



## Cross-border health threats in the EU

**SUMMARY** *Public health security, which is the responsibility of Member States, is currently coordinated at EU level through an early warning and response system (EWRS), the informal Health Security Committee and the European Centre for Disease Prevention and Control (ECDC). Recent public health threats, such as the H1N1 influenza pandemic, have shown that coordination at EU level has been effective, but is in need of improvement. The International Health Regulations, which have been in force since 2007, set out a global approach to health threats*

*European coordination mechanisms are currently limited to health threats from communicable diseases. The European Commission has proposed a revised system which would cover a wider range of health threats, including threats of biological, chemical, environmental or other origin. The proposed Decision would formalise the Health Security Committee, ensure better information exchange and coordination, and provide for optional joint procurement of vaccines.*

*Joint procurement of vaccines would bring a number of benefits, but also some difficulties and risks. The vaccines industry warns that joint procurement may discourage innovation and reduce the number of suppliers if contract volumes are too large and price is used as the dominant criterion.*

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### Glossary

**Epidemiology:** branch of medicine dealing with the transmission and control of disease.

**Pandemic:** outbreak of a disease over a wide geographic area.

**Communicable disease:** illness caused by bacteria, viruses or fungi which are transmitted to a person from other persons, animals or objects (also called infectious disease).

### Issue definition

Threats to public health do not stop at national borders. Diseases can spread rapidly across borders through travel, trade in food and feed, insects and other disease carriers. Health threats from biological or chemical substances can also spread through the air, water or through international transport of goods.

National preparation and international cooperation are needed to control the spread of diseases and to minimise their impacts. Measures for controlling the spread of diseases include monitoring and reporting, hygiene and vaccination. Impacts on human health can be minimised through medication and medical care. Societal impacts include disruption of essential services such as water and energy supplies, transport or medical care, caused by the absence of workers. These are addressed by



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business continuity planning. Communication to healthcare professionals and to the public plays an important role.

## Current EU approach

Public health measures and policies are the responsibility of Member States (MS). The EU plays a role in coordinating the activities of the MS. The Treaties (Article 168 [TFEU](#)) provide a legal basis for EU action complementing national policies in the field of serious cross-border threats to health, by monitoring, early warning and counter-measures.

### Early warning and response system

In 1998, a [legal framework](#) for responding to communicable diseases was established. MS are obliged to notify outbreaks of disease through an EU-wide early warning and response system (EWRS). This information is shared in real time across the Union. The health authorities of the MS exchange information and discuss the coordination of measures in a committee chaired by the European Commission. The EWRS has been used in a number of events such as [SARS](#) in 2003, the [H1N1 influenza pandemic](#) in 2009, and the [EHEC](#) outbreak in 2011.

### EU agencies

The [European Centre for Disease Prevention and Control](#) (ECDC), [established in 2005](#), identifies, assesses and communicates current and emerging threats to human health from communicable diseases. The centre manages the EWRS.

The EU has a role in the approval of medicines and vaccines. The [European Medicines Agency](#) (EMA), established in

1995, assesses vaccines and makes a scientific recommendation to the Commission, which grants the marketing authorisation.

### Health Security Committee

EU Health Ministers set up an informal [Health Security Committee](#) (HSC) in 2001, following bioterrorist attacks in the US. The HSC consists of MS officials, Commission staff and representatives of ECDC and EMA. The HSC exchanges information on health-related threats and shares information and experience on preparedness, response plans and crisis management strategies. Since 2007, the HSC's mandate has been extended beyond bioterrorist threats to pandemic preparedness and response, as well as coordination of emergency planning at EU level.

### International agreements

At global level, the [International Health Regulations](#) (IHR) were adopted by 194 countries in 2005 and entered into force in June 2007. Participating states have committed to informing the World Health Organisation (WHO) at once about outbreaks of diseases and other public health risks, and to ensure a proper public health response to the international spread of diseases, without unnecessary interference with international traffic and trade.

The [Global Health Security Initiative](#) (GHSI) is an informal partnership to strengthen preparedness and response to threats of biological, chemical, and radio-nuclear terrorism as well as pandemic influenza. Its participants are the European Union, France, Germany, Italy, the United Kingdom, Canada, Japan, Mexico, and the US.

### Shortcomings

According to the European Commission, differences in preparedness planning between MS can reduce the effectiveness of the response to a cross-border health threat. While there are adequate structures for addressing the threats from communicable diseases, capacities for other kinds of health threats are lacking.

## Lessons from the H1N1 pandemic

In June 2009, the WHO declared an H1N1 influenza pandemic, the first influenza pandemic for more than 40 years. Over 900 000 infections and 2 900 deaths were reported in Europe.<sup>1</sup> WHO and ECDC were involved in coordinating the response to the pandemic. The development of vaccines had already started before the pandemic was declared, and vaccines were authorised

and distributed as early as September 2009. Global vaccine production capacity was increased to about 4.9 billion doses per year, according to WHO estimates.

The majority of MS had advance purchase agreements, but there were differences in prices and in contract conditions regarding liability.

The H1N1 pandemic was the first serious test for the IHR and the European health security strategy. The response to the pandemic was [evaluated](#) by a large number of national and international organisations.

A [review for the WHO](#) concluded that the IHR helped improve preparedness for the pandemic, but that national implementation is still so insufficient that the world remains ill-prepared. It recommends revising the definition of a pandemic to take its severity into account and making advance agreements for vaccine distribution and delivery.

The [ECDC's review](#) concluded that the EU managed the pandemic quite well. It recommends flexible preparedness plans which take severity into account, better surveillance systems and faster sharing of analyses. It points out the importance of risk communication.

The [Assessment Report on EU-wide Pandemic Vaccine Strategies](#) for the European Commission states that the majority of MS want more flexible procurement contracts and favour joint procurement and stockpiling of vaccines. It points out that vaccination targets were not reached in

most MS and that communication needs to be improved.

According to Professor Ulrich Keil (Institute of Epidemiology and Social Medicine, Münster), the management of the pandemic was a "[huge marketing bubble](#)", based on bad science and intransparent decision procedures. The [Council of Europe](#) also took a critical view. It considered that the response was out of proportion to the actual threat, created unjustified public fears and wasted large sums of public money. It warns of possible influence of the pharmaceutical industry and calls for improved transparency and better handling of conflicts of interest.

The EP adopted a [resolution](#) on 8 March 2011 calling for improved cooperation and coordination, a revised definition of pandemic which takes severity into account, and grouped purchases of vaccines on a voluntary basis. The EP resolution emphasises the need to prevent conflicts of interest and insists that vaccine manufacturers accept liability for side-effects.

The text acknowledges that the EU was the best prepared region in the world, but points out that the overall preparedness was weakened by different levels of preparedness among MS and insufficient cooperation.

The [Council Conclusions of 13 September 2010](#) call upon the

Commission to develop a mechanism for joint procurement of vaccines and antiviral medication on a voluntary basis.

### EHEC outbreak in 2011

In May 2011, about 30 cases of a life-threatening E.coli infection were detected in Germany. On 22 May 2011, German authorities issued an alert to MS via the EWRS and notified the WHO. In the following weeks, there were thousands more cases in Germany and a few in other EU Member States. In total, there were about 4 000 infections including 50 deaths.

After the health minister of the German city state of Hamburg mentioned Spanish cucumbers as the source of the outbreak, sales of cucumbers all over Europe collapsed, and did not recover even after it became clear that they were not the source of the outbreak. ECDC cooperated with the German health authorities to identify fenugreek sprouts as the source of the outbreak. ECDC also supported clinicians treating EHEC patients with reference materials and facilitated the exchange of knowledge. ECDC concluded that the European model of a networked CDC works well and should be strengthened, but points out that faster reporting of cases is needed.

## Proposed approach

In December 2011, the Commission made a [proposal](#) for a [Decision](#) to strengthen and extend the legal framework regarding serious cross-border threats to health. It draws on lessons learned from the H1N1 pandemic and a stakeholder consultation, and takes into account the [EU health strategy 2008-2013](#) and the requirements of the IHR.

The proposal will be adopted under the ordinary legislative procedure, and has been assigned to the EP's Committee for Environment, Public Health and Food Safety.

The Commission has also put forward a proposal for a [Health for Growth programme \(2014-2020\)](#), which foresees expenditure of €36.4 million (9% of the total) for developing common approaches for better preparedness and coordination in health emergencies.

The Council is expected to discuss the proposal and the Health for Growth programme under the Danish presidency on 22 June 2012.

Compared to the present set-up, which covers only communicable diseases, the proposed framework includes health threats of biological, chemical, environmental (including climate change) and unknown origin, as well as public health emergencies of international concern.<sup>2</sup>

MS are to coordinate their efforts for monitoring, early warning, assessment and response. National preparedness plans are to be established, shared and coordinated. A network for epidemiological surveillance of communicable diseases is to be established, and the Commission may set up ad hoc monitoring networks for specific threats.

MS are to consult each other and coordinate their responses to a health threat. If the coordination of national responses is not sufficient, the Commission may adopt

temporary public health measures to be implemented by the MS.

In case of rapidly spreading, life-threatening diseases, the Commission can declare a European health emergency, independently of the World Health Organisation. This could speed up the authorisation of new vaccines.

The proposal formalises the Health Security Committee and extends its mandate to the coordination of preparedness and response plans, and to the coordination of MS' responses to health threats.

The proposal provides for joint procurement of medical counter-measures such as vaccines. Participation is voluntary and open to all interested MS.

## Benefits and risks of joint procurement

Joint procurement is seen to have the following advantages:

- stronger negotiating power leading to lower costs and uniform contract conditions
- pooling of skills and expertise, from which smaller MS especially would benefit
- reduction in administrative work
- improved stability of vaccine supply
- equitable access.

Pooled procurement of vaccines has been used by a number of international organisations.<sup>3</sup> Some difficulties have been experienced:

- divergent national procurement legislation
- limited flexibility for national requirements
- complex logistics.

Joint procurement entails a number of risks:

- dependence on external expertise
- disturbed market balances, leading to a shrinking supplier base

- reduced incentive for product innovation if lowest price is the sole criterion.

The market for pandemic vaccines is very unpredictable for manufacturers, with demand peaks in some periods, and zero demand in others. Since a large part of the costs are fixed, there is a risk that manufacturers do not invest in sufficient production capacity.<sup>4</sup>

All of the above elements need to be taken into account for setting up a joint procurement procedure that gives the best results in terms of cost efficiency and ensuring the supply of vaccines.

### Stakeholder views

The European Commission [consulted stakeholders](#) in 2011. The Commission's proposal is in line with the views expressed by the majority of the respondents.

#### NGOs

The European Public Health Alliance (EPHA) submitted a [response](#) to the consultation on health security in the EU. It calls for solidarity among MS to prevent a situation where some countries stockpile vaccines while others have no access. It highlights a need for more transparency, a system of training, and better public communication which avoids conflicting messages.

#### European Data Protection Supervisor

The [European Data Protection Supervisor](#) calls for clearer definitions and criteria for the processing of personal data which are collected for contact tracing.<sup>5</sup>

#### Vaccine industry

European vaccine manufacturers submitted a [reply to the Commission's Green Paper on the modernisation of EU public procurement policy](#), calling for procurement rules which ensure that:

- each MS can acquire vaccines which fulfil its public health needs and objectives
- the value of new vaccines is recompensed appropriately, to maintain strong incentives for innovation

- the sustainability of the vaccine sector or vaccine supply is not threatened
- award criteria are applied uniformly throughout the EU.

The pharmaceutical company Pfizer [remarked](#) that there are opposing objectives. On one hand, aggregation of demand may lead to greater competition among suppliers. On the other hand, competition may be reduced in the medium or longer terms if the value of the contract becomes too large and a lack of demand causes suppliers, especially smaller ones, to leave the marketplace. Consideration should therefore be given to so-called dynamic competition over time.

In its [lessons from pandemic influenza](#), the vaccine industry proposes to establish vaccine supply agreements beforehand, so that complex negotiations under intense time pressure in a crisis situation can be avoided.

### Main references

[Report of the review committee on the functioning of the International Health Regulations \(2005\) in relation to pandemic \(H1N1\) 2009](#), WHO, 5 May 2011

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[European Commission website on communicable diseases](#)

[European Commission website on preparedness and response to public health threats](#)

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## Endnotes

- <sup>1</sup> The pandemic of 2009 was much less severe than expected. In comparison, the influenza pandemic of 1918/1919 killed 50 to 100 million persons worldwide.
- <sup>2</sup> Threats from radiation are not included because formalised and well-functioning structures exist at national and international level under the Euratom treaty.
- <sup>3</sup> Joint procurement has been used by [UNICEF](#), [GAVI Alliance](#), the [Pan American Health Organization](#), and the [Gulf Cooperation Council](#).
- <sup>4</sup> Industry asserts that regular demand from seasonal influenza vaccination is needed in order to assure sufficient production capacity for responding to a future pandemic. ([Lessons from pandemic influenza A\(H1N1\): The research-based vaccine industry's perspective](#), Atika Abelin et al., Vaccine 29, p. 1135-1138, 2011.)
- <sup>5</sup> Contact tracing means identifying the relevant contacts of a person infected with a communicable disease and informing them of the exposure.