The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the Survey on ' Evaluation of Regulation (EU) 2022/2371 on serious cross-border threats to health'

On 5 December 2024, the CPME Board adopted the 'CPME response to the EMA Survey on implementation of ' Evaluation of Regulation (EU) 2022/2371 on serious cross-border threats to health' (CPME 2024/166 FINAL).

Contribution ID: 09bd55e7-069e-49db-b3ae-ce111c608414
Date: 05/12/2024 17:23:55

Evaluation of Regulation (EU) 2022/2371 on serious cross-border threats to health

Fields marked with * are mandatory.

Introduction

Regulation (EU) 2022/2371 aims to strengthen the EU health security framework by enhancing coordination between the European Commission, EU agencies, and Member States. The Regulation establishes a more robust mandate for the Health Security Committee (HSC), planning for prevention and response, joint procurement of medical countermeasures, emergency research and innovation, epidemiological surveillance, and an Early Warning and Response System (EWRS). It also creates networks of reference laboratories and substances of human origin.

This survey is conducted for the study supporting the evaluation of Regulation (EU) 2022/2371 on serious cross-border threats to health. The objective of the evaluation is to provide the European Commission with an evidence-based analysis of the Regulation’s functionality. The evaluation will encompass key criteria, as outlined in the Better Regulation Guidelines: effectiveness, efficiency, relevance, coherence, and EU added value.

This survey is part of a series of consultation activities conducted for this study. Your answers will be crucial in identifying both success factors and areas for improvement within Regulation (EU) 2022/2371. Ultimately, these findings will inform the Commission's decision-making process, enabling necessary adjustments for the Regulation’s enhancement.

Anticipating your valuable input, we estimate that the survey will take approximately 30 minutes of your time. Please note that data and information provided in this survey will be treated confidentially and processed to carry out the above-mentioned research and will not be disclosed to any third party. Survey results will be reported anonymously so as to not be attributable to any specific respondent unless otherwise agreed upon with the respondent in written form. Please see the European Commission’s privacy statement below for more information.

For any survey-related inquiries, please contact us via rana.orhanpees@ecorys.com. To reach the DG SANTE unit responsible for evaluating Regulation (EU) 2022/2371, please email SANTE-CONSULT-B2@ec.europa.eu.

We sincerely appreciate your participation in advancing the evaluation of Regulation (EU) 2022/2371.

Privacy statement:

European_Commission_Privacy_Statement.pdf

In giving your consent to participate in this survey, you understand that personal information collected about you, such as your name, will not be shared beyond the study team over the duration of the assignment and beyond. You understand that the information you provide will be used in reports and other deliverables to DG SANTE to help inform the evaluation of Regulation (EU) 2022/2371. You understand that no specific attribution will be made to you or your organisation in reporting.

☑ I consent to participating in this survey according to the terms described above.

Section 1 – Identification questions

* Where is your institution/organisation headquartered?

- ○ Austria
- ◉ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czechia
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg
- ○ Malta
- ○ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania
- ○ Slovak Republic
- ○ Slovenia
- ○ Spain
- ○ Sweden
- ○ Norway
- ○ Iceland
- ○ Liechtenstein
- ○ Switzerland
- ○ Other

* Which type of organisation do you work for?

- ○ International organisations (IOs)
- ○ EU institutions or agencies
- ○ National health authorities
- ○ National authorities from other sectors
- ○ Nongovernmental organisations (NGOs) operating at national level
- ◉ Nongovernmental organisations (NGOs) operating at EU level
- ○ Research and academia (e.g. universities, think tanks)
- ○ Businesses or consultancy
- ○ Social partners (e.g. industry associations, trade union organisations)
- ○ Other type of organisation

* Please type the name of your organisation.

Standing Committee of European Doctors (CPME)

Section 2 - Effectiveness

In this section, we will explore the effectiveness of Regulation (EU) 2022/2371 by seeking your insights on its contribution to achieving both the general and specific objectives. The evaluation of effectiveness will focus on how well the Regulation has achieved its objectives, such as reinforcing prevention, preparedness, and response capacity, and strengthening the health workforce and surveillance systems. This will involve assessing whether the anticipated results, like enhanced risk assessment and coordinated EU responses, have been realised or are on the good track. We will delve into the output and results of the Regulation, evaluating how successful it has been in achieving or progressing towards its intended goals. Additionally, we are interested in any unexpected or unintended effects that may have influenced progress towards specific objectives.

* The general objective of Regulation (EU) 2022/2371 is to provide a strengthened framework for health crisis preparedness and response at EU level; a rigorous, consistent and coordinated approach to preparing for and managing potential health crises in the EU. To what extent has this general objective been met?
  - ○ Not at all
  - ○ To a limited extent
  - ◉ To some extent
  - ○ To a large extent
  - ○ To a very large extent
  - ○ I do not know

* Could you please elaborate on your answer?

Future pandemics or severe health emergencies may look different to the past pandemic. It is possible that climate related emergencies become frequent in the European region in future. What has become clear is that the 'just in time' rationale used in commercial sectors cannot be applied to health systems without severe risks. It is necessary to adopt a 'just in case' model. The 'just in case' model must include a baseline capacity which is sufficient to ensure Universal Health Coverage ("UHC") and surge capacities which can be deployed to deal with extraordinary situations. These structures must be based on permanent and guaranteed funding, in full acceptance that obsolescence and opportunity costs cannot be avoided. (https://www.cpme.eu/api/documents/adopted/2020/11/CPME_AD_Brd_21112020_111.FINAL_.CPME_.COVID19.pandemic.preparedness.lessons.learned.pdf)
Also, cooperation with third countries and international organisations in the field of public health should be fostered. It's also important ensuring the exchange of information with the WHO on the measures taken pursuant to the Regulation. CPME supports fostering cooperation with third countries and international organisations, as well as expanding the geographical scope of the European Centre for Disease Prevention and Control (ECDC) to cover also other than EU and EEA countries. This would allow better collaboration with the WHO European Region and avoid duplication of work.

To what extent has Regulation (EU) 2022/2371 so far been able to meet its specific objectives?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Reinforce prevention, preparedness and response capacity regarding biological, chemical, environmental and unknown threats	○	◉	○	○	○	○
* Strengthen health workforce	○	◉	○	○	○	○
* Strengthen surveillance	○	○	◉	○	○	○
* Enhance risk assessments at the EU level	○	◉	○	○	○	○
* Enhance cooperation of Member States and EEA/EFTA countries	○	◉	○	○	○	○
* Strengthen the coordination of the EU level response carried out by the Health Security Committee (HSC)	○	○	◉	○	○	○
* Strengthen EU response to health emergencies by establishing rules on the recognition of health emergencies at the EU level	○	○	◉	○	○	○

Could you please elaborate on your answer? If you responded with "I do not know" for a particular objective, you can state "N/A".

	Elaboration
Reinforce prevention, preparedness and response capacity regarding biological, chemical, environmental and unknown threats	Prevention, preparedness and response could be further reinforced by better integrating the One Health Approach into the regulation for a better and coordinated response.
Strengthen health workforce	Insufficient action has been taken at the national level to address the growing shortage of doctors and other healthcare professionals. Without decisive measures to strengthen the health workforce, current projections indicate a breakdown in health service sustainability. The COVID-19 pandemic exacerbated existing staff shortages and severely strained doctors leading to many developing burnout and leaving the profession altogether. To uphold safe working conditions which uphold a high level of patient safety, we call for the European Commission to develop Safe staffing guidelines as a benchmark for health threat preparedness. These guidelines should be informed by a more granular set of health systems data to be systematically collected from Member States. In addition to action addressing workforce shortages, investment in training programs targeted at health care professionals can also help to prepare for future cross-border health threats. Training must be financed for all doctors and other healthcare professionals regardless of their attachment to health authorities (national, regional or local level). Cross disciplinary training can facilitate the collaboration among various disciplines involved in the implementation of medical countermeasures, ensuring cohesive and coordinated responses to emerging threats. Training should also address risk communication and public engagement to ensure that doctors and other healthcare professionals can effectively communicate with the public to convey accurate information about medical countermeasures.
Strengthen surveillance	CPME believes that training of doctors and other healthcare professionals is essential. They must have knowledge and skills to develop and implement the national preparedness plans, implement activities to strengthen crisis preparedness and surveillance capacities.

Enhance risk assessments at the EU level	HERA should be involved in carrying out risk assessments at the EU level. On the basis of the health systems data collected, the European Commission should develop concrete recommendations for ratios for resources per population unit for Member States to use as a benchmark for preparedness. This includes but is not limited to data on the stock of doctors and other healthcare professionals, stock of medicines, medical devices and personal protection equipment, intensive care and acute care bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed, and data on the 3 resourcing of public health departments, in particular per capita staffing levels for 'community medicine' 2 (please see CPME Position on the Commission's Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control).
Enhance cooperation of Member States and EEA/EFTA countries	Improve data collection and sharing related to infectious diseases. Member States need to align their data collection and reporting to improve data quality and comparability in the EU and EEA countries. These should be the development of common definitions of containment measures (e.g. isolation, quarantine, tracing) to ensure comparability of data. It needs also to be established better EU standards for health data interoperability.
Strengthen the coordination of the EU level response carried out by the Health Security Committee (HSC)	Coordination of the EU level response carried out by the HSC should be strengthened by making the necessary link with HERA, especially for the deployment of medical countermeasures and training needs.
Strengthen EU response to health emergencies by establishing rules on the recognition of health emergencies at the EU level	N/A

* If you compare the present situation with the situation before the COVID-19 pandemic, what is, in your view, the most significant change that you can link to the Regulation (EU) 2022/2371?

Compared to the period before the COVID-19 pandemic, the regulation was a cornerstone on improving prevention, preparedness, and response capacity at the EU level. Nonetheless, it would be worth connecting this initiative with DG HERA efforts on pandemic preparedness, namely the work carried out by the HSC. It should also be noted that the work of HSC and the different EU agencies (namely ECDC and EMA) should be closely interlinked with the overall aims of the serious cross-border threats to health regulation.
With the creation of HERA, the European Commission has rightly recognised a need for a new mechanism responsible for improving emergency preparedness and response, but this needs to be linked with the cross-border threats to health regulation. In terms of preparedness, HERA has made first steps to prioritise medical countermeasures, identify ways to bring novel antimicrobials to the market, and develop an innovation financing mechanism that has the potential to accelerate and de-risk research and development activities. More and more work is being done on joint procurement and on stockpiling and a dedicated strategy is expected soon and should be linked with the overall cross-border threats to health regulation. (https://www.cpme.eu/api/documents/adopted/2023/12/cpme_ad_14122023_142.final.hera.review.public.consultation.pdf)

* In your opinion, which positive effects related to preparedness at different levels (i.e. national, regional, EU) can be associated with this Regulation?

- [ ] EU and Member States are better prepared at national, regional, EU level
- [ ] Comprehensive and efficient overview of health threats at all levels
- [ ] More effective cross-border coordination during health emergencies
- [x] None of the above

* Could you elaborate on your answer?

N/A

* In your opinion, which positive effects related to training and capacity building can be associated with this Regulation?

- [ ] Continuously trained health specialists
- [ ] Increased number of training events and modules for healthcare workers
- [x] None of the above

* Could you elaborate on your answer?

HERA should have a more holistic view of health, by having a broader definition than medical countermeasures (MCM). The wording “public health countermeasures” would be more appropriate than “medical countermeasures”. This would allow for a holistic approach to health threats that includes recommendations on human resources for health, workforce distribution, training, shortages, capacity planning, supporting national capacity building for emergency preparedness, resource planning, joint procurement and above all protecting the most vulnerable. In this context, HERA can provide technical assistance and capacity-building support to EU member states with limited resources or expertise in medical countermeasure training. This would ensure that all countries in the EU have the necessary capabilities to respond effectively to health emergencies.

* In your opinion, which positive effects related to surveillance systems can be associated with this Regulation?

- [ ] Strengthened digitalised, integrated surveillance system at EU level
- [ ] Strengthened digitalised, integrated surveillance system at Member State level
- [x] None of the above

* Could you elaborate on your answer?

We respond to this question with the point of view of doctors. Where Member States share a border, 'Prevention, Preparedness and Response Planning' should include familiarity with public health structures and staff in the adjoining State and should involve conducting joint cross-border exercises. To reduce barriers to access, training should be provided during working time and at no expense to participating doctors or other healthcare professionals. Linked to this, HERA could organise training activities for healthcare staff and public health staff in the EU Member States, including preparedness capacities under the International Health Regulations. In these endeavours, it is paramount to ensure that training activities cover 'One-Health' both in terms of content and format of training, in recognition of the interlinks between human health, animal health and the environment as well as the high percentage of communicable diseases which are zoonotic. (https://www.cpme.eu/api/documents/adopted/2024/04/cpme.2024-082.final.response.hera.survey.mcms-1721744210.pdf)
Regarding surveillance systems, CPME believes that monitoring trends in communicable diseases in the wider European region is essential to assess the situation and respond to threats with evidence-based action. Therefore, CPME finds the communication between EU institutions, EU agencies and the national level crucial.

* In your opinion, which positive effects related to risk assessment and response can be associated with this Regulation?

- [ ] Enhanced risk assessment for health threats
- [ ] Assignment of responsibility of risk assessments for chemical, environmental, climate threats to relevant agencies
- [ ] Health Security Committee (HSC) adopted opinions and guidance on response measures to health threats
- [ ] Coordinated EU response to health threats via the Health Security Committee (HSC)
- [x] None of the above

* Could you elaborate on your answer?

The COVID-19 pandemic has shown the limited ability of the HSC to enforce and coordinate the national responses around control measures or to implement the agreed common approaches. It would be important to link HSC activities and opinions with the one carried out by DG HERA, especially on deployment of medical countermeasures.

* In your opinion, which positive effects related to access to information and public engagement can be associated with this Regulation?

- [ ] Diminished disinformation, increased availability and accessibility and uptake of accurate, evidence-based information
- [ ] Establishment of feedback, coordination and consultation mechanisms for civil society
- [ ] Establishment of risk communication strategies based on thorough understanding of needs of EU citizens
- [x] None of the above

* Could you elaborate on your answer?

CPME supports the improved coordination of clear division of competences between Member States, WHO and WHO-Europe, the EU and its agencies, and OECD as to the declarations of pandemics, subsequent containment or treatment measures, effective data collection and sharing and horizonal coordination on recommendations.

* In your opinion, which positive effects related to emergency response times can be associated with this Regulation?

- [ ] Faster response times to emerging health crises at Member State level
- [ ] Faster response times to emerging health crises at EU level
- [x] None of the above

* Could you elaborate on your answer?

In the perspective of European Doctors, faster response times to emerging health crises at EU level should be further improved by integrating in the regulation DG HERA and the necessary coordination between the HSC, EU agencies (EMA, ECDC) and DG HERA to have a better and more streamlined response to crises.

* In your opinion, which positive effects related to collaboration and support can be associated with this Regulation?

- [ ] Improved cooperation between public health authorities and other sectors (e.g. environment, transport)
- [ ] Greater financial and logistical support for Member States during health crises
- [x] None of the above

* Could you elaborate on your answer?

CPME welcomed the proposal to establish a new Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level. It is important that the preparation of national plans will be supported by ECDC and other EU agencies and also DG HERA. When preparing the public health assessment, the HSC should also involve DG HERA in such task and the regulation would benefit on having this integrated on article 20 (“Public health risk assessment”).

* In your opinion, which positive effects related to medical supplies and access can be associated with this Regulation?

- [ ] Better access to essential medical supplies during emergencies for Member States
- [ ] Increased sharing of scientific research and relevant health data across Member States
- [x] None of the above

* Could you elaborate on your answer?

N/A

* Are there any other positive effects that can be associated with this Regulation? If so, please elaborate.

The regulation aims to foster increased sharing of scientific research and relevant data across member states, but Prevention, preparedness and response planning should be strengthened by scoping a set of EU public health data and define relevant data to be collected at national level which should be shared (e.g. stock of doctors and other healthcare professionals including shortages, stock of medicines, medical devices and personal protection equipment, intensive care and acute care bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed). Identifying the data to be shared in advance offers procedure transparency, increases trust on the adopted countermeasures by Member States and facilitates the coordination of patients in border regions, in particular by understanding a Member State capacity to treat patients from nearby Member States.
Community medicine needs to be resourced and strengthened at all levels relevant to each Member State including national, regional and community level in order to ensure that the expertise and capacity is available to prevent and minimise threats from developing and spreading. The reference to community medicine refers to the medical specialty as described in Directive 2005/36/EC, Annex V, 1.3, covering titles in public health medicine, social medicine, epidemiology.

* In your opinion, which negative effects can be associated with this Regulation? Multiple answers possible

- [ ] Weakened digitalised, integrated surveillance system at EU level
- [ ] Weakened digitalised, integrated surveillance system at Member State level
- [ ] Increased bureaucratic burden on Member States
- [ ] Slower decision-making at Member State level due to the need for EU-level coordination
- [ ] Overreliance on EU institutions, weakening national public health systems
- [ ] Inefficient allocation of resources during health crises
- [ ] Unequal access to medical supplies across Member States
- [ ] Insufficient funding or resources for to implementing the Regulation
- [ ] Complexity in aligning national policies with EU-wide guidelines
- [ ] Reduced sovereignty in managing national health policies
- [x] Unclarity about the roles and mandates of Member States vis a vis the mandate of HERA and extended mandate of ECDC
- [ ] No negative effects noticed
- [ ] Other, please specify

* Could you elaborate on your answer?

The mandate of HERA and extended mandate of EMA and ECDC should be better reflected in the regulation to ensure better coordination between the different actors both in preparedness and response phases to public health emergencies. There should also be reflected a clear distinction of roles and mandates of member states vis a vis the mandates of the bodies above-mentioned.

* Have you observed any unexpected or unintended effects (either positive or negative) of the Regulation?

- ( ) Yes
- (•) No

* In your view, which conditions are necessary for an effective implementation of this Regulation?

Smooth and permanent communication between the European Commission, the ECDC, and the competent authorities responsible at national level by a network for the epidemiological surveillance of the communicable diseases. CPME believes that monitoring trends in communicable diseases in the wider European region is essential to assess the situation and respond to threats with evidence-based action. Therefore, CPME finds the communication between EU institutions, EU agencies and the national level crucial.

Also, regarding the platform for surveillance, CPME believes that human oversight is required at a strategic moment of the process when implementing automated real-time surveillance for the purpose of supporting communicable disease prevention and control.

Adequate resources, namely financial investments in pandemic preparedness, medical countermeasures and their deployment, and R&D. Also, enough human resources and training programmes for healthcare professionals are needed.

* To what extent are these conditions currently met?

- ○ Not at all
- ◉ To a limited extent
- ○ To some extent
- ○ To a large extent
- ○ To a very large extent
- ○ I do not know

Why are these conditions not, or not fully, being met?

The COVID-19 pandemic has shown a lack of comparable data and understanding of the situation on which to base decision-making and this was not fully addressed yet.
To complement the cross-border threats to health regulation, a HERA strategy for training and exercise on medical countermeasures could harness several unique opportunities that complement or enhance existing efforts at member state and European levels.

To what extent are the following factors important in determining whether Regulation (EU) 2022/2371 delivers on its objectives?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Financial resources dedicated to health issues at EU level	○	○	○	◉	○	○
* Financial resources dedicated to health issues at the national level	○	○	○	○	◉	○
* Human resources at EU level dedicated to health issues	○	○	○	○	◉	○
* Human resources at national level dedicated to health issues	○	○	○	○	◉	○

* Level of collaboration on health issues between Member States	○	○	○	○	○	◉
* Level of collaboration on health issues between Member States and EU bodies	○	○	○	○	◉	○
* Synergies across different EU programmes relevant for the response to cross-border health threats (e.g. EU4Health, RescEU)	○	○	○	○	○	◉
* Sufficient level of expertise, data and/or knowledge within the Member State	○	○	○	○	◉	○
* Clear and simple funding application process	○	○	◉	○	○	○
Other	○	○	○	○	○	◉

* What are, based on your experience, the weaknesses in the implementation of the Regulation on the ground?

Health financing cannot be treated as if it were a commercial sector. We need to fund for ‘just in case’ and not ‘just in time’. Despite the end of the pandemic phase of COVID-19, funding for resilient health systems must remain a priority. In order to be prepared for future challenges, health systems must be strategically planned and sustainably resourced and cannot simply rely on political reactions in crisis situations.

* What are, in your view, the underlying causes of these weaknesses?

Lack of long-term planning, not enough coordination between existing structures, the sense of urgency seen during the pandemic was quite lost in the post-COVID-19 phase. Variability on national capacities lead to different crisis responses, and ECDC should better support member states identifying and closing such national gaps to have a more harmonized EU capacity and response.

Section 3 - Efficiency

In this section, our focus is on evaluating the cost-effectiveness of Regulation (EU) 2022/2371. We will examine the relationship between the resources allocated (e.g. budget, time, and other resources), the activities carried out (e.g. preparedness plans, surveillance systems, and audits) and their impacts. The study will consider whether the outputs, such as training events and digitalised surveillance system, were delivered cost-effectively and within the expected timeframe. By estimating changes in activities related to the Regulation's implementation, we aim to estimate the potential benefits associated with these activities.

In assessing the costs of the Regulation, our goal is to account for all expenses associated with its implementation. We strive to link incurred costs, time spent, and human resources allocated to new or modified activities related to the Regulation wherever possible. This includes the budget allocated by stakeholders—representing the necessary resources for implementation of the Regulation—the time stakeholders invest in monitoring and reporting on related activities, and the human resources dedicated to comply with the provisions of the legislation. In particular, we look for information on the variation of the resources and time against the situation of the previous legislative text (i.e. Decision No 1082/2013/EU). The resources and time should be related to the costs borne to:

- provide information and submit reports to comply with administrative obligations included in legal rules.
- adjust the activities to the requirements of the legal rules (i.e. implementation costs, direct labour cost, overhead, equipment costs, material costs and costs for external services).

Section 3a - Efficiency (comparison of costs, savings, and benefits against Decision No 1082/2013/EU)

This section includes questions for the comparison of Regulation (EU) 2022/2371 against the provisions in the previous legislative text (i.e. Decision No 1082/2013/EU) that might imply incremental costs, cost savings and other benefits.

Can you quantify the inputs necessary for the preparedness and response planning, before the implementation of the Regulation's Article 5 on the Union prevention, preparedness and response plan?

Input	Activity	Frequency of activity per year	Response
Allocated budget (in EUR/year)			N/A
Time invested (in Person-day/year)			N/A
Human resources (in FTE/year)			N/A

To what extent have these inputs changed for the preparedness and response planning because of the implementation of the Regulation's Article 5 on the Union prevention, preparedness and response plan?

Input	Large decrease (more than 15%)	Moderate decrease (between 5% and 15%)	Unchanged (±5%)	Moderate increase (between 5% and 15%)	Large increase (more than 15%)	I do not know
Allocated budget for the implementation of the Regulation	○	○	○	○	○	◉
Time invested for the implementation of the Regulation	○	○	○	○	○	◉
Human resources for the implementation of the Regulation	○	○	○	○	○	◉

Section 3b - Efficiency (Regulation provisions affecting costs, savings, and benefits)

This section includes questions for new provisions of the Regulation that might imply incremental costs, cost savings and other benefits.

Can you quantify the inputs necessary to implement the national prevention, preparedness and response plan of the Regulation's Article 6 on national prevention, preparedness and response plans?

Input	Activity	Frequency of activity per year	Response
Allocated budget (in EUR/year)			N/A
Time invested (in Person-day/year)			N/A
Human resources (in FTE/year)			N/A

To what extent have these inputs changed because of the implementation of Regulation (EU) 2022/2371?

Input	Large decrease (more than 15%)	Moderate decrease (between 5% and 15%)	Unchanged (±5%)	Moderate increase (between 5% and 15%)	Large increase (more than 15%)	I do not know
Allocated budget for the implementation of the Regulation	○	○	○	○	○	◉
Time invested for the implementation of the Regulation	○	○	○	○	○	◉
Human resources for the implementation of the Regulation	○	○	○	○	○	◉

Can you quantify the inputs necessary for the following activities compared to before the implementation of Regulation (EU) 2022/2371?

Please see per activity identified, a number of sub-activities that might be relevant for your organisation. If you have additional inputs related to a certain activity, please specify this.

Please also specify the unit of measurement (EUR/year, Person-day/year or FTE/year).

If the activity is not relevant for your organisation, please leave the box empty and move on to the next type of activity.

Setting new preparedness plans

	Activity	Unit of Measurement	Response
Risk assessment			N/A
Resource mapping			N/A
Capacity building			N/A
Scenario planning			N/A
Aligning with EU guidelines			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

N/A

Surveillance systems

	Activity	Unit of Measurement	Response
Data protection protocols			N/A
Digital integration			N/A
Training for data analysts			N/A
Interagency data sharing			N/A
Public health intelligence monitoring			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

Conducting tests and audits

	Activity	Unit of Measurement	Response
Testing protocol development			N/A
Regular audits of health facilities			N/A
Performance review meetings			N/A
Documentation and reporting			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

N/A

Setting up new competent authorities in the new networks in Member States

	Activity	Unit of Measurement	Response
Designation of competent authorities			N/A
Resource allocation			N/A
Defining roles and responsibilities			N/A
Training and capacity building			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

Participation in meetings

	Activity	Unit of Measurement	Response
Time spent on meeting preparation and participation			N/A
Documentation			N/A
Follow-up on action points			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

Coordination of working groups

	Activity	Unit of Measurement	Response
Selection of participants			N/A
Coordination			N/A
Reporting and accountability			N/A
Knowledge sharing			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

Involvement of civil society by EU and Member States in outbreak response

	Activity	Unit of Measurement	Response
Public awareness campaigns			Support harmonised and coordinated communication among EU member states, to ensure consistent messaging and enhance public trust. Prepare the population and promote a sense of EU responsibility and solidarity through the development of an EU-level strategy, recommendations and materials for public information to prepare and equip citizens to address health threats, especially tailored to vulnerable populations including those living with chronic diseases. HERA could leverage existing work being done including through promotion of public projects for citizen information provision to enhance emergency preparedness.
Feedback mechanisms for public input			N/A
Collaboration with NGOs and community organisations			N/A
Regular updates			N/A

Are there any other sub-activities that should be considered? If so, please elaborate and state their unit of measurement and your response.

Section 3c - Efficiency (variation of outputs)

These questions aim to assess how the implementation of Regulation (EU) 2022/2371 has affected the outcomes or outputs of related activities.

To what extent have the outputs changed due to the implementation of the provisions of Regulation (EU) 2022/2371? We have provided the following list of output categories related to the Regulation:

1. Training events and modules for healthcare workers
2. Digitalised integrated surveillance systems
3. Stress tests and audits in Member States
4. Network of reference laboratories
5. Assigning responsibility of risk assessments
6. Health Security Committee (HSC) adopts opinions and guidance
7. Mechanism for EU-level recognition of health threats
8. Risk communication strategies

For each output category, please identify activities relevant for your organisation. For instance, under training events and modules for healthcare workers, you might specify the increase in output related to the number of training events attended by healthcare workers or the on-the-job training modules provided for them and duration thereof.

Describe the activity as specifically as possible.

If the output is not relevant for your organisation, please leave the box empty and progress to the next type of output.

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Training events and modules for healthcare workers."

Training events and modules for healthcare workers	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Curriculum development							N/A
Workshops and seminars							N/A

Certification programmes							N/A
On-the-job training							N/A
Evaluation and feedback mechanisms							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Digitalised integrated surveillance systems."

Digitalised integrated surveillance systems	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Data collection and analysis							N/A
Integration of data sources							N/A
Monitoring and reporting							N/A
Technology investments							N/A
Public health research							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Stress tests and audits in Member States."

Stress tests and audits in Member States	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Designing stress tests							N/A
Conducting audits							N/A
Reporting and evaluation							N/A
Implementation of recommendations							N/A
Stakeholder engagement							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Network of reference laboratories."

Network of reference laboratories	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Development of laboratory standards							N/A
Coordination among laboratories							N/A
Sharing best practices							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Assigning responsibility of risk assessments."

Assigning responsibility of risk assessments	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Defining roles and responsibilities							N/A
Developing risk assessment frameworks							N/A
Other, please specify:							N/A

HSC adopts opinions and guidance

Health Security Committee (HSC) adopts opinions and guidance	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Drafting guidelines							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Mechanism for EU-level recognition of health threats."

Mechanism for EU-level recognition of health threats	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Establishing recognition protocols							N/A
Implementing response frameworks							N/A
Feedback, coordination, and consultation mechanisms							N/A
Engaging civil society							N/A
Collecting public feedback							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for the output you identified to fall under "Risk communication strategies."

Risk communication strategies	Please shortly elaborate on what this entails for your organisation.	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
Developing tailored communication plans							N/A
Training for effective communication							N/A
Other, please specify:							N/A

Please mark an "X" in the column that best represents your estimated increase or decrease for other output that did not fall under any category above.

Other	Please list activities that fall under this output category here	Large decrease (>15%)	Moderate decrease (5-15%)	Unchanged (±5%)	Moderate increase (5-15%)	Large increase (>15%)	I do not know
1. Please specify output							N/A
2. Please specify output							N/A
3. Please specify output							N/A

Section 4 - Relevance

In this section, we aim to assess the relevance of Regulation (EU) 2022/2371 by exploring key aspects related to its scope, objectives, and alignment with current needs and future challenges within the EU. The relevance criterion will assess the extent to which the Regulation addresses the needs it was designed to meet, specifically better preparedness for health crises at the EU level and improved coordination and response during health crises. This includes evaluating the Regulation's alignment with current health challenges and its ability to adapt to new health threats. We will also assess the degree to which the intervention addresses the specific needs of all relevant stakeholder groups.

Regulation (EU) 2022/2371 has several objectives. To what extent do you think these objectives have been relevant throughout the implementation period (i.e. from 2022 to the present day)?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* A strengthened framework for health crisis preparedness and response	○	○	○	○	○	◉
* Reinforce prevention, preparedness and response capacity	○	○	○	○	○	◉
* Strengthen health workforce	◉	○	○	○	○	○
* Strengthen the surveillance system to detect possible health threats including social determinants	○	○	○	○	○	◉
* Enhance risk assessments at the EU level including social determinants	○	○	○	○	○	◉
* Enhance Member State cooperation on ECDC networks	○	○	○	○	○	◉
* Enhance Member State cooperation on EU reference laboratories	○	○	◉	○	○	○
* Enhance Member State cooperation on other Member State networks	○	○	○	○	○	◉
* Strengthen the EU-level response coordination in the Health Security Committee (HSC)	○	○	◉	○	○	○
* Strengthen EU response to health emergencies by establishing rules on the recognition of health emergencies at the EU level	○	○	◉	○	○	○

To what extent are the objectives of the Regulation relevant in the future?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* A strengthened framework for health crisis preparedness and response	○	○	○	○	◉	○
* Reinforce prevention, preparedness and response capacity	○	○	○	○	◉	○
* Strengthen health workforce	○	○	○	○	◉	○
* Strengthen the surveillance system to detect possible health threats including social determinants	○	○	○	○	◉	○
* Enhance risk assessments at the EU level including social determinants	○	○	○	○	◉	○
* Enhance Member State cooperation on ECDC networks	○	○	○	◉	○	○
* Enhance Member State cooperation on EU reference laboratories	○	○	◉	○	○	○
* Enhance Member State cooperation on other Member State networks	○	○	○	◉	○	○
* Strengthen the EU-level response coordination in the Health Security Committee (HSC)	○	○	○	○	◉	○
* Strengthen EU response to health emergencies by establishing rules on the recognition of health emergencies at the EU level	○	○	○	○	◉	○

* Could you suggest any current cross-border health threats currently missing from the scope of the Regulation? Multiple answers possible

- ☐ Nuclear threats
- ☐ Radiological threats
- ☐ Wars
- ☐ Democratic shifts
- ☑ Other

If other, please specify:

Shortages of doctors and other healthcare professionals represent a serious hazard to health which can exacerbate existing health threats such as infectious diseases. Health workforce planning systems and preparedness plans need to sufficiently detail safe staffing levels as well as take concrete steps to achieve these objectives.

To what extent do the following problems addressed by the Regulation continue to require action at EU level?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Insufficient preparedness for health crises at the EU level	○	○	○	○	◉	○
* Insufficient EU-level coordination and response during a health crisis	○	○	○	○	◉	○
* Insufficient data sharing reporting requirements and analysis regarding health systems indicators	○	○	○	○	◉	○

* In your opinion, are any problems missing that are/should be tackled by the Regulation? Please elaborate.

A broader definition of Medical Countermeasures needs to be used. We would advocate for the inclusion of public health countermeasures allowing for a holistic approach to health threats that includes recommendations on human resources for health, workforce distribution, training, shortages, capacity planning, supporting national capacity building for emergency preparedness, resource planning, joint procurement and above all protecting the most vulnerable. Furthermore, the health systems data referred to in Article 13 paragraph 2 sub point f needs to be further define categories of relevant health systems data such as stock of doctors and other healthcare professionals, stock of medicines, medical devices and personal protective equipment, intensive care and acute care bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed.

Section 5 - Coherence

This section explores the coherence of Regulation (EU) 2022/2371, both internally and externally. We will consider internal coherence, assessing how well the various components of the Regulation support each other. We will also examine how well the Regulation works with other existing legislation and policies, such as the European Health Data Space and the International Health Regulations. Furthermore, we will look at the coherence with national interventions.

Section 5a - Coherence (internal)

* To what extent are the objectives and activities of Regulation (EU) 2022/2371 coherent?

- ○ Not at all
- ○ To a limited extent
- ◉ To some extent
- ○ To a large extent
- ○ To a very large extent
- ○ I do not know

Could you elaborate on your answer?

*

The objectives of the regulation could benefit from better alignment with the mandate of HERA, especially regarding joint procurement and stockpiling, to better synchronize such activities with HERA's overarching strategy to avoid duplication of work and ensure efficiency. HERA capacities could be utilized to inform the epidemiological surveillance, early warning systems, and health system assessment foreseen in the regulation. Developing a coordination framework could streamline efforts between HERA, the Commission and the HSC. Furthermore, alignment between HERA annual work plan and the regulation preparedness and response plans could ensure coherence into a broader strategic planning.

* To what extent are there inconsistencies among the requirements and provisions of the Regulation, if any?

- ○ Not at all
- ○ To a limited extent
- ○ To some extent
- ○ To a large extent
- ○ To a very large extent
- ◉ I do not know

* Could you elaborate on your answer?

N/A

* Are there overlaps?

- ○ Not at all
- ◉ To a limited extent
- ○ To some extent
- ○ To a large extent
- ○ To a very large extent
- ○ I do not know

* Could you elaborate on your answer?

N/A

* Would you like to provide any further comments or insights on the internal coherence of the Regulation?

N/A

Section 5b - Coherence (external)

* To what extent are the objectives of Regulation (EU) 2022/2371 coherent with the priorities of Member States in the area of health?

- ○ Not at all
- ○ To a limited extent
- ○ To some extent
- ○ To a large extent
- ○ To a very large extent

I do not know

* Could you elaborate on your answer?

N/A

* Do you have any specific examples of coherence or lack thereof?

N/A

To what extent is Regulation (EU) 2022/2371 coherent with other EU policies and/or actions at EU level?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Pharmaceutical Strategy for Europe	○	○	○	○	○	◉
* European Health Data Space	○	○	○	○	○	◉
* EU4Health Programme	○	○	○	○	○	◉
* Reinforced mandate of EMA	○	○	○	○	○	◉
* Commission Decision establishing HERA	○	○	○	○	○	◉
* Other	○	○	○	○	○	◉

* Could you elaborate on your answer?

The functioning of the digital platform for surveillance and the mechanism to exchange electronic health data are still unclear. Considering the upcoming European Health Data Space, CPME highlights the need to discuss with stakeholders the implementation of the digital platform for surveillance, in particular the access to retrieve relevant health data and non-personal data from electronic health records and health databases, while respecting the principle of minimisation, medical confidentiality, data security, personal data and privacy. CPME emphasises the continuous need to reduce administrative burdens for doctors and other healthcare professionals and that the integrated surveillance system does not affect negatively clinical practice.

CPME would request transparency during the comitology procedure and the involvement of doctors and other healthcare professionals when preparing the implementing and delegated acts related to the digital platform for surveillance.

To what extent is Regulation (EU) 2022/2371 coherent with international policies?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know

* International Health Regulations	○	○	○	○	○	◉
* TRIPS Agreement on Public Health	○	○	○	○	○	◉
* The Global Preparedness Monitoring Board (GPMB)	○	○	○	○	○	◉
* Other	○	○	○	○	○	◉

* Could you elaborate on your answer?

N/A

* Would you like to provide any further comments or insights on the external coherence of the Regulation?

N/A

Section 6 – EU added value

This section focuses on the added value of Regulation (EU) 2022/2371, specifically exploring the benefits of EU-level intervention compared to national or regional action. The evaluation of EU added value will determine the benefits of implementing the Regulation at the EU level, as opposed to national or regional levels. This includes assessing whether the Regulation has led to improved, timely, and more efficient health crisis preparedness and response across the EU. The following elements of EU added value have been identified:

- The development of an EU health crisis and pandemic preparedness plan
- National plans and transparent reporting of capacities
- Introduction of Early Warning and Response System (EWRS)
- Strengthened, integrated surveillance systems
- Enhanced risk assessment for health threats
- Possibility for joint procurement
- Training for healthcare and public health staff organised by the European Commission
- Increased power to enforce a coordinated response at EU level through the Health Security Committee (HSC)
- An improved mechanism for recognition of and response to public health emergencies

To what extent do the elements introduced by Regulation (EU) 2022/2371 go beyond what could reasonably be expected from Member States acting independently?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know

* The development of an EU health crisis and pandemic preparedness plan	○	○	○	○	◉	○
* National plans and transparent reporting of capacities	○	○	○	◉	○	○
* Introduction of Early Warning and Response System (EWRS)	○	○	○	○	◉	○
* Strengthened, integrated surveillance systems	○	○	○	◉	○	○
* Enhanced risk assessment for health threats	○	○	○	◉	○	○
* Possibility for joint procurement of medical countermeasures	○	○	○	○	◉	○
* Training for healthcare and public health staff organised by the European Commission	○	○	○	○	◉	○
* Increased power to enforce a coordinated response at EU level through the Health Security Committee (HSC)	○	○	○	◉	○	○
* An improved mechanism for recognition of and response to public health emergencies	○	○	○	○	◉	○

To what extent could the elements introduced by Regulation (EU) 2022/2371 have been achieved in the absence of the Regulation?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* The development of an EU health crisis and pandemic preparedness plan	○	○	○	○	○	◉
* National plans and transparent reporting of capacities	○	○	○	○	○	◉
* Introduction of Early Warning and Response System (EWRS)	○	○	○	○	○	◉
* Strengthened, integrated surveillance systems	○	○	○	○	○	◉
* Enhanced risk assessment for health threats	○	○	○	○	○	◉
* Possibility for joint procurement	○	○	○	○	○	◉
* Training for healthcare and public health staff organised by the European Commission	○	○	○	○	○	◉
* Increased power to enforce a coordinated response at EU level through the Health Security Committee (HSC)	○	○	○	○	○	◉

* An improved mechanism for recognition of and response to public health emergencies	○	○	○	○	○	◉

To what extent do you think that the objectives of Regulation (EU) 2022/2371 are best met by action at the EU level?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Reinforce prevention, preparedness and response capacity regarding biological, chemical, environmental and unknown threats	○	○	○	○	◉	○
* Strengthen health workforce	○	○	○	○	◉	○
* Strengthen surveillance	○	○	○	○	◉	○
* Enhance risk assessments at EU level	○	○	○	○	◉	○
* Enhance cooperation of Member States and EEA/EFTA countries	○	○	○	◉	○	○
* Strengthen the coordination of the EU level response carried out by the Health Security Committee (HSC)	○	○	○	○	◉	○
* Strengthen EU response to health emergencies by establishing rules on the recognition of health emergencies at EU level	○	○	○	○	◉	○

To what extent is EU level coordination needed in each of the areas covered by the Regulation?

	Not at all	To a limited extent	To some extent	To a large extent	To a very large extent	I do not know
* Prevention, preparedness and response plan	○	○	○	○	◉	○
* Epidemiological surveillance, EU reference laboratories and ad hoc monitoring	○	○	○	◉	○	○
* Early warning and response	○	○	○	○	◉	○
* Public health emergency at Union level	○	○	○	○	◉	○

* What would be the consequences of stopping or withdrawing Regulation 2022/2371?

The EU has an important role to play in coordinating the preparedness and response to serious cross border threats to health and the Regulation provides a good legal instrument which formalizes the earlier institutional arrangements for pandemic preparedness. EU joint procurement of medical countermeasures is a clear added value of HERA which should be linked with this regulation. Withdrawing the Regulation would lead to increased uncertainty regarding the roles of EU institutions and agencies in a pandemic and would contribute to delaying decisive action on addressing urgent health threats. Nonetheless, the regulation could be strengthened by smoothly linking it with the EMA and ECDC extended mandates and also with DG HERA.

Section 7 - Concluding remarks

We would like to offer opportunities for further engagement on this study. If you are open to a follow-up interview based on your survey responses, or if you are interested in participating in a public webinar, please let us know by providing your contact details below. All information will be treated with the utmost security and confidentiality and will be accessible only to the study team for the purposes of this project.

Please indicate your interest in the following engagement opportunities:

- [x] I am open to a follow-up interview based on my survey responses.
- [x] I am interested in participating in the public webinar.
- [ ] I am not interested in further engagement at this time.

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Thank you

Thank you for your input. Your insights are important in evaluating the functioning of Regulation (EU) 2022/2371 on serious cross-border threats to health. We appreciate the time and responses you have provided. For any survey-related inquiries, please contact us via rana.orhanpees@ecorys.com. In case you wish to reach the DG SANTE unit responsible for the evaluation of the Regulation, please send an email to SANTE-CONSULT-B2@ec.europa.eu.

Contact

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