Cross-border threats to health
EU action on preparedness and response

SUMMARY

Serious threats to health – such as those due to infectious disease outbreaks or environmental factors – do not respect borders. They do, however, require cross-border cooperation and a coordinated response.

Decision No 1082/2013/EU is the framework for European Union action on health emergencies. It provides for information exchange, risk assessment and joint procurement, among other mechanisms. The EU-level response is coordinated by the Health Security Committee. The European Centre for Disease Prevention and Control meanwhile plays a crucial role in identifying, assessing and communicating threats to health from communicable diseases. Parliament has adopted own-initiative and legislative resolutions focusing both on the general and more specific aspects of cross-border threats to health.

At global level, all EU Member States are party to the legally binding International Health Regulations that require them to develop, strengthen and maintain core public health capacities for surveillance and response. Implementation is coordinated by the World Health Organization.

Going forward, Member States have expressed interest in exploiting the potential of joint procurement beyond pandemic influenza vaccines. Moreover, a joint action on strengthened International Health Regulations and preparedness in the EU has recently been launched, focusing, in particular, on countering biological and chemical terror attacks in Europe across the health, security and civil protection sectors.

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Hope for the best, prepare for the worst

Health threats do not respect borders. Past public health crises — such as the 2009 H1N1 influenza (swine flu) pandemic, the 2011 Escherichia coli outbreak in Germany, the 2014-2016 Ebola epidemic in West Africa or Zika in 2015 and 2016 in the Americas — show that new infections can emerge at any time. Also, growing health problems, such as antimicrobial resistance, cannot be confined to a geographical region or a Member State but require cooperation and coordination. A 2019 report by the Global Preparedness Monitoring Board, published under the auspices of the World Health Organization (WHO), makes a compelling case for preparedness: 'The world is at acute risk for devastating regional or global disease epidemics or pandemics that not only cause loss of life but upend economies and create social chaos.' This briefing looks at how the EU is preparing for public health emergencies.

EU instruments and activities to counter cross-border health threats

According to Article 168 of the Treaty on the Functioning of the EU (TFEU), a high level of human health protection must be ensured in all Union policies and activities. Union action must cover the 'monitoring, early warning of and combating serious cross-border threats to health'.

**Glossary**

**Antimicrobial resistance**: when a microbe evolves to become more or fully resistant to antimicrobials that could previously treat it.

**Communicable disease**: an infectious disease caused by a contagious agent transmitted from person to person by direct contact with an infected individual or by indirect means, such as exposure to a vector, animal, product or environment, or exchange of fluid, contaminated with the contagious agent.

**Epidemic**: an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.

**Epidemiological surveillance**: the collection, recording, analysis, interpretation and dissemination of data on communicable diseases and related special health issues.

**Medical countermeasures**: any medicines, medical devices, other goods or services aimed at combating serious cross-border threats to health, as referred to in Decision 1082/2013/EU.

**Public health emergency of international concern**: an extraordinary public health event that constitutes a public health risk to other States through the international spread of disease and potentially requires a coordinated international response.

**Pandemic**: an epidemic that has spread over several countries or continents, usually affecting a large number of people.

**Preparedness**: the ability of governments, professional response organisations, communities and individuals to anticipate, detect and respond effectively to, and recover from, the impact of likely, imminent or current health emergencies, hazards, events or conditions.

**Serious cross-border threat to health**: a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin that spreads, or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.

Article 168 TFEU specifies that EU action in public health is designed to complement and support the actions of the Member States, which have the main responsibility for health policy. Major health threats with a cross-border or international impact have been identified as an area where Member States can act more effectively together. Protecting citizens from such threats – to improve surveillance and preparedness for epidemics and bioterrorism, and increase capacity to respond to new health challenges such as climate change – is one of the three strategic objectives of EU health policy.

The Cross-border Health Threats Decision

Decision No 1082/2013/EU on serious cross-border threats to health (the Cross-border Health Threats Decision) provides the framework for EU action relating to crisis preparedness and response. Activities under the decision focus on the epidemiological surveillance, monitoring, early warning and assessment of, as well as response to, cross-border health threats. Categories covered by the decision include:

- threats of biological origin, consisting of communicable diseases (such as pandemic influenza); antimicrobial resistance and healthcare-associated infections relating to communicable diseases (‘related special health issues’); and biotoxins (including marine biotoxins and mycotoxins) or other harmful biological agents;
- threats of chemical origin, such as those caused by the acute release of dangerous substances, either deliberately in an attack or during an accident or an explosion;
- threats of environmental origin, including those widely associated with climate change, such as extreme weather events;
- threats of unknown origin;
- events that may constitute public health emergencies of international concern, such as the Ebola and Zika virus outbreaks (see also 'International cooperation').

Exchange of information on preparedness planning

The Cross-border Health Threats Decision supports information exchange and best practice-sharing between EU Member States on their preparedness activities, and provides a structure on the basis of which to develop national preparedness plans to address the different types of cross-border health threats. Such plans cover, for instance, hospitals' readiness for increased admissions; arrangements for stockpiling medical products; and draft measures in case of an outbreak, such as school closures or action to ban mass gatherings.

Early warning and response system

Serious cross-border threats to health are notified through the early warning and response system (EWRS). The web-based, restricted-access EWRS allows EU Member States to send alerts about events with a potential impact on the EU, share information, and coordinate their response. It is hosted by the European Centre for Disease Prevention and Control (ECDC). An updated EWRS version went live in October 2018.

Public health risk assessment and response coordination

Following an alert, Member States consult each other in the Health Security Committee (HSC, see text box above), in liaison with the European Commission, with a view to coordinating both the

Coordination of the EU-level response

The Cross-border Health Threats Decision requires Member States and the Commission to consult each other in the Health Security Committee (HSC), mandated to support the exchange of information on policy, strategy and technical issues relating to health security. The HSC coordinates preparedness and response planning, as well as the Member States' public health responses and crisis communication. It is made up of representatives from the ministries of health. The Commission provides the HSC's secretariat and presidency, and operates its Health Emergency Operations Facility. The HSC convenes twice a year for plenary; other meetings are planned on an ad-hoc basis.
national responses to a health threat, and the risk and crisis communication aimed at informing the public and healthcare professionals. Where necessary, the HSC can ask the Commission to provide a risk assessment, including possible public health measures. Depending on the nature of the threat, the risk assessment is either carried out by the ECDC, the European Food Safety Authority (EFSA), other EU agencies or the Commission, for instance, by mandating the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) in the event of a chemical threat. The risk assessment takes into account information provided by other entities, in particular the WHO (see also 'International cooperation').

**RescEU, Voluntary Pool and European Medical Corps**

In March 2019, new rules strengthening the EU civil protection mechanism entered into force. They provide for a European reserve of capacities to respond to disasters (the rescEU reserve), owned and hosted by the Member States. RescEU capacities will initially include a fleet of firefighting planes and helicopters. Further means are due to be added over time, including those needed to respond to medical emergencies (medical evacuations, field hospitals, etc.) and events related to chemical, biological and radio-nuclear (CBRN) hazards. The European Emergency Response Capacity (also known as European Civil Protection Pool or Voluntary Pool) was established in 2013 under the mechanism. It constitutes a reserve of resources, such as experts, equipment and transportation services, to respond to disasters inside and outside the EU. Recent response operations carried out by the Voluntary Pool include those following cyclone Idai in Mozambique (March 2019), the forest fires in the north of Europe (July 2018), and the health emergencies in central and western Africa (2014-2018). The European Medical Corps was set up in response to the shortage of trained medical teams during the Ebola outbreak in West Africa in 2014. It is part of the Voluntary Pool.

In the event of a serious cross-border health threat going beyond national response capacities, an EU Member State may also request assistance from other Member States through the **EU civil protection mechanism** under Decision No 1313/2013 (see text box above).

**Joint procurement**

The Cross-border Health Threats Decision also provides for the **joint procurement** of medical countermeasures. The aim behind this voluntary mechanism is to secure more equitable access, improved security of supply, and more balanced prices. The joint procurement agreement (JPA), approved by the Commission in April 2014, has so far been signed by 25 EU Member States. Through the JPA, the signatories can engage in joint purchase procedures. In addition to pandemic influenza vaccines and antivirals, the JPA also covers countermeasures such as medicines and medical devices; laboratory tests; diagnostic kits for seasonal influenza or pandemic influenza; decontamination products, masks and personal protective equipment; or other goods and services, depending on the need triggered by a serious cross-border threat to health.

**Possibility to declare a public health emergency**

The Cross-border Health Threats Decision introduces the possibility for the Commission to recognise a situation of public health emergency, independently of the WHO (for more on this, see 'International cooperation').
European Commission

The Commission supports Member States and takes complementary action across specific policy areas that require adequate levels of preparedness and response.

Antimicrobial resistance

The 2017 European One Health action plan against antimicrobial resistance (AMR) is based on three pillars: 1) making the EU a best practice region on AMR; 2) boosting research, development and innovation; and 3) shaping the global agenda on AMR. In 2017, as part of its action, the Commission set up an AMR One Health network of government experts and EU agencies (ECDC, EMA, and EFSA) for sharing ideas. A joint action (EU-JAMRAI) on AMR and healthcare-related infections (HCAI) is under way. Its overall objective is to ensure that policies on AMR and HCAI control are adopted and implemented across EU Member States in a coordinated manner. The progress report on the action plan’s implementation is updated regularly. According to Directorate-General for Health and Food Safety (DG SANTE), as of July 2019, five Member States had a fully developed national One Health action plan on AMR, while six Member States do not yet have one in place. Full implementation of the action plan and working ‘with our international partners to advocate for a global agreement on the use of and access to antimicrobials’ are among the health priorities of the new Commission, according to President Ursula von der Leyen’s mission letter to Health and Food Safety Commissioner Stella Kyriakides.

Vaccination

The Commission’s April 2018 communication on strengthened cooperation against vaccine-preventable diseases presents a framework for actions under three key pillars: 1) tackling vaccine hesitancy and improving vaccination coverage; 2) sustainable vaccination policies in the EU; and 3) EU coordination and contribution to global health. A joint action on vaccination (EU-JAV) was launched in September 2018. The Commission is co-funding related projects under Horizon 2020, including to support Ebola vaccine trials and the development of influenza vaccines. A joint EU/WHO Global Vaccination Summit took place in September 2019. Communication on vaccination and fighting misinformation will be among the priorities for Commissioner Kyriakides.

European Centre for Disease Prevention and Control: surveillance, preparedness, response, advice

The European Centre for Disease Prevention and Control (ECDC) is an EU agency with the mission to identify, assess and communicate current and emerging threats to health from communicable diseases. Its core activities include surveillance, preparedness, response and advice. The ECDC collects, analyses and disseminates surveillance data on communicable diseases and related special health issues from EU and European Economic Area (EEA) countries. It operates the epidemiological surveillance platform TESSy, to which Member States upload their surveillance data, and coordinates surveillance networks. It supports the Member States and the Commission in the area of public health preparedness, including by disseminating good practices through the provision of tools, such as that for health emergency preparedness self-assessment (HEPSA). Furthermore, the ECDC provides technical support for the EU-level response to disease threats. It operates the early warning and response system (EWRS); produces rapid risk assessments and epidemiological updates; and can provide outbreak response in support of countries or international organisations, as in the 2018 mission in response to the Ebola outbreak in the Democratic Republic of Congo. Finally, the ECDC provides scientific opinions, also at the request of the Commission, the European Parliament or a Member State, about the risks posed by infectious diseases. Health Commissioner Kyriakides has referred to the ECDC as a ‘key partner … to strengthen and develop continent-wide disease surveillance and early warning systems.'
European Parliament

Over the past decade, Parliament has adopted several own-initiative and legislative resolutions that focus on both general and more specific aspects of tackling cross-border threats to health. For instance, in its March 2011 resolution on the evaluation of the management of H1N1 influenza (2009-2010) in the EU, Parliament highlighted the need to introduce a common procedure for the joint procurement of medical countermeasures to allow Member States to benefit, on a voluntary basis, from equitable access, advantageous prices and order flexibility for a given product. The resolution fed into the preparation of the Cross-border Health Threats Decision.

Parliament’s October 2015 resolution on the Ebola crisis called for the establishment of a permanent European rapid response capability comprising experts, laboratory support staff, epidemiologists and logistics facilities, including mobile laboratories, that can be deployed swiftly. Its April 2016 resolution on the Zika virus outbreak welcomed the ECDC’s monitoring of the situation, and suggested that the ECDC should establish an expert committee in tropical communicable diseases to provide for efficient coordination and monitoring of the measures that need to be put in place in the EU. Moreover, it pointed out the need for a coordinated approach at EU and international level in the fight against the Zika outbreak, and welcomed the launch of the European Medical Corps.

In its April 2018 resolution on vaccination, Parliament strongly supported the joint procurement agreement that gives Member States and the Commission a framework to procure vaccines jointly, and called on Member States not yet having signed the agreement to do so, to ensure that all EU citizens are covered by it. Parliament also expressed concern at the wide variation in the vaccines recommended, provided or mandated by Member States, and that this variation in vaccination coverage worsens health inequalities and undermines efforts to eliminate preventable diseases.

Parliament has also repeatedly alerted to the climate dimension of cross-border threats to health (see text box). In its legislative resolution of February 2019 on the proposal for a decision on a Union civil protection mechanism, Parliament considers it essential that Member States undertake adequate prevention and preparedness actions to deal with disasters, and in particular, with forest fires. Given that the EU has been confronted in recent years with particularly intense and widespread forest fires, Parliament asks that additional measures be taken at Union level. It recalls that wildfire prevention is also vital in view of the global commitment to reduce CO2 emissions.

More recently, in its legislative resolution of March 2019 on the proposal for a regulation establishing the Neighbourhood, Development and International Cooperation Instrument, Parliament introduces amendments with a view to fostering the international dimension of EU policies (‘complementing action through the EU framework programme for research and innovation to tackle global public health threats, develop safe, efficient and affordable vaccines and treatments against poverty-related and neglected diseases, and improve responses to health challenges including communicable diseases, antimicrobial resistance and emerging diseases and epidemics’).

In its March 2019 resolution on the annual strategic report on the sustainable development goals (SDGs), Parliament calls on the Commission to work towards strengthening the capacity to prevent Health threats from climate change

The European Academies’ Science Advisory Council (EASAC) comprises the national science academies of the EU Member States plus Norway and Switzerland and aims to provide European policy-makers with independent, evidence-based advice on scientific issues. EASAC’s report of June 2019 makes the case for urgent climate action to protect human health. Put succinctly: climate change will bring about a diverse range of risks for human health, through different exposure pathways, and risks will increase as temperatures rise. The top priority is to stabilise the climate and to accelerate efforts to limit greenhouse gas emissions. Recommendations regarding health focus, inter alia, on a ‘health in all policies’ approach and health risk communication, including engaging the public and countering misinformation.
and manage global health threats, such as antimicrobial resistance. On specific threats, Parliament’s September 2018 resolution on a European One Health action plan against antimicrobial resistance notes that AMR requires urgent and coordinated EU, global and intersectoral action. It calls for a clear commitment from the EU and Member States to building partnerships and launching a cross-cutting global strategy to combat AMR. Parliament welcomes cross-border research into antimicrobial stewardship and the prevention of infection, such as the EU-funded i-4-1-Health Interreg project, and calls on the Commission to increase funding for measures to prevent healthcare-associated infections.

Council

Several Council conclusions have invited the Member States to continue and extend cooperation on preparation, monitoring, early warning and coordinated responses on matters relating to public health emergencies. The April 2009 conclusions on the influenza A/H1N1 infection called on the Commission to continue to facilitate information sharing and cooperation between the Member States, in particular on risk evaluation, risk management and medical countermeasures to the A/H1N1 virus within the EU. The October 2009 conclusions on the H1N1 pandemic invited the Commission to report on and develop a voluntary mechanism for joint procurement of vaccines and antiviral medication by Member States, allowing common acquisition of these products or common approaches to contract negotiations with the industry, addressing issues such as liability, availability and price of medicinal products as well as confidentiality. The September 2010 conclusions on lessons learned from the A/H1N1 pandemic invited the Commission to consider working together on joint procurement and common approaches to contract negotiations for medicines.

The December 2015 conclusions on lessons learned from the Ebola outbreak in West Africa stressed the importance of coordination of preparedness research at European and global levels; invited Member States to maintain appropriate capacities; and invited the Commission to identify opportunities to improve coordination mechanisms.

The June 2016 conclusions on the next steps under a One Health approach to combat antimicrobial resistance stressed that the success of the fight against AMR relies on the commitment and willingness of governments to ensure the implementation of the initiatives under the approach, and on the will of the Member States to cooperate within the EU and internationally. The Member States and the Commission are called upon to ensure that the EU takes a common approach in the global discussions on AMR.

The December 2018 Council recommendation on strengthened cooperation against vaccine-preventable diseases recognises that the cross-border nature of vaccine-preventable diseases would benefit from more coordinated EU action. Among other things, it welcomes the Commission’s intention to work towards strengthening vaccine supply by considering developing a virtual European data warehouse on vaccine need; envisaging the design of a mechanism for the exchange of vaccine supply between Member States in the event of an outbreak; and exploring possibilities for joint procurement of vaccines or antitoxins to be used in pandemics, unexpected outbreaks and in cases of small-scale vaccine demand (i.e. a small number of cases or very specific populations to be covered).

The June 2019 Council conclusions on the next steps towards making the EU a best practice region in combating antimicrobial resistance call on the Member States to strengthen and coordinate their response to counteract the cross-border spread of resistant infections. They call on the Member States and the Commission to increase capacity in all Member States to respond to the threats from AMR and thus reduce the current differences in outcomes; coordinate Member States’ positions and work towards a common ‘EU voice’, as a best practice region in international fora, that declares the urgent need to address AMR and consistently pushes for an accelerated global
response in multilateral and bilateral relations; and calls on the Commission to make use of the AMR One Health network to enhance cooperation with and between Member States.

**International cooperation on health security issues**

The Cross-border Health Threats Decision stipulates that ‘cooperation with third countries and international organisations in the field of public health should be fostered’. At global level, the EU collaborates with the Global Health Security Initiative (GHSI), an informal, international partnership to strengthen health preparedness and response to threats of biological, chemical, radionuclear terrorism and pandemic influenza. Its members are Canada, the European Union, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. The WHO serves as an advisor. The European Commission communicates the outcomes of the discussions within the GHSI to all EU countries through its Health Security Committee.

All EU Member States are party to the International Health Regulations (IHRs), a binding agreement ‘to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade’. The IHRs are also designed to reduce the risk of disease spread at international airports, ports and ground crossings. The WHO coordinates the implementation of the IHR. Under the IHR, EU Member States have to develop, strengthen and maintain core public health capacities for surveillance and response, and report to the WHO on IHR implementation. They are required to notify the WHO of any event that may constitute a public health emergency of international concern (PHEIC). The Commission and the ECDC coordinate their activities with the WHO. The Cross-border Health Threats Decision introduced a public health emergency declaration by the Commission, which differs significantly from the PHEIC declaration.

**Interested parties' views**

**Advisory bodies**

In its March 2012 opinion on the Cross-border Health Threats Decision, the European Economic and Social Committee (EESC) welcomed the approach adopted, but stressed that civil society must be involved both in preparedness planning and crisis communication.

The European Committee of the Regions (CoR), in its May 2018 opinion on the EU civil protection mechanism, underlined that risk assessment and risk management planning provisions need to be drawn up in partnership with local and regional authorities, and called for EU action to focus on providing technical training assistance so that the capacity of communities for self-help can be enhanced. In its June 2019 opinion on the cross-border dimension in disaster risk reduction, the CoR highlighted the need to set up a shared database in certain cross-border areas, and stressed that it is necessary to promote a shared cross-border alert system. Moreover, it expressed the hope that scientific committees would be set up, bringing together specialist expertise based on similar risk factors for homogeneous areas (for instance, Mediterranean forest fires, flooding in central Europe, etc.).

**Stakeholders**

In a 2011 stakeholders' consultation that fed into the elaboration of the Cross-border Health Threats Decision, a majority of respondents argued for all serious cross-border health threats to be included in the European Union’s health security policy. The Health Security Committee was seen as a useful platform for public health risk management and risk communication, and for coordinating the EU-level response to public health consequences of serious cross-border threats to health. Civil society advocates, such as the European Public Health Alliance (EPHA), have pleaded in favour of instituting a European Commission Vice-President for Health, whose responsibilities would include ‘to identify, prevent and prepare for potential health threats and coordinate a swift and efficient EU response
together with international partners to health emergencies'. Regarding antimicrobial resistance more specifically, the EPHA-led AMR Stakeholder Network have issued a joint statement and call to action on AMR. In September 2019, in an open letter, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and other stakeholders stressed the importance of sustaining EU progress in fighting AMR, urging the Members of the European Parliament to bring AMR to the forefront of EU interinstitutional discussions and to support the establishment of a dedicated AMR parliamentary group.

Academia

According to a research article on pandemic legislation in the EU (E.M. Speakman et al., 2017), it is currently unclear what national pandemic governance exists in EU Member States as it has not been mapped. Legal analysis and empirical evaluation of implementation and impact have therefore not been possible. The authors propose comprehensive mapping to create the necessary comparative data, drawing on the United States' experience with policy surveillance: 'Until national pandemic governance is mapped and evaluated, we cannot know if it is lawful, ethical or effective'. ECDC-commissioned research describes the development of a public health emergency preparedness (PHEP) competency model for EU countries (M.A. Soto et al., 2018). The model is designed to support developers of PHEP training initiatives by ensuring that public health professionals are able to demonstrate the knowledge and skills needed when faced with cross-border health threats. The authors argue that, while knowledge and skills may not be enough, the competencies provide a common foundation on which training programmes can be based. An analysis of the EU legal system for health emergencies (S. Antolić, 2019) concludes that there is still room for improved collaboration, suggesting that further action should be undertaken to bring the coordination and network for public health emergencies surveillance, preparedness and response planning to a higher level.

Outlook: are we ready?

The joint actions on AMR (EU-JAMRAI) and vaccination (EU-JAV) are ongoing (see also 'European Commission'). A roadmap, based on the Commission communication and the Council recommendation, tracks the implementation of vaccine-related action. It includes exploiting the possibilities of joint procurement of vaccines or antitoxins to be used in pandemics and unexpected outbreaks and in cases of small vaccine demand. Framework contracts for the joint procurement of pandemic influenza vaccines were signed in March 2019. The Commission has pointed out that the potential of joint procurement reaches beyond vaccines for pandemics, and that Member States could benefit from extending the agreement to cover medical countermeasures for other infectious diseases, such as botulism (caused by Clostridium botulinum), anthrax, hepatitis B and polio. Future potential uses could also include countermeasures for rare infectious diseases; CBRN countermeasures; seasonal influenza vaccine; antiretroviral medicines against HIV/AIDS; tuberculosis and hepatitis treatments or vaccines; and reference laboratories services. The first joint procurement procedure of botulism antitoxin was completed in 2016, with the participation of four Member States and the Commission. In the July 2019 Health Security Committee plenary, Member States expressed interest in additional joint procurement procedures, including for personal protective equipment, diphtheria antitoxin, tuberculin and BCG vaccines (against tuberculosis).

A 2019 EPRS study found that European added value is clearly achieved in the facilitation of synchronised responses to pandemics/epidemics and simplification of the response to safety issues, as well as reduction of cross-border threats. In this context, a new joint action on strengthened International Health Regulations and preparedness in the EU (SHARP JA) has recently been launched; it comprises a total of 30 countries and will run from April 2019 to March 2022. SHARP JA aims to support implementation of the IHR and preparedness against biological and chemical terror attacks in Europe across the health, security and civil protection sectors. It also organised the One
Health Security Conference, hosted by the Finnish Council Presidency in October 2019, to strengthen international health security.

Finally the Joint Research Centre's Disaster Risk Management Knowledge Centre (DRMKC) has initiated the second report in the ‘Science for Disaster Risk Management’ series, to be finished by the end of 2020.

MAIN REFERENCES


Special Report No 28/2016: Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done, European Court of Auditors, 2016.

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