrying out risk assessments and developing protection and rescue plans and procedures ([253]).
Collaborative surveillance	The systematic strengthening of capacity and collaboration among diverse stakeholders, both within and beyond the health sector, with the ultimate goal of enhancing public health intelligence and improving the evidence base for decision-making ([254]).
Contact tracing	Measures to identify persons who have been exposed to a source of a serious cross-border health threat, who are at risk of infection, being infectious, or having developed a communicable disease. This identification is carried out through manual or technological means, with the sole objective of rapidly identifying potentially newly infected persons, who may have come into contact with existing cases, in order to reduce further onward transmission ([255]).

([250]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([251]) WHO, *Laboratory biosecurity guidance*, Geneva, 2024, Licence: CC BY-NC-SA 3.0 IGO, https://iris.who.int/bitstream/handle/10665/377754/9789240095113-eng.pdf?sequence=1.

([252]) WHO, *Laboratory biosecurity guidance*, Geneva, 2024, Licence: CC BY-NC-SA 3.0 IGO, https://iris.who.int/bitstream/handle/10665/377754/9789240095113-eng.pdf?sequence=1.

([253]) Access to European Union Law; see EUR-Lex, 'Civil Protection', accessed 3 November 2025, https://eur-lex.europa.eu/EN/legal-content/glossary/civil-protection.html

([254]) WHO, *Defining collaborative surveillance: a core concept for strengthening the global architecture for health emergency preparedness, response, and resilience (HEPR)*, Geneva, 2023, Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/9789240074064. .

([255]) Article 3(4) of Regulation (EU) 2022/2371.

Crisis	A serious, unexpected and often dangerous situation having such a wide-ranging impact or political significance, that it requires timely policy coordination and response at Union level. The situation may affect or threaten human lives, the environment, critical infrastructure or core societal functions and it may be caused by natural or man-made disasters ([256]).
Early warning	The timely and effective provision of information that allows action to be taken to avoid or reduce risks and the adverse impacts of a crisis, and to facilitate preparedness for an effective response ([257]).
Early warning system	A system for the identification of potential threats and crises, mainly through notifications, forecasts and alerts ([258]).
Event-based surveillance	The organised collection, monitoring, assessment and interpretation of mainly unstructured ad hoc information regarding health events or risks, which may represent an acute risk to human health. ([259]).
Food-borne outbreak	An incidence of two or more human cases of the same disease and/or infection, where the cases are linked, or are probably linked, to the same food source ([260]).
Hazard	Anything that has the potential to cause harm to humans, animals, the environment or property. The existence of a hazard does not necessarily mean it poses a threat (for example, a zoonotic pathogen is a hazard because it has the potential to cause disease in humans, but it is not necessarily a threat unless people are exposed to it and transmission occurs) ([261]).
Health crisis	A crisis or serious incident resulting from threats of various origins, including those related to humans, animals, plants, food, biological, chemical, environmental or unknown sources, which impacts public health and requires urgent action by the authorities ([262]).
Health system	Consists of all the organisations, institutions, resources and people whose primary purpose is to improve health ([263]). The Union plan does not differentiate between a health system, a public health system or a system for healthcare services.

([256]) ECDC, *HEPSA – health emergency preparedness self-assessment too: User guide*, Stockholm, 2018, https://www.ecdc.europa.eu/sites/default/files/documents/Technical-Doc-HEPSA-tool-update-dec-18.pdf.

([257]) Article 4(5) of Decision No 1313/2013/EU.

([258]) ECDC, *HEPSA – health emergency preparedness self-assessment too: User guide*, Stockholm, 2018, https://www.ecdc.europa.eu/sites/default/files/documents/Technical-Doc-HEPSA-tool-update-dec-18.pdf.

([259]) WHO, *Early detection, assessment and response to acute public health events: Implementation of early warning and response with a focus on event-based surveillance*, Geneva, 2014, https://www.who.int/publications/i/item/WHO-HSE-GCR-LYO-2014.4.

([260]) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31, ELI: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003L0099).

([261]) ECDC, *Recommendations for preparedness planning for public health threats,* Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([262]) Article 2(3) of Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/522/oj).

([263]) WHO, *Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies*, WHO Document Production Services, Geneva, 2010, ISBN 978 92 4 156405 2, https://iris.who.int/handle/10665/258734.

Incident	An event which has the potential to significantly disrupt, or actually disrupts, the provision of essential services, including national systems safeguarding the rule of law ([264]). Additionally, the detection of biological, chemical or physical hazards in food, feed or humans which might result in or indicate a possible public health risk. This occurs when more than one person is exposed to the same hazard, or when the number of human cases or hazard detections exceeds expectations, and where cases are (probably) linked to the same food or feed source ([265]).
Indicator-based surveillance	The objective-driven, regular, and systematic reporting, collection, monitoring, analysis and interpretation of structured data on communicable disease cases and pathogen isolates ([266]).
Integrated surveillance	A strategy that combines and coordinates different surveillance activities to improve disease detection, prevention, and response, often by linking data and systems across various sources and levels of a health system.
Medical countermeasures (MCMs)	Medicinal products and devices for human use, and other essential goods and services, that are necessary for preparing and responding to serious cross-border health threat ([267]).
One Health	A multi-sectoral approach which recognises the interconnected nature of human health, animal health, and the environment, and that effective actions to tackle threats to health must consider all three dimensions ([268]).
Passenger Locator Form (PLF)	A secure form, completed at the request of public health authorities, that collects passengers' data to assist these authorities in managing a public health events by facilitating the tracing of passengers crossing borders ([269]).
Public health measure	A decision or action aimed at preventing, monitoring or controlling the spread of diseases or contamination in order to combat severe risks to public health or mitigate their impacts ([270]).
Public health risk	The occurrence of a hazard that can pose a risk to human health ([271]).

([264]) Article 2(3) of Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: http://data.europa.eu/eli/dir/2022/2557/oj).

([265]) Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55, ELI: https://eur-lex.europa.eu/eli/dec_impl/2019/300/oj).

([266]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([267]) Article 3(10) of Regulation (EU) 2022/2371.

([268]) Article 3(7) of Regulation (EU) 2022/2371.

([269]) Article 1a "Definitions" of Commission Implementing Decision (EU) 2021/858 of 27 May 2021 amending Implementing Decision (EU) 2017/253 as regards alerts triggered by serious cross-border threats to health and for the contact tracing of passengers identified through Passenger Locator Forms (OJ L 188, 28.5.2021, p. 106, ELI: http://data.europa.eu/eli/dec_impl/2021/858/oj).

([270]) Article 3(9) of Regulation (EU) 2022/2371.

([271]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

Recovery	The medium- and long-term rebuilding and sustainable restoration of critical infrastructure, services, housing, facilities and livelihoods, required for the full functioning of a community or society affected by a disaster. These efforts should align with the principles of sustainable development and the "build back better" approach to make these more resilient and reduce future disaster risks ([272]).
Resilience	The ability of a system to absorb, adapt and recover from disruptions. It involves the capacity to withstand shocks, maintain essential functions during crises and recover to a state of normal functioning in an efficient manner ([273]).
Risk	The likelihood of an adverse event occurring and the associated negative consequences ([274]). It encompasses the potential for loss or disruption and is evaluated as a combination of the magnitude of such loss or disruption and the likelihood of the incident taking place ([275]).
Risk assessment	The overall process of identifying, analysing and evaluating risks ([276]).
Risk analysis	The process of understanding the nature, and determining the level, of risks ([277]).
Risk identification	The process of finding, recognising and describing risks ([278]).
Serious cross-border threat to health	A life-threatening or otherwise serious health hazard of biological, chemical, environmental or unknown origin, that spreads or poses a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level to ensure a high level of human health protection ([279]).
Simulation exercise	A training activity that recreates real-life scenarios to help develop, assess, and test the functional capabilities of emergency systems, procedures and mechanisms to respond to outbreaks and public health emergencies ([280]).
Situational awareness	The continuous process of collecting, analysing, and sharing reliable information to provide decision-makers with a clear and unified common picture of the situation ([281]).

([272]) UN General Assembly, 'Report of the open-ended intergovernmental expert working group on indicators and terminology relating to disaster risk reduction', 1 December 2016, https://www.preventionweb.net/files/50683_oiewgreportenglish.pdf?startDownload=true.

([273]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([274]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([275]) Article 2(6) of the Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: http://data.europa.eu/eli/dir/2022/2557/oj).

([276]) ECDC, *Recommendations for preparedness planning for public health threats*, Stockholm, 2025, https://www.ecdc.europa.eu/sites/default/files/documents/recommendations-preparedness-planning-public-health-threats.pdf.

([277]) ISO 31073:2022(en) Risk management — Vocabulary.

([278]) ISO 31073:2022(en) Risk management — Vocabulary.

([279]) Article 2 and 3 of Regulation (EU) 2022/2371.

([280]) WHO, *WHO Simulation Exercise Manual*, Geneva, 2017, License: CC BY-NC-SA 3.0 IGO, https://iris.who.int/server/api/core/bitstreams/b7f2aa99-15c1-4e95-a0d6-c1006db0493f/content.

([281]) Access to European Union Law; see EUR-Lex, 'Integrated political crisis response (IPCR)', EUR-Lex website, accessed 3 November 2025, https://eur-lex.europa.eu/EN/legal-content/glossary/integrated-political-crisis-response-ipcr.html.

Solidarity	The principle enshrined in the Treaty on the Functioning of the European Union which requires Member States to offer help when another Member State is affected by a crisis and requests assistance ([282]). When a crisis has cross-border impacts, the EU's role is to ensure efficient coordination of measures and facilitate collaboration to foster an effective crisis response.
Surveillance	The systematic ongoing collection, collation and analysis of data for public health purposes, along with the timely dissemination of public health information to facilitate the assessment of needs and to guide effective public health responses ([283]).
Syndromic surveillance	The public health monitoring method that collects and analyses health-related data in real-time relying on clinical observations rather than laboratory-confirmed diagnoses ([284]).
Threat assessment	The overall cross-sectoral process of identifying, analysing and evaluating the origin and magnitude of an emerging threat and its associated risks ([285]).
Vulnerability	The characteristics and circumstances of a community, system or asset that make it susceptible to the damaging effects of a crisis ([286]).
Whole-of-government approach	The whole-of-government approach that brings together all relevant sectors across all levels of administration spanning local, regional, national, EU and international levels to ensure effective prevention, preparedness and response to health crises. While it promotes multisectoral and multidisciplinary collaboration, policy coherence and sharing of resources, it also aims to comprehensively address the interactions and cascading effects of risks and threats ([287]). In this vein, civil-military cooperation is vital for strengthening prevention, preparedness and response to health crises, and it is therefore included among the key sectors considered in the Union plan ([288]).

([282]) Article 222 of the TFEU.
([283]) Article 1 of the IHR 2005 (amended in 2014, 2022 and 2024).
([284]) WHO, *WHO guidance on research methods for health emergency and disaster risk management*, Geneva, revised 2022, Licence: CC BY-NC-SA 3.0 IGO, https://wkc.who.int/our-work/health-emergencies/research-methods/sections-and-chapters.
([285]) European Commission, 'Risk assessment', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-security-and-infectious-diseases/risk-assessment_en.
([286]) ECDC, *HEPSA – health emergency preparedness self-assessment too: User guide*, Stockholm, 2018, https://www.ecdc.europa.eu/sites/default/files/documents/Technical-Doc-HEPSA-tool-update-dec-18.pdf.
([287]) European Commission, 'EU preparedness union strategy', European Commission website, accessed 3 November 2025, https://commission.europa.eu/topics/preparedness_en.
([288]) WHO, *National civil-military health collaboration framework for strengthening health emergency preparedness: WHO guidance document*, Geneva, 2021, License: CC BY-NC-SA 3.0 IGO, https://iris.who.int/handle/10665/343571.

Whole-of-society approach	The whole-of-society approach fosters an inclusive culture of preparedness and resilience ([289]). It acknowledges and promotes the full and effective contributions of all relevant stakeholders to risk prevention and the management of emergencies. Such stakeholders include individuals, families and communities, governments, intergovernmental organisations, the private sector and industry, faith groups, civil society, the media, academia, research organisations and voluntary associations. Whole-of-society action is essential for achieving national unity and global solidarity in managing the risks and impacts of all types of emergencies, overall health security, and the resilience of communities and countries ([290]).
Zoonoses / Zoonotic diseases	Diseases and/or infections that can be transmitted directly or indirectly between animals and humans ([291]).

([289]) European Commission, 'EU preparedness union strategy', European Commission website, accessed 3 November 2025, https://commission.europa.eu/topics/preparedness_en.

([290]) WHO, *Everyone's business: Whole-of-society action to manage health risks and reduce socioeconomic impacts of emergencies and disasters*, Geneva, 2020, ISBN 978-92-4-001508-1, https://www.who.int/publications/i/item/9789240015081.

([291]) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31, ELI: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003L0099).

ANNEX 2: Relevant international agreements and legislation

The following table provides an overview of relevant agreements and legislation in place at international and EU levels to prevent, prepare for and respond to serious cross-border threats to health. The list should not be viewed as exhaustive, and the overviews are not meant to be comprehensive. Neither do they provide a complete overview of the contents of the legislations included in the table. Instead, they offer a summary of the elements of the listed agreements and legislation that are relevant to the Union plan.

Table 11. Key legislation in place at EU and international levels to prevent, prepare for and respond to serious cross-border threats to health.

Name of the legal act/treaty	Description
Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health	The Regulation reinforces prevention, preparedness and response planning and capacities for serious cross-border health threats of biological, chemical, environmental or unknown origin. It establishes the HSC and defines its role across the entire health crisis management cycle. It contains provisions on joint procurement of MCMs, lays down a framework for advanced integrated surveillance in the EU, and defines the EU procedure for early warning of events, public health risk assessments and the declaration of a public health emergency.
Regulation (EU) 2022/123 of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices	The Regulation defines the European Medicines Agency's (EMA) role in preparing for and responding to public health threats. It includes provisions for the EMA to monitor and report on the availability of medicines and medical devices, and offer guidelines and expert support related to the use of medicines.
Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (as amended by Regulation (EU) 2022/2370)	The Regulation lays down the responsibilities of the European Centre for Disease Prevention and Control (ECDC), covering communicable disease prevention and preparedness planning, and risk assessment and support during crisis response. The Regulation also specifies Member States' reporting and notification obligations to the ECDC.
Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level	The Regulation lays down provisions on the activation of the emergency framework, the establishment of a Health Crisis Board, monitoring and safeguarding the supply of crisis-relevant MCMs as well as emergency financial support provided by the Union in the event of a public health threat.
Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC	The Regulation lays down requirements for the design and manufacture of personal protective equipment placed on the Union market.

Regulation (EU) 2023/1322 of the European Parliament and of the Council on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006	The Regulation establishes the European Union Drugs Agency and lays down its general tasks in relation to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues.
Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')	The Regulation lays down rules and measures for the prevention and control of animal diseases transmitted between animals or between animals and humans in the Member States.
Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	The Regulation lays down rules for the placing on the market, making available on the market or putting into service in the European Union of medical devices for human use and their accessories. The Regulation also applies to clinical trials of such medical devices and their accessories.
Regulation (EU) 2017/746 of the European Parliament and of the Council on in-vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	The Regulation lays down rules for the placing on the market, making available on the market or putting into service in the European Union of medical devices for human use intended for in-vitro diagnostics and their accessories. It also applies to performance studies on in-vitro diagnostic medical devices and their accessories.
Regulation (EU) 2016/399 of the European Parliament and of the Council on the rules governing the movement of persons across borders (Schengen Borders Code).	Under this Regulation, persons crossing internal borders between Member States are, in principle, not subject to border controls. Among other things, it contains provisions on border control of persons crossing the external borders of Member States, entry conditions and the temporary reintroduction of border control at internal borders.
Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products	The Regulation improves the functioning of the internal market through the harmonisation of rules on the making available on the market and use of biocidal products, while ensuring a high level of protection of both human and animal health and the environment.
Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (CER Directive)	The CER Directive lays down obligations for Member States to take specific measures to ensure the provision of vital services for maintaining critical societal and economic activities in the internal market. The Member States must adopt national resilience strategies, carry out risk assessments, identify their critical entities in 11 sectors and enable them to fulfil their obligations under the Directive. The Directive also lays down rules on the supervision of critical entities.

Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)	The NIS2 Directive sets out requirements as regards cybersecurity risk-management measures and incident reporting for essential and important entities in 18 critical sectors. The Directive also sets out measures as regards cooperation at national level and at European level, with a view to promoting a high common level of cybersecurity across the Union.
Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism	The Decision defines the UCPM's aim to strengthen EU and Member State cooperation and coordination on disaster prevention, preparedness, and response. The Mechanism promotes Member State solidarity while ensuring national responsibility for disaster management. It outlines rules with general and specific objectives to improve protection and preparedness at Member State and Union levels, facilitate rapid and efficient response and public awareness, enhance scientific knowledge on disasters and step up cross-border cooperation and coordination.
Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act)	The Internal Market Emergency and Resilience Act (IMERA) instrument aims to strengthen the resilience of the EU's single market during emergencies. It establishes a framework for crisis management ensuring the free movement of goods, services, and people, and addresses supply chain disruptions. The IMERA includes measures for transparency, coordination, and swift response during emergencies, enhancing cooperation among EU member states to maintain economic stability and consumer protection.
Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847	The European Health Data Space (EHDS) Regulation establishes a common framework for the use and exchange of personal electronic health data across the EU. It enhances individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes. It fosters a health-specific data environment that supports a single market for digital health services and products. Additionally, the regulation establishes a harmonised legal and technical framework for electronic health record systems, fostering interoperability, innovation, and the smooth functioning of the internal market. This regulation will become applicable in stages by 2031.

Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (recast) (Text with EEA relevance)	The recast Urban Wastewater Treatment Directive objectives include the protection the environment and human health from urban wastewater discharges. The Directive requires Member States set up urban wastewater surveillance, establishing national systems between competent authorities responsible for public health and for urban wastewater management. Member States must develop a list of parameters relevant for public health to be monitored in urban wastewater, and consider the following health parameters for inclusion in such a list: SARS-CoV-2 and its variants, poliovirus, influenza virus and emerging pathogens. Member States are required to monitor relevant health parameters in urban wastewater in the event of a public health emergency. In addition, the Directive requires a monitoring obligation for the presence of antimicrobial resistance (AMR) in urban wastewater.
Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (Text with EEA relevance)	The Seveso III Directive lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection throughout the Union in a consistent and effective manner. It applies to over 12 000 industrial establishments across the EU.
Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)	The Regulation establishes a support framework and procedures for cooperation of Member States on health technologies at Union level. It lays down that any information, data, analysis and other evidence required for the joint clinical assessment of health technologies is submitted by the health technology developer only once at Union level. Moreover, it outlines the common rules and methodologies for the joint clinical assessment of health technologies.
Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products	Regulation (EU) 2017/625 establishes a harmonised framework for official controls across the agri-food chain to ensure compliance with EU rules on food and feed safety, animal health, plant health, and animal welfare. It strengthens cooperation and coordination between Member States and EU institutions to guarantee a high level of protection for human, animal and plant health. The Regulation sets out general and specific objectives to improve the efficiency, uniformity and transparency of controls, enhance risk-based approaches, support rapid and appropriate corrective actions, and reinforce EU capacities through reference laboratories, coordinated audits, and cross-border collaboration.

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC	Directive 2003/99/EC establishes the EU framework for the surveillance, monitoring and reporting of zoonoses, zoonotic agents, and related antimicrobial resistance. It aims to strengthen cooperation between Member States and EU bodies to ensure early detection, consistent data collection and coordinated responses to zoonotic threats. The Directive outlines key duties to improve public health protection, ensure harmonised monitoring across the Union, facilitate rapid information exchange, deepen scientific understanding of zoonotic risks, and enhance preparedness and cross-sector coordination under the One Health approach.
Food Hygiene Package - Regulation (EC) No 852/2004 — General food hygiene and Regulation (EC) No 853/2004 — Hygiene rules for food of animal origin	The Food Hygiene Package lays down comprehensive EU rules governing food hygiene, official controls and responsibilities of food business operators to ensure a high level of food safety throughout the supply chain. It strengthens consistency and cooperation between Member States and the EU by harmonising hygiene requirements, establishing clear risk-based control systems and promoting shared responsibility for safe food production. The framework sets general and specific objectives to protect consumer health, guarantee traceability and transparency, reinforce scientific and risk-based standards, and support effective cross-border coordination and rapid response in case of food safety incidents.
WHO's International Health Regulations, (IHR 2005 amended)	The IHR contains provisions for collaboration, and coordination among States Parties and the WHO to enhance prevention, detection, preparedness, and response efforts to public health events of international concern (PHEIC) including pandemic emergencies, while avoiding unnecessary interference with international traffic and travel. IHR is legally binding on 196 countries, including the 194 WHO Member States, as well as the Holy See and Liechtenstein. All the EU Member States are States Parties to the IHR. Many IHR provisions concern issues that are regulated at EU level requiring coordinated implementation of the IHR across the EU. IHR amendments of 2024 aim to enhance global readiness, surveillance and response to public health emergencies, taking into account COVID-19 lessons, in line with key EU global health priorities.

ANNEX 3. EU Governance structures

EU governance structures, support mechanisms and capacities

Health Security Committee

The **Health Security Committee (HSC)** ([292]) plays an important role in the coordination of prevention, preparedness, and response to cross-border health crises. Established in 2001, the HSC serves as the EU platform where national representatives from Member States convene to exchange information, discuss prevention, preparedness and response to health security matters, consult each other and coordinate on national response measures, including research needs and risk communication messages. The HSC can also adopt joint opinions as well as guidance on prevention, control and response measures during health crises.

The HSC is chaired by the Commission and operates at two working levels: the **senior level group** and **technical working groups** dedicated to specific subjects ([293]). The senior level group meets at least twice a year and engages in strategic and political discussions on cross-border health threats and adopts HSC opinions by consensus. Technical working groups, including a General Working Group, which is the only permanent technical working group of the HSC, meet more regularly to discuss general coordination as well as technical and operational matters. The HSC **liaison officers** are Member State representatives for day-to-day contact with the secretariat of the HSC, which is run by the Commission. Representatives of relevant Union agencies and bodies, as well as the European Parliament and WHO may participate in HSC meetings as observers ([294]). The HSC should ensure regular consultation with public health experts, international organisations such as the North Atlantic Treaty Organization (NATO) and other national and regional centres for disease prevention and control. Where relevant, the HSC also coordinates the response to public health emergencies with the Health Crisis Board, where it is established in accordance with Regulation (EU) 2022/2372.

([292]) Articles 4, 10 and 21 of Regulation (EU) 2022/2371.

([293]) European Commission, 'List of authorities represented in the Health Security Committee', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management/list-authorities-represented-health-security-committee_en.

([294]) European Commission, 'Health Security Committee: Rules of procedure for the Health Security Committee', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management_en#:~:text=Health%20Security%20Committee-,Rules%20of%20procedure,-List%20of%20authorities.

EU Health Task Force

The **EU Health Task Force (EUHTF),** established by the ECDC, is composed by pools of experts ready to provide rapid, on-demand assistance on prevention, preparedness and response to communicable diseases or unknown diseases. The EUHTF can be deployed on field missions or for remote support in an EU Member State or an EEA country or outside the EU based on a request for support ([295]). The EUHTF is managed by the ECDC with guidance from the EUHTF Advisory Group. It collaborates and can complement other assistance mechanisms under the UCPM as well as the Global Outbreak and Response Network (GOARN) mechanism.

The EUHTF is composed of a permanent capacity of ECDC staff members and three pools of experts. ECDC is in charge of the daily operations of the Task Force. One such pool is the ECDC pool involving experts from ECDC. Another pool is the ECDC Fellowship Pool involving experts from the ECDC Fellowship Programme including The European Programme for Intervention Epidemiology Training (EPIET), The European Public Health Microbiology Training Programme (EUPHEM), and affiliated national field epidemiology programmes. While the External Expert Pool is composed of external experts. The Commission, along with at least two Member States, can mobilise the EUHTF Enhanced Emergency Capacity during a public health emergency at Union level with its pools being fully mobilised to assist the HSC during health crises.

Health Crisis Board

Should the Council decide to activate the emergency framework for MCMs in accordance with Regulation (EU) 2022/2372, the **Health Crisis Board** is established to ensure coordination of action by the Council, the Commission, the relevant Union bodies, offices, agencies, and Member States to ensure the supply of and access to crisis-relevant MCMs. The Health Crisis Board supports high-level coordination and decision-making by bringing together representatives from Member States, the Council, the Commission, and relevant Union bodies and agencies ([296]). The Health Crisis Board also coordinates with the Emergency Response Coordination Centre (ERCC) to close operational gaps in accessing crisis-relevant MCMs and their raw materials, and to ensure, where necessary, the corresponding on-site monitoring and coordination tasks. The Health Crisis Board assists and provides guidance to the Commission in the preparation and implementation of measures under Regulation (EU) 2022/2372. The Health Crisis Board may issue opinions.

The Health Crisis Board brings together high-level Member State representatives to expedite the supply of and access to crisis-relevant MCMs and raw materials, and

([295]) Article 11 of Regulation (EC) No 851/2004.
([296]) Article 5 of Regulation (EU) 2022/2372.

ensure the coordination of the relevant tasks ([297]). It coordinates with the HSC ([298]) and with the HERA Board where appropriate ([299]), to effectively respond to the threat.

The Health Crisis Board is co-chaired by the Commission and the Member State holding the rotating presidency of the Council. A representative from the European Parliament and a Member State representative of the HSC are invited to Health Crisis Board meetings as observers. Relevant Union institutions, bodies and agencies, and the ACPHE, may participate as observers. International organisations such as the WHO or NATO, and national authorities, including central purchasing bodies, and healthcare organisations and associations, can also be invited as observers. The Health Crisis Board may establish subgroups or working groups on an ad-hoc basis to support its activities.

EU Civil Protection Mechanism

The **EU Civil Protection Mechanism (UCPM)** ([300]) is the EU's framework for facilitating and strengthening civil protection cooperation between EU Member States and Participating States in preventing, preparing for, and responding to various types of disasters, including non-health crises that are outside the scope of the Union plan. The UCPM is designed to respond to emergencies, accidents, human-induced disasters and natural hazards, such as forest fires, earthquakes and disease outbreaks, that occur either inside or outside the European Union.

Any country hit by a disaster, in Europe and beyond, can request emergency assistance, such as medical teams, equipment and relief supplies, through the UCPM. The Commission plays a key role in coordinating the disaster response and contributing to the transport and/or operational costs of deployments. The UCPM coordinates these efforts via the European Emergency Response Coordination Centre (ERCC), which manages assistance requests and deployments. Under the UCPM framework, the Commission and Member States work together to enhance risk assessments, disaster risk management, and knowledge building and sharing ([301]).

To tackle the challenges of emergency medical response, the EU has developed the **European Civil Protection Pool** (ECPP) ([302]) to improve the operational readiness and quality of the UCPM response to disasters. Member States and UCPM Participating States can commit response capacities on a voluntary basis to the ECPP,

([297]) Article 5 of Regulation (EU) 2022/2372.
([298]) Article 10(3) of Regulation (EU) 2022/2371.
([299]) See also recital 4 of Regulation (EU) 2022/2372.
([300]) Council Decision 2001/792 (Euroatom) of 21 October 2001 establishing a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions (OJ L 297, p. 7, ELI: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32001D0792).
([301]) Union Civil Protection Knowledge Network, accessed 3 November 2025, https://civil-protection-knowledge-network.europa.eu/.
([302]) European Civil Protection and Humanitarian Aid Operations, 'European Civil Protection Pool', European Commission website, accessed 3 November 2025, https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/european-civil-protection-pool_en.

making them available for UCPM response operations. Through the ECPP, the UCPM can mobilise different types of emergency medical support, including emergency medical teams (EMTs).

Additionally, as an integral part of the UCPM, **rescEU** ([303]) was established as a 'last resort' strategic reserve of European disaster response capabilities and stockpiles, fully funded by the EU. rescEU provides a safety net via EU-funded disaster response capabilities to fill resource gaps when national or ECPP assets are insufficient. rescEU strengthens Europe's disaster preparedness by establishing strategic reserves of emergency response capacities, including medical capabilities, such as field hospitals, therapeutics, critical medical supplies, personal protective equipment, and equipment to respond to chemical, biological, radiological, and nuclear emergencies.

Emergency Response Coordination Centre

At the core of the UCPM is the **Emergency Response Coordination Centre (ERCC)** ([304]), the Commission's operations centre that ensures 24/7 operational capacity to facilitate rapid coordination and support during natural hazards and human-induced disasters, delivering assistance such as relief items, expertise, civil protection teams and specialised equipment. The ERCC monitors risks and events as part of its early warning capability, develops situational awareness, supports the development of response capacities and coordinates the provision of aid to affected countries that request assistance. It acts as the main coordination centre by connecting national authorities, EU agencies, and international partners to share information and manage resources in real time. The ERCC can, in the context of the UCPM, respond to health and non-health related emergencies.

In the case of health crises, the ERCC supports joint operations such as deployment of experts, transporting medical equipment, organising patient transfers, and handling logistics and practical arrangements to ensure the smooth delivery of medical aid, including emergency medical teams to support efforts on the ground. The ERCC also coordinates citizens' repatriations as part of EU consular support (e.g. during the COVID-19 pandemic). Finally, the ERCC serves Member States and the EU when the Integrated Political Crisis Response (IPCR) arrangements are activated, or the solidarity clause is invoked.

Scientific Advice Mechanism

The **Scientific Advice Mechanism (SAM)** ([305]) aims to deliver independent, evidence-based scientific advice upon request from the College of Commissioners. Its three-part

([303]) European Civil Protection and Humanitarian Aid Operations, 'RescEU', European Commission website, accessed 3 November 2025, https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/resceu_en.
([304]) Article 7 of Decision (EU) No 1313/2013.
([305]) Scientific Advice Mechanism to the European Commission, accessed 3 November 2025, https://scientificadvice.eu/.

structure is designed to ensure that EU policies are informed by the latest scientific knowledge ([306]). It comprises:

- **The Group of Chief Scientific Advisors**: A panel of eminent scientists providing high-level policy recommendations to the Commissioners.
- Science Advice for Policy by European Academies (**SAPEA**): A consortium that synthesises evidence from over 100 academic institutions and learned societies across Europe.
- **The SAM Secretariat**: A Commission unit that coordinates SAM's activities.

SAM's role includes synthesising evidence by mobilising expert networks during emergencies, and offering strategic policy guidance to ensure EU actions are based on solid scientific evidence. It also engages with stakeholders, fostering dialogue between the scientific community, policymakers, and the public to promote trust and transparency.

Commission Expert Groups

Commission expert groups are consultative bodies established by the Commission to provide advice and expertise on policy initiatives and legislative proposals. These groups, composed of experts from various sectors, play a crucial role in, for example, shaping EU policy and offering input on delegated acts of EU legislative proposals.

HERA Board

In the area of MCMs, the **HERA Board** is composed of the representatives of the Member States and chaired by the Commission, while EU institutions and agencies may participate as observers ([307]). The task of the HERA Board is to assist and advise the Commission in the formulation of strategic decisions concerning Commission's activities on MCMs, contributing to leveraging Member States' resources and capacities. This entails work on the assessment of health threats and intelligence gathering; promoting advanced research and development; addressing market challenges and boosting the Union's open strategic autonomy in production; swift procurement and distribution; increasing stockpiling capacity; and strengthening knowledge and skills in preparedness and response related to MCMs. In view of the information that is exchanged during meetings of the HERA Board, its work can help decision-making on measures at national level to improve the availability of and access to MCMs. The HERA Board meets 3-4 times a year.

([306]) European Commission, 'The Scientific Advice Mechanism – Outputs and impacts', European Commission website, 2 April 2025, accessed 3 November 2025, https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/scientific-advice-mechanism-outputs-and-impacts-2025-04-02_en.

([307]) Commission Decision of 16.9.2021 establishing a Health Emergency Preparedness and Response Authority (HERA), C(2021)6712, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=intcom:C(2021)6712.

The HERA Board is supported by the **HERA Advisory Forum** consisting of Member State experts in the area of health security, research and industrial policy ([308]). The Advisory Forum exchanges technical information and pools knowledge on MCMs to provide scientific knowledge and advice to the HERA Board. As a subgroup of this Forum, a **Joint Industrial Cooperation Forum** has been set up to link Member States and industry representatives in the whole-of-society approach. It complements the Commission's broader intelligence tools and bodies by focusing specifically on the industrial aspects of preparedness. It aims to identify market failures and supply chain dependencies that could limit the production capabilities of relevant MCMs and their raw materials. The **Civil Society Forum** ensures exchanges with academia and civil society and provides recommendations to the Advisory Forum on specific matters related to health crisis preparedness and response, with a focus on MCMCs, and monitors relevant research, industrial and policy developments.

Advisory Committee on Public Health Emergencies

While the main role of the **Advisory Committee on Public Health Emergencies (ACPHE)** ([309]) is to support the Commission in decision making related to the formal recognition and termination of public health emergencies at Union level, and to advise on response measures. While on stand-by, the ACPHE is actively engaging in activities to maintain full readiness.

ACPHE brings together experts from 16 different economic sectors and disciplines including human health, media, transportation, business, veterinary services and academia ([310]). It convenes in person annually for a general assembly, with additional online meetings. These meetings, chaired by the Commission, aim to facilitate collaboration, refine working methods and enhance operational readiness. The ECDC and EMA participate as permanent observers, and the WHO may also participate as an observer.

When requested by the Commission or the HSC, ACPHE advises on whether a threat constitutes a public emergency at Union level and on response measures building on the scientific advice and risk assessments produced by EU agencies, WHO and other relevant agencies or bodies, as appropriate ([311]).

([308]) European Commission, 'HERA Advisory Forum', European Commission website, accessed 31 October 2025, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/hera-advisory-forum_en.

([309]) Register of Commission Expert Groups and Other Similar Entities, 'Advisory Committee on Public Health Emergencies' (ACPHE), European Commission website, accessed 3 November 2025, https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3914.

([310]) Register of Commission Expert Groups and Other Similar Entities, European Commission website, accessed 3 November 2025, https://ec.europa.eu/transparency/expert-groups-register/screen/home?lang=en.

([311]) Article 24 of Regulation (EU) 2022/2371.

Expert Group on Public Health

The **Expert Group on Public Health** ([312]), advises and guides the Commission on public health matters, related to both communicable and non-communicable diseases – as well as health systems. The Commission chairs the expert group, which comprises representatives of Member States' health ministries.

In June 2025 ([313]) a temporary sub-group on serious cross-border threats to health was established, which has been tasked to review draft delegated acts that are prepared by the Commission under the serious cross-border threats to health Regulation.

Expert Group on Health Systems Performance Assessment

The **Expert Group on Health Systems Performance Assessment** ([314]) was set up to provide EU countries with a forum to exchange experiences in the field of health system performance assessment. It aims to support national policymakers by identifying tools and methodologies to develop health system performance assessments. International organisations such as WHO and the OECD proactively contribute to the work of the Expert Group. Each year, it focuses on a specific priority area ([315]), such as quality of care, integrated care, and primary care, for which it develops evidence, frameworks and good practice examples.

Clinical Trials Coordination Mechanism

The **Clinical Trials Coordination Mechanism** advises on clinical trials and their funding, with a focus on identifying and prioritising the most promising medicinal products and clinical studies relevant to EU public health objectives, particularly those that enhance preparedness for and response to public health emergencies. The Clinical Trials Coordination Mechanism is established as a dedicated sub-group of the HERA Board. The group is composed of Member State representatives with technical expertise in clinical research and funding mechanisms.

([312]) Register of Commission Expert Groups and Other Similar Entities, 'Expert group on public health', European Commission website, accessed 3 November 2025, https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3884.

([313]) Register of Commission Expert Groups and Other Similar Entities, 'Sub-group on serious cross-border threats to health', European Commission website, accessed 3 November 2025, https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&fromMainGroup=true&groupID=105492.

([314]) European Commission, 'Health systems performance assessment', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-systems-performance-assessment/overview_en.

([315]) European Commission, 'Priority areas for HSPA', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-systems-performance-assessment/priority-areas-hspa_en.

AMR One Health Network

The **AMR One Health Network (OHN)** brings together government experts from the human health, animal health, and environmental sectors, EU scientific agencies working in One Health domains (ECDC, EMA, ECHA, EEA, and EFSA), international organisations, independent experts, as well as EU-level professional and civil society organisations. The network is coordinated by the Commission. Within the AMR OHN, members collaborate to facilitate mutual learning, share best practices and innovative ideas, build consensus, compare progress made in key areas, and, where necessary, accelerate national efforts to tackle antimicrobial resistance (AMR). It thus plays an important role in the prevention of further spread of AMR and other health crises including those caused by infections with antimicrobial resistant microorganisms.

European Group on Ethics in Science and New Technologies

An independent, multi-disciplinary body appointed by the President of the Commission, the **European Group on Ethics in Science and New Technologies (EGE)** provides the Commission with high quality, independent advice on all aspects of EU legislation and policies, where ethical, societal and fundamental rights issues intersect with the development of science and new technologies. The group's legal mandate is enshrined in Commission Decision 2021/156 and its amending Commission Decision 2024/1997, and it reports to the President of the Commission and to the College of Commissioners as a whole. The EGE has been working on the topics of planetary ethics, democracy, values in policy making, pandemics and crisis management, genome editing, artificial intelligence and the future of work.

The EGE is tasked with integrating ethical considerations into scientific and technological policies at international level, at inter-institutional level in cooperation with the European Parliament and the Council, and within the Commission itself. EGE members are appointed for their expertise in the fields of law, natural and social sciences, philosophy and ethics. This ensures an independent, interdisciplinary perspective on the ethical questions arising from scientific and technological innovation and cross-border crises. The EGE acts as a key reference point for the 27 National Ethics Councils in the EU and further afield within the international ethics framework.

Informal Commission Expert Group on Global Health in Development Cooperation

In the Informal Commission Expert Group on Global Health in Development Cooperation, Member States' experts provide the Commission with advice and expertise on the development, implementation, and assessment of its global health policies. This collaboration aims to stimulate and improve joint EU efforts in the field of global health, with a focus on development cooperation and international partnerships.

Further EU coordination mechanisms and structures

Critical Medicines Alliance

The **Critical Medicines Alliance** (CMA) ([316]), set up in January 2024, is a consultative mechanism that brings together relevant stakeholders from EU Member States, key industries, civil society, and the scientific community. The CMA discusses the industrial challenges contributing to shortages of critical medicines to formulate recommendations for action areas and priorities by and propose solutions to strengthen the supply of critical medicines in the EU.

European Climate and Health Observatory

The **European Climate and Health Observatory** ([317]), a joint initiative between the Commission and the European Environment Agency, aims to support Europe in preparing for and adapting to the impacts of climate change on human health by providing access to relevant information and tools. It fosters information exchange and cooperation between relevant international, European, national, sub-national and non-governmental entities. Some of the Observatory's partners include the ECDC, EFSA and WHO.

Team Europe approach

The **Team Europe approach** brings together the EU, Member States, and financial institutions to pool resources, expertise, and efforts for more effective and impactful support for a coordinated global response to crises and development challenges. Team Europe was initially put in place to ensure a coordinated and comprehensive response between the EU and its Member States to the COVID-19 pandemic and its consequences. The new approach became the backbone of **Global Europe** (the EU's main financial instrument for international cooperation during the 2021–2027 period) and its programming.

European Council

The **Integrated Political Crisis Response (IPCR)** ([318]) of the European Council is the central EU mechanism for rapid and coordinated decision-making at EU political level for major and complex crises. The activation, political control and strategic direction of the IPCR is under the leadership of the Presidency of the Council ([319]). The IPCR provides a flexible framework that can be scaled depending on the severity and

([316]) European Commission, 'Critical Medicines Alliance', European Commission website, accessed 3 November 2025, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en.
([317]) European Climate and Health Observatory, accessed 3 November 2025, https://climate-adapt.eea.europa.eu/en/observatory.
([318]) Council Implementing Decision (EU) 2018/1993.
([319]) Article 222 of the TFEU.

characteristics of the crisis. Once activated, the IPCR has three operational modes including a monitoring mode (for situational awareness); an information sharing mode (for collecting and analysing data); and a full activation mode (for active coordination for the preparation of response measures).

The IPCR arrangements consist of supporting elements that are essential to ensure informed decision-making within the Council and an effective political coordination and collaboration at Union level. It facilitates a common understanding of the crisis through regular **integrated situational awareness and analysis (ISAA)** reports, enables the identification of urgent needs and gaps, and promotes solidarity measures.

The Committee of Permanent Representatives of the Governments of the Member States to the European Union **(Coreper)** has oversight of the implementation of the IPCR arrangements. The Presidency of the Council leads on communication to the public from the IPCR with the support of the informal **Crisis Communicators' Network** composed of communication experts from Members States.

During a public health emergency at Union level, the Health Crisis Board and the HSC work closely with the IPCR mechanism to ensure that political coordination at EU level is supported by public health expertise and operational input from Member States, including by exchanging information and sharing the opinions and guidance of the HSC and the Health Crisis Board ([320]). The ERCC serves the Member States and the EU as central 24/7 contact point when IPCR arrangements are activated, or the solidarity clause is invoked.

Council of the EU

The **Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)** ([321]) is one of the configurations of the Council of the European Union, where government ministers from all EU Member States meet to discuss, negotiate, and adopt policies and legislation. EPSCO brings together health ministers from EU Member States to coordinate and adopt policies that strengthen public health preparedness and response. EPSCO shapes legislation and strategies to improve health systems resilience, cross-border cooperation, and crisis management, ensuring effective EU-wide action during health emergencies. While it does not execute measures directly, EPSCO's decisions guide member states and the Commission in protecting the health of the population and enhancing EU health security frameworks.

([320]) Article 20(1) of Regulation (EU) 2022/2371.

([321]) European Council / Council of the European Union, 'Employment, Social Policy, health and Consumer Affairs Council configuration (EPSCO)', European Council/Council of the European Union website, accessed 3 November 2025, https://www.consilium.europa.eu/en/council-eu/configurations/epsco/.

European Parliament

The European Parliament has several committees, including the **SANT Committee** ([322]). The SANT Committee – formally known as the Subcommittee on Public Health within the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) – was voted by Members of the European Parliament to become a fully-fledged committee in December 2024, thereby assuming responsibility for health policy previously overseen by the broader ENVI committee.

The SANT Committee is responsible for files related to health policy including preparedness and response to health crises, pharmaceuticals and medical devices, mental health and patients' rights, as well as health aspects of bioterrorism, and supervises inter-institutional relations with other health authorities at EU or global level, such as the ECDC and the WHO.

([322]) European Parliament, 'Committee on Public Health', EP website, accessed 3 November 2025, https://www.europarl.europa.eu/committees/en/sant/home/highlights.

ANNEX 4. Relevant EU agencies and bodies

Cross-agency task force on One Health

The **Cross-agency task force on One Health** ([323]) is a collaborative framework established by five EU agencies (ECDC, EMA, EFSA, EEA and ECHA) to address health threats at the human-animal-environment interface. The coordination of the task force will rotate among the agencies with each term will lasting 18 months.

The network promotes a holistic, interdisciplinary approach to preventing and managing risks such as zoonotic diseases, antimicrobial resistance (AMR), food safety threats, and emerging pandemics. The objectives of the cross-agency task force include

- Facilitating strategic coordination of the work of the agencies on implementing One Health;
- Promoting research coordination and One Health-driven agenda setting;
- Providing a forum for the coordination of activities to update, inform and support EU policymakers and other relevant stakeholders in their goal to prioritise One Health, providing scientific advice in key areas such as food safety, global public health, biodiversity, and chemical pollution; and
- Strengthening joint activities and the sharing of information on One Health aspects among the agencies, including by identifying interlinkages, interdependencies and fields of cooperation and providing a platform for the exchange of good practices within individual agencies.

The role of Agencies under Regulation (EU) 2022/2371

Under Regulation (EU) 2022/2371, one or more relevant EU agencies is tasked to carry out joint risk assessments of the potential severity of threats to public health, including possible health measures. These agencies include the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), Europol, the European Medicines Agency (EMA), the European Union Drugs Agency (EUDA), and the European Environment Agency (EEA) and Europol. Each EU agency and body has a specific mandate and role in the prevention, preparedness, and response to health crises which are described below.

([323]) One Health cross-agency task force, 'Strengthening EU agencies' scientific advice on One Health', EFSA website, accessed 31 October 2025, https://www.efsa.europa.eu/sites/default/files/documents/news/one-health-cross-agency-task-force.pdf.

European Centre for Disease Prevention and Control

The **European Centre for Disease Prevention and Control (ECDC)** ([324]) is responsible for identifying, assessing and reporting on current and emerging communicable disease threats to human health, ensuring accessible information dissemination. The mandate of the ECDC was strengthened as part of the European Health Union initiative. The ECDC supports the EU's and Member States' prevention, preparedness and response to serious cross-border health threats through collecting and analysing data on infectious diseases, issuing early warnings, providing risk assessments, monitoring epidemiological data, coordinating disease surveillance, and offering scientific advice on communicable diseases. The ECDC also provides transparent and reliable information on health risks to the public, along with scientific and technical advice, opinions, guidelines, and science-based recommendations.

The ECDC is supported by three interrelated structures that together ensure the effective governance, scientific integrity and coordination between the Centre and EU Member States and EEA countries.

- The **Management Board**, composed of representatives from all Member States, the Commission, and independent experts, oversees the Centre's operational and strategic direction, budget, and work programme. Together, these bodies ensure that the ECDC functions with transparency, accountability, and scientific integrity in its mission to strengthen Europe's defences against infectious disease threats.
- The **Advisory Forum** consists of representatives from the Member States, the Commission, and other stakeholders, providing scientific and strategic advice to ensure that the ECDC's work reflects the needs and priorities of national public health authorities. It fosters cooperation, exchange of best practices, and alignment of prevention efforts across Europe.
- The ECDC Coordinating **Competent Bodies** (CCBs) are national authorities or institutions formally designated by each Member State. A system has been put in place that allows for the interaction between the ECDC and the CCBs in three different levels:
    - High-level relational and coordination interactions between ECDC and the CCBs take place at the level of a **National Coordinator**.
    - Strategic and overarching interactions related to a specific disease group or public health function take place at the level of **National Focal Points**.
    - Technical and operational interactions related to specific areas within the domains of a disease group or public health function take place at the level of the **Operational Contact Points**.

([324]) European Centre for Disease Prevention and Control (ECDC), accessed 3 November 2025, https://www.ecdc.europa.eu/en.

European Medicines Agency

The **European Medicines Agency (EMA)** ([325]) is responsible for scientific evaluation, supervision, and safety monitoring of medicines, and its tasks include facilitating development and access, monitoring safety, and providing information regarding medicines. The mandate of the EMA was strengthened as part of the European Health Union initiative. The EMA monitors events that could lead to emergencies and, in the event of a crisis, manages supply and demand issues for medicines and medical devices while also providing scientific support to the development of high-quality, safe and effective medicines.

The coordination between Member States and the EMA is supported by a governance structure that ensures scientific consistency, regulatory alignment, and efficient decision-making in the area of medicines regulation and safety.

- The EMA **Management Board** is the Agency's primary governing body. It oversees the EMA's strategic direction, budget, and performance, and ensures that the Agency serves the public interest across all Member States.
- The **Network of National Competent Authorities:** Each Member State has a National Competent Authority responsible for regulating medicines at the national level. These authorities work closely with the EMA through committees, working parties, and task forces by sharing data, expertise, and resources as part of a coordinated European medicines regulatory network.
- Several **Scientific Committees**, comprising representatives from Member States' national authorities, are responsible for assessing marketing authorisation applications, safety issues, and other regulatory matters using the pooled expertise from across the EU. Key committees include:
    - Committee for Medicinal Products for Human Use (**CHMP**)
    - Pharmacovigilance Risk Assessment Committee (**PRAC**)
    - Committee for Advanced Therapies (**CAT**)
    - Committee for Orphan Medicinal Products (**COMP**)

EMA and national regulators also take any necessary action to protect patients in the event of safety-related issues. The EMA and ECDC jointly coordinate independent vaccine effectiveness and safety studies through their **Vaccine Monitoring Platform** ([326]).

A collaborative network of the **Heads of Medicines Agencies** from EU Member States and EEA countries works closely with the EMA to harmonise regulatory practices and coordinate responses to EU-wide challenges, such as medicine shortages or public health emergencies.

The EMA **Emergency Task Force (ETF)** was established under the revised pharmaceutical legislation and reinforced during the COVID-19 pandemic. The ETF is

([325]) European Medicines Agency (EMA), accessed 3 November 2025, https://www.ema.europa.eu/en/homepage.
([326]) EMA, 'Vaccine Monitoring Platform', EMA website, accessed 3 November 2025, https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/vaccine-monitoring-platform.

an advisory and support body comprising experts from the EMA and Member States. It is activated during health emergencies to coordinate countries, healthcare providers, and industry stakeholders to address supply chain disruptions and ensure equitable resource distribution. The ETF supports accelerated scientific advice, clinical trial coordination, and rapid evaluation of medicinal products during crises.

While not part of the EMA's formal governance structure, **Steering Committees** are essential operational and planning bodies that help align regulatory actions, share expertise, and support EU-wide coordination across the European medicines regulatory network. Examples of Steering Committees are:

- The **Executive Steering Group on Shortages and Safety of Medicinal Products** (the 'Medicine Shortages Steering Group' - MSSG) addresses issues related to shortages and safety of medicinal products ([327]). When a public health emergency or major event is recognised, the MSSG establishes lists of critical medicines and monitors its supply and demand to identify any potential or actual shortages of these medicines.
- The **Executive Steering Group on Shortages of Medical Devices** (also known as the Medical Device Shortages Steering Group or MDSSG) manages the availability of medical devices during public health emergencies within the EU. It monitors the supply situation, identifies potential or actual shortages, and assesses their impact on healthcare systems and public health.

European Food Safety Authority

The **European Food Safety Authority (EFSA)** ([328]) provides independent scientific advice on risks related to food and feed safety, nutrition, animal health and welfare, plant health, and the environment, while ensuring a high level of consumer protection. In the event of a health crisis, the EFSA supports the response by providing scientific advice, assessing food and feed-related risks, advising on measures to protect public health, and liaising with Member States to ensure coordinated communication messages.

Coordination between EU Member States and the **European Food Safety Authority (EFSA)** is supported by a multi-level governance framework that ensures scientific cooperation, information exchange, and alignment on food safety and related public health issues.

- The **Management Board** is EFSA's main governing body, comprising of representatives appointed by the Commission, the European Parliament, and the Council of the EU, including individuals with expertise in risk assessment, public health, food safety, and of representatives from civil society and food

([327]) Article 3 of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

([328]) European Food Safety Authority (EFSA), accessed 3 November 2025, https://www.efsa.europa.eu/en.

chain interests. It provides overall strategic oversight, approves budgets, and ensures accountability for EFSA's activities.

- The **Advisory Forum** plays a central role in Member State coordination. It comprises of representatives from the national food safety authorities or competent bodies of all EU Member States, along with observers from EEA/EFTA countries and the Commission.
- Each Member State designates a **national EFSA Focal Point** - typically a food safety or public health authority – to act as a liaisons between EFSA and national institutions, helping coordinate communication, data sharing, research collaboration, and capacity building.
- EFSA operates a range of **scientific networks** involving experts from national authorities across Member States. These networks and temporary **working groups** address specific issues such as zoonotic diseases, pesticides, GMOs, foodborne outbreaks, and risk/crisis communication, enabling shared risk assessments and harmonised methodologies.

While the **Chief Veterinary Officers (CVOs)** of EU Member States are not part of EFSA's internal governance, they play a key role in interfacing with EFSA on matters related to animal health and welfare, zoonoses, and other issues at the human-animal-environment interface, which are particularly relevant under the One Health approach.

European Environmental Agency

The **European Environmental Agency (EEA)** ([329]) supports the EU's health crisis governance by providing high-quality, evidence-based data on environmental factors that influence public health. The EEA is responsible for collecting a broad range of environmental data that is then used to develop knowledge to support and inform policy development and implementation. In the event of a health crisis, the EEA contributes by identifying environmental risk factors that can impact public health.

The EEA is supported by three interrelated structures that ensure effective governance, scientific integrity, and strong coordination between the Agency and EU Member States and EEA countries.

- The **Management Board,** composed of representatives from EU Member States and EEA countries the Commission, the European Parliament, and independent experts, plays a key role in overseeing the effective and efficient functioning of the EEA as well as its strategic direction.
- The **Bureau** provides recommendations to the Management Board and takes executive decisions to ensure its effective operation.
- Composed of up to 20 independent scientists, the **Scientific Committee** provided independent scientific advice and expertise in areas key to the agency's work.

([329]) European Environment Agency (EEA), accessed 3 November 2025, https://www.eea.europa.eu/en.

The EEA works in close collaboration with 38 member and cooperating countries through the European Environment Information and Observation Network (Eionet).

European Chemicals Agency

The **European Chemicals Agency (ECHA)** ([330]) is responsible for the implementation of the EU's chemical legislation and policy to ensure the safe use of chemicals, and it plays a vital role in protecting human health and the environment from the risks posed by chemicals. The ECHA supports preparedness and response to health crises by identifying and assessing hazardous substances, providing independent, high-quality scientific opinions and facilitating access to information on chemical safety.

ECHA is supported by the following key structures that ensure effective governance, scientific integrity, and coordination within EU Member States and EEAcountries:

- The **Management Board,** composed of representatives from EU Member States and EEA countries, the Commission, the European Parliament, and key stakeholders, oversees ECHA's strategic and financial planning.
- The **Member State Committee** works to resolve differences of opinion on draft decisions proposed by the Agency and makes proposals for the identification of substances of very high concern.
- Several scientific committees – such as the **Risk Assessment Committee** and the **Committee for Socio-economic Analysis** – work to provide expert opinions on the risks, classification, restriction, and safe use of chemical substances. These committees ensure the scientific quality and independence of ECHA's regulatory decisions and recommendations. The **Biocidal Products Committee (BPC)** – ensures the safe and effective use of biocidal products in the EU, by providing scientific opinions and guidance on the approval of active substances and the authorisation of biocidal products.
- The **Forum for Exchange of Information on Enforcement**, that coordinates a network of Member State competent authorities responsible for enforcement. One of the Forum's Subgroups is the **Biocidal Products Regulation (BPR) Subgroup** which is a network of the enforcement authorities responsible for the BPR.

European Union Drugs Agency

The **European Union Drugs Agency (EUDA)** ([331]) is responsible for providing independent, evidence-based information on drugs, drug use, and their consequences, supporting EU policymaking and contributing to the protection of public health. In the event of a health crisis, the EUDA supports the response by monitoring, providing expertise, assessing drug-related risks, issuing drug alerts, conducting risk and treat assessments, and communicating and advising on response measures.

([330]) European Chemicals Agency (ECHA), accessed 3 November 2025, https://echa.europa.eu/.
([331]) European Union Drugs Agency (EUDA), accessed 3 November 2025, https://www.euda.europa.eu/index_en.

The work of the EUDA is supported by two statutory bodies that advise and assist in the decision-making process of the EUDA:

- The **Management Board,** composed of representatives from EU Member State and EEA countries, the Commission, the European Parliament, and other stakeholders, oversees the Agency's strategic direction and financial planning.
- The **Scientific Committee**, composed of independent experts in fields related to drug use, delivers opinions on scientific matters concerning the activities of the EUDA.

European Union Agency for Law Enforcement Cooperation

The **European Union Agency for Law Enforcement Cooperation (Europol)** ([332]) supports EU Member States in preventing and combating forms of serious cross-border crime and terrorism, including organised crime and forms of crime affecting public health such as the trafficking of counterfeit medicines or the disruption of critical health infrastructure. During health crises, Europol supports Member States, EU institutions and EU agencies and bodies by preventing, detecting, identifying and disrupting threats that would exploit these crises.

Europol is supported by key structures that ensure effective governance, scientific integrity, and coordination within EU Member States and EEA countries:

- The **Management Board,** composed of one representative from each Member State and one representative of the Commission, provides strategic guidance, and oversees the implementation of Europol's tasks.
- The **Member States' Liaison Officers** serve as direct links between Europol and their national law enforcement authorities. They play a key role in real-time information exchange, operational coordination, and joint investigations.
- Europol also works with **Advisory and Oversight Bodies**.

Europol also has in place strategic partnerships and collaborates with the Commission, national Law Enforcement Authorities, and other relevant EU agencies and bodies.

([332]) European Union Agency for Law Enforcement Cooperation (Europol), accessed 3 November 2025, https://www.europol.europa.eu/.

ANNEX 5. Global governance framework

Table 12. Summary of roles and responsibilities of key global stakeholders involved in the prevention, preparedness and response to serious cross-border threats to health.

Name	Role and tasks in prevention, preparedness and response to health crises
World Health Organization (WHO)	The **World Health Organization** (WHO) serves as the leading and coordinating authority on international health initiatives, acting as a fundamental pillar of the multilateral health system, and maintaining a close partnership with the EU. In the area of global health security, the WHO supports the implementation of the WHO emergency preparedness and response framework, established in the IHR (2005 amended) and the WHO Pandemic Agreement, by regular exchanges of information and alerts, consultation, coordination and joint activities. The WHO has access to the Early Waring and Response System (EWRS) and participates regularly as an observer in the HSC meetings. The WHO also works with the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), and the World Organisation for Animal Health (WOAH), all together known as the "Quadripartite organisations". Together, the Quadripartite developed the One Health Joint Plan of Action (2022-2026) ([333]), designed to create sustainable and holistic solutions to better manage threats to human, animal, plant, and environmental health, and to prevent potential future pandemics. The Quadripartite are also working on practical guidance on how to implement the One Health Joint Plan of Action at National Level. The WHO has several networks to respond to public health events, including the Global Outbreak Alert and Response Network (GOARN) ([334]) aiming to rapidly detect, verify, and respond to acute health events with the deployment of experts, specialists and resources to the affected countries to support outbreak investigation and strengthen local response capacity. WHO/Europe (officially titled the WHO Regional Office for Europe), is one of the six WHO regional offices, serving the 53 Member States of the WHO European Region. Preparedness 2.0 is the strategy and action plan on health emergency preparedness, response and resilience of the WHO/Europe ([335]). The Commission collaborates closely with WHO/Europe to ensure readiness and response to health crises affecting the EU ([336]).

([333]) WHO, 'One Health Joint Plan of Action', WHO website, accessed 3 November 2025, https://www.who.int/teams/one-health-initiative/quadripartite-secretariat-for-one-health/one-health-joint-plan-of-action.

([334]) Global outbreak alert and response network (GOARN), accessed 3 November 2025, https://goarn.who.int/.

([335]) WHO, 'Strategy and action plan on health emergency preparedness, response and resilience in the WHO European Region (Preparedness 2.0)', WHO website, accessed 3 November 2025, https://www.who.int/europe/teams/who-health-emergencies-programme-(whe)/preparedness-2.0.

([336]) EU is also involved via EIOS, Epidemic Intelligence from Open Sources; see WHO, 'Epidemic Intelligence from Open Sources', WHO website, accessed 3 November 2025, https://www.who.int/initiatives/eios.

Centres for Disease Control (CDCs)	The ECDC works closely with **Centres for Disease Control (CDCs)** in non-EU countries at bilateral and multilateral levels to address cross-border threats to health and improve global health security. The ECDC has formal agreements with several national CDCs ([337]) ([338]), as well as with continental and regional CDCs in Africa ([339]) and the Caribbean. In 2019, on the initiative of the ECDC, the Network of ECDC focal points in CDCs in third countries was established to exchange information and expertise to respond effectively to threats posed by infectious diseases.
United Nations (UN)	The **United Nations (UN)** ([340]) plays a crucial role in global health security by coordinating international efforts to prevent, detect, and respond to health crises. Through its specialised agencies, such as the WHO, the UN supports countries in strengthening health systems, improving disease surveillance, and managing disease outbreaks. The UN facilitates collaboration between governments, humanitarian organisations, and other stakeholders to ensure rapid and effective response to health crises. The UN has several bodies and agencies involved in the prevention, preparedness, and response to health crises, including: - The **Food and Agriculture Organization of the UN (FAO)** addresses zoonotic disease risks linked to food security and animal health. - The **UN Nations Children's Fund (UNICEF)** which supports child health and promotes vaccination campaigns. - The **UN Development Programme (UNDP)** works on building resilient health systems and supports recovery efforts following crises. - The **UN Environment Programme (UNEP)** tackles environmental factors affecting health, including climate-related health risks. The **International Atomic Energy Agency (IAEA)** ([341]) is an autonomous international organisation withing the UN system and is an intergovernmental forum for scientific and technical cooperation in the nuclear field. It works to ensure that nuclear science and technology is used safely, securely, and for peaceful uses.

([337]) Formal agreements exist with several national CDCs, including with Albania, Australia, Canada, China, Israel, Japan, Kosovo, Mexico, Moldova, Montenegro, Serbia, Singapore, Republic of North Macedonia, South Korea, Thailand, the United Kingdom and the United States.

([338]) ECDC, 'Memoranda of Understanding with CDCs', ECDC website, accessed 3 November 2025, https://www.ecdc.europa.eu/en/about-us/who-we-work/international-activities#read-more.

([339]) ECDC, 'Africa CDC – ECDC Partnership', ECDC website, accessed 20 November 2025, https://www.ecdc.europa.eu/en/about-ecdc/partners-and-networks/international-cooperation/africa-cdc-ecdc-partnership.

([340]) United Nations, 'Health', UN website, accessed 3 November 2025, https://www.un.org/en/global-issues/health. .

([341]) International Atomic Energy Agency (IAEA), accessed 3 November 2025, http://iaea.org/about/overview.

Global Health Security Initiative (GHSI)	The **Global Health Security Initiative (GHSI)** ([342]) is an informal, international partnership established to strengthen collective preparedness and response to threats posed by chemical, biological, radiological, nuclear, and pandemic influenza hazards. Founded in 2001, GHSI brings together a network of countries and organisations, such as the WHO, to coordinate strategies, share information, and improve capabilities for health emergency management. Its focus is to enhance global health security by fostering collaboration on risk assessment, early detection, and response to health crises, thereby reducing the impact of infectious disease outbreaks and other public health emergencies worldwide. The GHSI has several technical and scientific working groups including the Chemical Events Working Group, the Biological Threats Working Group, the Radio-Nuclear Threats Working Group, and the Pandemic Respiratory Viruses Working Group.
World Organisation for Animal Health (WOAH)	The WOAH is an intergovernmental organisation that has been working to improve animal health since 1924. The WOAH monitors the emergence and development of animal diseases in terrestrial and aquatic animals, either domestic or wild. The WOAH also ensures its Members have the tools, capacity and support they need to strengthen their Veterinary Services and respond to the threats posed by animal diseases.
United Nations Office for Disarmament Affairs (UNODA)	The Office for Disarmament Affairs supports multilateral efforts to achieve general and complete disarmament under strict and effective international control. The Office also works to address the humanitarian impact of major conventional weapons and emerging weapon technologies, such as autonomous weapons. The Biological Weapons Convention under the UNODA prohibits the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons.
Organisation for the Prohibition of Chemical Weapons (OPCW)	As the implementing body for the Chemical Weapons Convention, the Organisation for the Prohibition of Chemical Weapons (OPCW), with its 193 Member States, oversees the global endeavour to permanently and verifiably eliminate chemical weapons. The OPCW is not a United Nations (UN) organisation, however, the OPCW has a close working relationship with the UN. At the request of the UN Secretary-General, the OPCW has a mandate to closely cooperate with the UN by placing its resources at the Secretary-General's disposal for investigating alleged uses of chemical weapons.
Group of 7 (G7)	The G7 is an informal grouping of the world's seven most advanced economies, plus the EU, to discuss global economic and geopolitical issues. Under the G7, the Global Partnership against the Spread of Weapons and Materials of Mass Destructions aims to prevent the proliferation of chemical, biological, radiological, and nuclear (CBRN) weapons and related materials.
Group of 20 (G20)	The G20 is an international forum for economic cooperation, comprising 19 member counties and the EU, together representing a vast majority of the global GDP, international trade, and world's population. In addition to economic and financial matters, the G20 also discusses socio-economic issues, such as health.
Organisation for Economic Co-operation and Development (OECD)	The OECD is an international organisation that works to build better policies for better lives. The OECD serves as a forum and knowledge hub for data, analysis and best practices in public policy.

([342]) Global Health Security Initiative, accessed 3 November 2025, https://ghsi.ca/.

North Atlantic Treaty Organization (NATO)	NATO is a defensive alliance with its members committed to safeguarding the freedom and security of all Allies, against all threats. NATO works through political and military means. The EU is a partner to NATO.
Global research collaboration for infectious disease preparedness (GloPID-R)	The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) is a network of research funding organisations in the area of infectious disease preparedness research. The network coordinates funding organisations globally to enhance research preparedness and facilitate an effective and rapid response to epidemic or pandemic infectious diseases. The GloPID-R secretariat is funded through the Horizon R&I framework programme.
Global Polio Eradication Initiative	The Global Polio Eradication Initiative (GPEI) is a public-private partnership with the goal of eradicating the highly infectious viral childhood disease poliomyelitis. It is made up of national governments and the six GPEI core partners (the WHO, Rotary International, the US Centers for Disease Control and Prevention, UNICEF, the Gates Foundation, and Gavi, the Vaccine Alliance).
Gavi, the Vaccine Alliance	The Gavi is an international institution aiming to save lives and protect people's health by increasing equitable and sustainable use of vaccines. Gavi works to introduce and scale up vaccines, strengthen health systems to increase equity in immunisation, improve sustainability of immunisation programmes and to ensure healthy markets for vaccines and related products.
The Global Fund	The Global Fund is a worldwide partnership to defeat AIDS, tuberculosis (TB) and malaria and ensure a healthier, safer and more equitable future for all. It is the world's largest multilateral funder of global health grants in low- and middle-income countries.
Coalition for Epidemic Preparedness Innovations (CEPI)	The CEPI is a global partnership working to accelerate the development of vaccines and other biological countermeasures against epidemic and pandemic threats.
Pandemic Fund	The Pandemic Fund is a multilateral financing mechanism dedicated exclusively to strengthening critical pandemic prevention, preparedness, and response capacities and capabilities of low- and middle-income countries through investments and technical support at the national, regional, and global levels
Transatlantic Taskforce on Antimicrobial Resistance (TATFAR)	The Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) ([343]) was established in 2009 following a US-EU summit to address the urgent global challenge of AMR. It is a collaborative effort between the US, Canada, the European Union, Norway, and the United Kingdom, focusing on improving the appropriate use of antimicrobials, enhancing AMR surveillance, preventing drug-resistant infections, and fostering the development of new antimicrobial drugs.

([343]) Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), accessed 3 November 2025, https://www.cdc.gov/tatfar/php/about/index.html.

ANNEX 6: Overview of EU-funded actions, grants, and projects related to health crises

The Commission has several funding instruments that contribute to preparedness, prevention and response to health crises by addressing several key areas such as strengthening surveillance, laboratory capacity, advancing knowledge on surveillance, and research and development of MCMs. Below is a summary of some of these instruments.

EU4Health

The EU4Health Programme ([344]) is a funding instrument within the Multiannual Financial Framework (2021–2017), is designed to strengthen health systems and preparedness, also addressing the weaknesses in health systems revealed by the COVID-19 pandemic. It is the largest EU health programme to date, with an indicative budget of EUR 4.4 billion over seven years (2021–2027). The programme aims to improve and foster health in the Union, protect people from serious cross-border threats to health, improve medicinal products, medical devices and crisis-relevant products, and strengthen health systems. The EU4Health Programme is implemented through annual Work Programmes that support a broad range of actions, including a strand on crisis preparedness. The Commission is responsible for the management of the EU4Health Programme and is supported by the European Health and Digital Executive Agency (HaDEA) ([345]) to implement actions under the programme.

Horizon Europe

Horizon Europe ([346]) is the EU's flagship funding programme for research and innovation. The programme facilitates collaboration and strengthens the impact of research and innovation in developing, supporting and implementing EU policies while tackling global challenges and strengthening the EU industrial competitiveness. It supports the creation and better diffusion of scientific knowledge and new technologies. The indicative funding amount for Horizon Europe for 2021–2027 is EUR 93.5 billion. Horizon Europe's Pillar II is organised into clusters, including cluster focused on health, which aims to improve and protect the health and well-being of citizens of all ages. This cluster seeks to generate new knowledge, develop innovative solutions, and incorporate a gender perspective, where relevant, to prevent, diagnose,

([344]) European Commission, 'EU4Health', European Commission website, accessed 3 November 2025, https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en.

([345]) European Health and Digital Executive Agency, 'Funded projects: Overview of all funded projects under the Horizon Europe – Health programme', European Commission website, accessed 3 November 2025, https://hadea.ec.europa.eu/programmes/horizon-europe/health/funded-projects_en..

([346]) European Commission, 'Horizon Europe', European Commission website, accessed 3 November 2025, https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en.

monitor, treat and cure diseases. The Commission is responsible for the management of the activities under this cluster of Horizon Europe and is supported by HaDEA in the implementation of those actions.

Union Civil Protection Mechanism

The Union Civil Protection Mechanism funds both multi-country and single-country capacity-building projects, exercises, and technical support actions, including those related to emergency health response. Funding sources and information on selected projects can be found on the UCPM Knowledge Network ([347]).

Recovery and Resilience Facility

The Recovery and Resilience Facility ([348]) is the centrepiece of **NextGenerationEU** ([349]), a temporary recovery instrument designed to support Europe's economic recovery from the COVID-19 pandemic and to build a greener, more digital and more resilient future. Within the 2021–2026 period, the **Recovery and Resilience Facility (RRF)** offers grants and loans to support reforms and investments in EU Member States. RRF funds are provided to Member States in accordance with their national Recovery and Resilience plans, which serve as roadmaps for reforms and investments aimed at making EU economies greener, more digital and more resilient.

Cohesion Policy Funds

Cohesion policy is the European Union's primary investment policy, aimed at reducing disparities and enhancing economic, social, and territorial cohesion. In this regard, EU Cohesion policy supports investment in health services and infrastructure as they are critical to regional and territorial development, social inclusion, and competitiveness. Its investments play a vital role in supporting Member States and regions in facilitating equal access to health, social and long-term care and creating more effective and resilient healthcare systems. This includes enhancing preparedness and adaptability of the healthcare sector, ensuring that systems are equipped to manage emerging health challenges effectively.

While the European Social Fund Plus (ESF+) supports investments in services, human capital and social inclusion, the European Regional Development Fund (ERDF) focuses on investments in infrastructure, equipment and cooperation across borders in health. For the 2021–2027 programming period, Member States have allocated EUR 7.3 billion from the ERDF and across national, regional and Interreg programmes. Examples of ERDF investments include health infrastructure and equipment for

([347]) UCPM Knowledge Network, accessed 3 November 2025, https://civil-protection-knowledge-network.europa.eu.

([348]) European Commission, 'The Recovery and Resilience Facility', European Commission website, accessed 3 November 2025, https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility_en.

([349]) NextGenerationEU, accessed 3 November 2025, https://next-generation-eu.europa.eu/index_en.

community-based, primary, secondary, tertiary and hospital care, digitalisation of health services, mobile health units, and cross-border service provision.

As part of the Cohesion policy mid-term review, new specific objectives prioritising civil preparedness were introduced. This would allow to address investments in healthcare infrastructure, such as (field) hospitals and medical emergency infrastructure and equipment, stockpiling and cybersecurity.

InvestEU Programme

The InvestEU programme provides the European Union with crucial long-term funding by leveraging private and public funds in support of Europe's sustainable recovery. It helps to mobilise private investments for the EU's top policy priorities, such as the green, and digital transition, innovation and social investments and skills.

Under InvestEU, the HERA Invest, is an EU-backed financing initiative launched by the Commission and the European Investment Bank (EIB) which aims to support small and mid-sized companies (SMEs) developing MCMs against major health threats such as:

- Pathogens with pandemic or epidemic potential
- Chemical, biological, radiological, and nuclear (CBRN) threats
- Antimicrobial resistance

The initiative provides venture loans covering up to 50% of project costs, helping bridge funding gaps and stimulate innovation in health emergency preparedness and response across Europe.

So far, three European SMEs have been provided with a loan by the EIB. These are Fabentech, developing broad-spectrum therapeutics against biological threats (notably toxins), SNIPR Biome developing CRISPR-based antibacterial therapies targeting antimicrobial resistance (AMR) and Leyden Labs, developing intranasal antibody therapies for respiratory viruses.

Examples of EU-funded actions, grants, and projects under EU4Health and Horizon Europe

The following sections outline some illustrative examples of actions, grants, and projects specifically funded under the EU4Health and Horizon Europe programmes. Information presented is indicative, subject to availability of resources and adoption of the annual budget and work programmes. Moreover, it does not prejudge the outcome of the negotiations on the Multiannual Financial Framework.

Surveillance

Action	Description	EU contribution (EUR)	Period
Direct grants to Member States' authorities: Union and national surveillance systems (Joint Action UNITED4Surveillance)	This joint action aims to support Member States and the Union in the implementation of digitalised, integrated surveillance systems at Union and national level, to ensure better detection of early signals for accurate risk assessment and response.	7 000 000	2023-2026
Setting up a coordinated surveillance under the One Health approach (OH4Surveillance)	OH4Surveillance supports the participating countries to set up and scale up One Health surveillance to priority pathogens in an efficient, coordinated and collaborative manner. The scope of the project is limited to One Health surveillance aiming to protect public health through the early detection of emerging and re-emerging zoonotic pathogens in animals and environment.	10 000 000 15 000 000	2024-2026 2027-2028
Direct Grants to Member States for improving national integrated surveillance systems	The aim of the direct grant is to support Member States to improve their surveillance system in line with and building on the outcomes of the JA UNITED4Surveillance. The activities that could be carried out towards scaling up national surveillance systems aim to facilitate the required national capacity building for the development of interoperable, reliable and modern national surveillance systems. The action will be driven by digital transformation, making use of relevant available health data and public health research results.	83 400 000	2025-2030
Direct Grants to Member States' authorities for enhancing Whole Genome Sequencing and/or RT-PCR national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats	Set of several direct grants covering over 20 EU Member States and neighbouring countries for enhancing WGS and/or RT-PCR national infrastructures and capacities. Depending on pre-existing capabilities, these grants are covering the creating of new national laboratory infrastructure both at central, regional, and local level, against HERA's priority pathogens and/or AMR.	53 800 000	2022-2027

Laboratories

Action	Description	EU contribution (EUR)	Period
EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The purpose of this application is to set up and coordinate a network of national reference laboratories for the two diseases. This is achieved through establishment of a EURL designated for pertussis and diphtheria, and by maintaining the reference laboratory functions. This project will focus to enhance protection and preparedness against pertussis and diphtheria in Europe.	2 625 000	2025-2031
EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The EU funded project on EURL-PH-VBV provides comprehensive scientific and technical support on detection and characterisation methods, interpretation of results in line with EU laboratory case definitions, laboratory surveillance, outbreak preparedness, and response strategies. A key focus of the EURL-PH-VBV is to promote uniformity in laboratory testing and activities across the EU to ensure the generation of standardised data.	3 500 000	2025-2031
EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The support will be delivered in the field of AMR in bacteria of public health relevance, and relate to reference diagnostics, reference material resources, external quality assessments, scientific advice and technical assistance, collaboration and research, monitoring, alert and support in outbreak response to bacteria resistant to antimicrobials and training. The capacity building activities are the overarching goal of this endeavour is to assess, develop and improve strategies for prevention and control of AMR in target priority pathogens.	6 975 000	2025-2031
EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The main objective of the EURL-PH-LEGI is to promote best practices and support EU Member States and EEA countries in the field of diagnosing, testing, and typing methods for Legionella. This aims to ensure reliable and comparable data, strengthen laboratory capacities, and improve the surveillance, notification, and reporting of cases.	2 275 000	2025-2031
EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The EURL-PH-ERZV consortium provides scientific and technical expertise on high-risk viral pathogens of public health concern, including poxviruses, arenaviruses, hantaviruses, filoviruses, henipaviruses, lyssaviruses, and novel emerging viruses such as disease X. These pathogens pose significant challenges for diagnostics, surveillance, and outbreak management.	3 500 000	2025-2031

EU Reference Laboratory for public health in the field of Antimicrobial Resistance (AMR) in bacteria	The EURL aims to strengthen national expert laboratories' capacities and to support a uniform surveillance, notification and reporting of diseases or the causative bacterial agents. By promoting good practice and alignment on diagnostics in the network member laboratories, an efficient, rapid and coordinated response according to the ECDC surveillance reporting system will be enhanced.	2 893 000	2025-2031
Delivering a Unified Research Alliance of Biomedical and public health Laboratories against Epidemics (DURABLE)	DURABLE aims to provide high-quality scientific information in record time to support Commission's decision-making in preparing for and responding to cross-border health threats and assessing the impact of countermeasures. DURABLE will coordinate a global collaboration, from pathogen detection, evolutionary analysis and threat characterisation, with One Health approach, to data and information collection and sharing, for optimal threat response. DURABLE is a unique multidisciplinary consortium with complementary expertise to meet this challenge and build productive interactions with the Commission and other stakeholders.	25 000 000	2023-2027

Health system preparedness and resilience

Action	Description	EU contribution (EUR)	Period
European Partnership for pandemic preparedness (BE READY Partnership)	BE READY Partnership aims to enhance the EU's preparedness for predicting and responding to emerging infectious health threats. This will be achieved by improving the coordination of funding for research and innovation at the EU, national, and regional levels, directed towards common objectives outlined in an agreed-upon Strategic Research and Innovation Agenda, and by strengthening the readiness of the research ecosystem, including networks of "ever-warm" research sites and infrastructures.	120 000 000	2026-2032
Joint Action HEROES	The objective of this action is to improve health workforce planning for long-term forecasting of the demand for health workforce and use of health workforce planning to address structural challenges with shortages of professionals and support modernisation of healthcare delivery.	7 000 000	2023-2026

Nursing Action	The aim of this action is to increase the supply of nurses and improve retention in the EU Member States. Over 36 months, it will develop evidence-based strategies for recruitment and retention, scale up mentorship programmes, promote nurses' health and well-being, support safe staffing practices, and enhance the integration of digital solutions into nursing workflows.	1 300 000	2025-2027
Seven Actions to provide training for health workforce, including digital skills	The objective is to support training initiatives for clinical and non-clinical staff with a focus on digital skills and other relevant skills needed for surge capacity in crises and for the transformation of health systems, reaching 20.000 health professionals	16 000 000	2023-2026
Joint Action CIRCE	The objective of this action is to transfer good practices in primary care among Member States. Specifically, six good practices coming from four Member States (Belgium, Portugal, Slovenia, and Spain) will be transferred to 40 new implementation sites in 12 Member States. Strong primary care is a cornerstone of accessible, effective and resilient health systems.	10 000 000	2023-2026
Improving access to healthcare for refugees and people displaced from Ukraine benefitting of temporary protection in Member States	Two complementary actions were funded to address this challenge. The first one supported Bulgaria, Czechia, Estonia, Hungary, Latvia, Lithuania, Moldova, Poland, Romania, and Slovakia in reducing health inequalities, strengthening health systems, improving access for refugees and displaced persons from Ukraine, and integrating displaced health workers. The second one used the resilience test methodology for migration in the health systems of Latvia, Czechia, Romania, Poland, and Moldova.		

Vaccination

Action	Description	EU contribution (EUR)	Period
Vax-Action: tackling effectively vaccine hesitancy in Europe (VAX-Action)	The project aims to support EU Member States and relevant stakeholders to implement a combination of tailored, evidence-based interventions aimed to reduce vaccine hesitancy. It addresses the need to understand what type of interventions are now available, which are effective, how to translate effective interventions to new contexts, and to explain the unsuccessful ones to create opportunities for learning and redesign.	1 400 000	2023-2026

Antimicrobial resistance

Action	Description	EU contribution (EUR)	Period
Joint Action on Antimicrobial Resistance and Health Associated Infections 2 (EU-JAMRAI 2)	Following the 2017 EU One Health Action Plan against AMR to make Europe a best practice region and the first European Joint Action (JA) on AMR and Healthcare-Associated Infections (EU-JAMRAI), this new JA, EU-JAMRAI 2, will support Member States/Associated Countries (MS/AC) in their efforts to develop and update their National Action Plan (NAP) on AMR.	50 000 000	2024-2028
EU One Health AMR Partnership (EUP OH AMR)	The European partnership on One Health AMR is one of the key partnerships that has been identified by the EC within the framework of the Horizon Europe programme to support R&I to respond to the challenges of AMR. EUP OH AMR (2025-2035) will contribute to the objectives of the EU Action Plan on antimicrobial resistance (AMR), to combat the critical societal challenge of AMR and reduce the burden of AMR by: • Enhancing European and global synergy, collaboration between the different One Health sectors and multiple disciplines, and alignment of strategic OH AMR R&I and policies to break silos; • Boosting AMR R&I to generate knowledge and develop solutions to prevent and tackle AMR; • Facilitating knowledge valorisation of R&I into products, policy and practice.	75 000 000	2025-2035

Vector-borne diseases

Action	Description	EU contribution (EUR)	Period
Sterile Insect Technique (SIT) approach as tool to suppress yellow fever mosquito (Aedes aegypti) on Cyprus and to build capacity for the use of this vector control technique in the Union	The project aims to contribute to the work of the Ministry of Health of Cyprus to train, supervise laboratory technicians for the production of Aedes aegypti mosquitos to be used in Cyprus to suppress Aedes aegypti.	500 000	2024-2027

Medical countermeasures

Action	Description	EU contribution (EUR)	Period
Ever-warm facilities (EU FAB) for vaccines and therapeutics production	The EU FAB network comprises vaccine producers in the EU (Belgium, Ireland, the Netherlands, Spain). The actions of the network will close the gap between manufacturing and scaling up of vaccine production, while ensuring the capacity of the industry to produce life-saving medicines. EU FAB will reserve manufacturing capacities for the EU to produce vaccines in case of public health emergencies.	160 000 000 (per year)	2023-2027
Joint action on comprehensive and sustainable strategic stockpiles of medical countermeasures used in crisis	This Joint Action (JA Stockpile) will contribute to better preparedness against serious cross-border threats to health, more sustainable stockpiles of MCMs, faster distribution, deployment and dispensing of MCMs, better collaboration between Member States, better evidence-base for future proposals on stockpiling of MCMs and thus strengthening of European independence in crisis.	10 000 000	2025-2028
European Vaccines Hub for Pandemic Readiness (EVH)	To ensure Europe's vaccines readiness and responsiveness to pandemics, this project will create the European Vaccine Hub (EVH) by aligning existing nationally funded vaccine R&D investments into a collaborative network for the end-to-end vaccine delivery.	102 000 000	2025-2029

Wastewater surveillance

Action	Description
Joint Action EU-Wastewater Integrated Surveillance for Public Health (EU-WISH)	EU-WISH brings together 25 EU Member States and EEA countriess and Ukraine to strengthen national capacities for wastewater surveillance for public health. It will map priority targets for wastewater-bases surveillance and define, harmonise and expand wastewater monitoring strategies, technical procedures and relevant operational approaches including effective, easily interpretable, and actionable communication of wastewater-bases surveillance parameters.
Global Consortium for Wastewater and Environmental Surveillance for Public Health (GLOWACON)	GLOWACON, the Global Consortium for Wastewater and Environmental Surveillance for Public Health brings together diverse partners from across sectors and countries to share knowledge, expertise, and resources, with the goal of creating a safer and healthier world for all.GLOWACON's mission is to promote the institutionalisation of wastewater and environmental surveillance within public health systems, and to develop a global sentinel system for epidemic outbreaks. This system will enable early threat detection, prevention, and real-time monitoring, supporting public health decision-making and pandemic preparedness. By building on existing local, national, and regional efforts, and governed by a mechanism agreed upon by participating stakeholders, the sentinel system creates a voluntary network of data sharing that transcends borders and time zones to detect and respond to health threats more quickly and effectively, saving lives and protecting communities.
EU Wastewater Observatory for Public Health	The European Wastewater Surveillance Dashboard, an innovative tool designed to track the spread of infectious diseases by analysing wastewater across Europe. this platform integrates data from various sources throughout Europe, combining near real-time wastewater monitoring with existing national and research-based dashboards. By providing early warnings for emerging pathogens and health crises, the dashboard facilitates rapid responses to disease outbreaks. This capability reduces the time it takes for health systems to react, ultimately protecting citizens across the EU.
The European Super-Sites for Wastewater Surveillance	The European Super-Sites are a network of strategically located sites across the European Union and other areas of EU-interest, designed to enhance public health surveillance by monitoring wastewater for pathogens and other health indicators. They are integrated into the EU Wastewater Observatory for Public Health. Positioned near key transportation nodes, including airports and train stations or at other locations such as hospitals, these sites provide critical epidemiological insights into the presence and spread of pathogens, serving as early warning systems for new threats entering through international travel. The main purpose of the European Super-Sites is to deliver timely and accurate data to health authorities, aiding in public health decision-making. They collaborate with the aviation industry to include samples from aircraft and airfields, thus broadening the scope of surveillance.
Support strategies, capacity and data for global wastewater and environmental surveillance	Collaboration with the WHO and UNEP to develop wastewater and environmental surveillance strategies, building capacity (especially in low-resource and strategic settings), and foster transparent information exchange.

ANNEX 7: Digital platforms for public health intelligence in the EU/EEA

Name (abbreviation)	Purpose
Digital European Exchange Platform (DEEP)	Platform of the Commission to collect and connect data from various wastewater surveillance activities and transform the data into actionable information for the public.
Epidemic Intelligence from Open Sources tool (EIOS) ([350])	Monitoring open sources of information, building on a long-standing collaboration between the WHO and the Commission. The EIOS initiative is a WHO programme that supports countries and partners in early detection of public health threats by using open-source data, improving analytical capacities, and providing better tools and insights for decision-making. EIOS acts as an early detection platform, with a significant portion of public health events being first identified through the system before official notification.
European surveillance portal for infectious diseases (EpiPulse)	Platform owned and operated by the ECDC and used by MSs, candidate countries, potential candidate countries, other non EU/EEA countries, partner organisations for the integrated indicator- (EpiPulse Cases) and event-based (EpiPulse Events) surveillance of infectious disease origin in the EU/EEA to collect, analyse, share and discuss infectious disease data. Interlinked to the EWRS to facilitate sharing of situational awareness for incident management.
European Respiratory Virus Surveillance Summary (ERVISS)	Weekly integrated epidemiological summary of the ECDC and the WHO for influenza, respiratory syncytial virus (RSV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (128).

([350]) WHO, 'Epidemic Intelligence from Open Sources (EIOS)', WHO website, accessed 3 November 2025, https://www.who.int/initiatives/eios.

ANNEX 8. Alert information systems in the EU for managing health crises

Name (abbreviation)	Purpose
Advanced Technology for Health Intelligence and Action IT System (ATHINA)	System of the Commission for identification, analysis and management of supply chain vulnerabilities of MCMs. Platform for gathering information on demand and supply of MCMs, analysing intelligence to detect supply chain vulnerabilities or risks and supporting threat assessment related to MCMs. Enables the exchange of information related to needs and availability of MCMs.
Animal Disease Information System (ADIS)	System of the Commission for tracking the evolution of infectious animal diseases with National competent authorities in the EU/EEA and participating countries
Common Emergency Communication and Information System (CECIS)	System of the Commission for coordination of EU-wide emergency support, including medical assistance and logistics together with National competent authorities in the EU and UCPM Participating States
Customs Risk Management System (CRMS2)	System of the Commission for the exchange of risk related infromation between national customs authorities. The Crisis Management module of CRMS2 supports coordination of customs risk management and controls of the customs authorities.
Early Warning and Response System (EWRS)	System of the Commission, operated by the ECDC, for information exchange, alert notification and management of serious cross-border threats to health with National EWRS competent authorities in the EU/EEA and participating countries. It facilitates also cross-border contact-tracing, medical evacuation, risk assessment and prevention, preparedness and response planning. EWRS allows for the processing of sensitive non-confidential (SNC) information and is interlinked with the EpiPulse system. EU agencies associated countries and the WHO have visibility to some of its functionalities. Member States and the Commission are joint controllers of the personal data in the EWRS.
Early Warning System on new psychoactive substances (EWS)	First step in a three-step legal framework designed to allow the European Union to rapidly detect, assess, and respond to health and social threats caused by new psychoactive substances (NPS). EuDA's work of the EWS aims to build, maintain, and strengthen situational awareness, preparedness, and response activities at national- and EU-level to NPS in collaboration with National focal points/national EWS correspondents, the Commission and relevant EU agencies an bodies.
European Community Urgent Radiological Information Exchange (ECURIE)	System of the Commission for early notification and information exchange on radiological or nuclear emergencies
European Flood Awareness System (EFAS)	System of the Commission for probabilistic flood early warning information up to 10 days in advance. Part of the Copernicus Emergency Management Service.
European Public Warning System (EU-Alert)	Framework for national systems on emergency alerts to mobile phones based on Cell Broadcast technology

HERA Stakeholders HUB	Secure portal of the Commission for collaboration and information exchange with MCM developers, producers, and economic operators across the EU, including pharmaceutical manufacturers and suppliers. Supports matchmaking, structured communication, and coordinated response to supply chain vulnerabilities.
Rapid Alert System for Dangerous Non-Food Products (Safety Gate)	EU rapid alert system for dangerous non-food products ([351])
Rapid Alert System for Blood and Blood Components (RAB)	System of the Commission for communication with National vigilance contact points for substances of human origin regarding serious adverse reactions or events related to blood
Rapid Alert System for Food and Feed (RASFF)	System of the Commission to notify risks to human health from food or feed, including contaminants or infectious agents
Rapid Alert System for Tissues and Cells (RATC)	System of the Commission for communication with National vigilance contact points for substances of human origin on adverse events involving human tissues and cells
Rapid Alert for quality defects of medicinal products	System of the EMA for communication with National competent authorities, the Commission and international partners of urgent information related to quality defects and recalls of medicinal products
Pharmacovigilance Rapid Alert	System of the EMA for rapid exchange of information with National competent authorities and the Commission on safety concerns related to medicines

([351]) European Commission, 'Safety Gate: EU rapid alert system for dangerous non-food products', European Commssion website, accessed 20 November 2025, https://ec.europa.eu/safety-gate.

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