Universiteit Leiden
The Netherlands

Shaping European Health Policies from below: The influence of the Committee of the Regions

Krieps Dupong, Elisabeth

Citation
Krieps Dupong, E. (2024). *Shaping European Health Policies from below: The influence of the Committee of the Regions*.

Version:	Not Applicable (or Unknown)
License:	License to inclusion and publication of a Bachelor or Master Thesis, 2023
Downloaded from:	https://hdl.handle.net/1887/3764976

Note: To cite this publication please use the final published version (if applicable).

Student: Elisabeth Krieps Dupong

Student number: S319769

Supervisor: Dr. Ir. A.A.H.E. (Ellen) van Reuler

Leiden University BSc Political Science Specialisation International Relations and Organisations

BAP: European Health Policies

Date of submission: 24/05/2024

Word count: 7399

Embargo Statement: Public

Bachelor Thesis

Shaping European Health Policies from below:

The influence of the Committee of the Regions

Table of Contents

I. Introduction

"The COVID-19 pandemic made it harshly clear that all levels of governance need to join forces to combat major health threats. [...]. The European Health Union has the potential to make a real difference in the lives of people across the EU, but it can only succeed if local and regional authorities are at the centre of it."

- Vascos Alves Cordiero, President of the European Committee of the Regions (CoR, 2023)

The COVID-19 pandemic exposed profound health inequalities in Europe, especially across its regions. European regions were affected by the crisis to different degrees and responded according to the means available, explaining some variation in excess mortality (Bayerlein, 2024, p. 6). There are many reasons for the asymmetric impact of COVID-19, such as disparities between rural and urban areas or the economic situation of individual regions (p. 39). The region's needs and health challenges differ, even within member states (Scholz, 2020, p. 4). Before and since the pandemic, the European Union had announced ambitious plans to improve access to proper health care across Europe. In the COVID-19 health crisis context, the EU has introduced programmes such as the NextGeneretionEU recovery fund and the Health Emergency Preparedness and Response (HERA) to help Member States and regions recover and prepare themselves better for future epidemics. In these new initiatives and other policy areas, the European Union has emphasised the will to increase dialogue with the sub-national governments and local stakeholders to improve the efficiency of the policies on the ground (Scholz, 2020, p. 36).

However, the limited participation of local authorities and regional governments in the EU's policy and governance process remains a concern (Weatherill, 2005, p. 14). Many regional authorities are dissatisfied with the EU's top-down approach and are wary of its interference in domestic affairs (Dellmuth, 2021, pp. 121-122). This regional scepticism threatens the EU's integration process and its overarching goals, including achieving universal healthcare. Moreover, the EU relies on sub-state authorities to implement the policies agreed upon by the institutions and Member states, underscoring the importance of their cooperation (Weatherill, 2005, p. 3). Consequently, the EU increasingly recognises the pivotal role of regional governments, particularly in times of crisis, and strives to foster deeper relations with local actors.

Research on the EU's policy-making process has shown that decision-making does not only lie in the hands of the European Union's supranational institutions or member states but a great variety

of government levels (Hooghe & Marks, 2001; Bach, 2012; Pazos-Vidal, 2019; Schakel, 2020). A multi-governance perspective reveals that even regional government levels impact policymaking in Brussels (Schakel, 2020, p. 768). However, the extent to which the European regions have or can influence the European Union's health policies is still unclear. Regional interests and needs in EU affairs at the EU level are represented through the Committee of the Regions (CoR) (Schönlau, 2020, p. 198). The CoR is a consultative committee whose opinion is asked by the European Union's legislators on key areas of regional concern and policies that do explicitly target regions (Schakel, 2020, p.767). The consultative role involves publishing amendments and recommendations on the Commission's policy proposals, including health policies.

This research paper will analyse the consultative documents of the CoR to determine the region's interests and then compare them to the policy agreed upon in the EU. This inquiry is interesting for several reasons. For instance, local and regional authorities have come to play an essential role in implementing European legislation and battling health crises on the ground. Also, recent developments on the EU level indicate the increased power of the CoR in the policy-making process.

The thesis will be divided into eight chapters to answer the research question. After the introduction, the academic literature and the theories needed to formulate the research question will be reviewed. Then, the theoretical framework will explore the theories used to determine expectations and potential answers to the research question. The theoretical framework also includes the conceptual definitions of critical terms. The fourth chapter on the methodology introduces the research design, the case selection used to test the hypothesis, and explanations of how and which data will be obtained. Finally, the analysis follows, which will be pursued by discussing the findings. In the final chapter, conclusions and implications are drawn.

II. Literature Review

1. The EU's governance model

The body of literature on the governance system of the European Union is rich and diverse. However, the two academics, Hooghe and Marks, have shaped the field. They evaluated state-centric and multi-level models of European governance in the different stages of EU policymaking to find out which is the most fitting for the Union (2001, p. 3). According to the authors, the traditional state-centric model claims that policy outcomes are tailored to the interests of national governments (p. 2). In that case, the supranational institutions of the EU serve the goals of the EU member states, which are constrained by domestic politics (p. 4). Conversely, the

multi-governance model claims that decision-making competencies are shared across multiple levels of government, including the sub-national, national, and supranational (p.5).

In the academic field of EU governance and policymaking, the latter model has, over the years, come to be accepted as the standard. There is widespread agreement that since the Maastricht Treaties (1992) and the acceleration of European integration, political and legal responsibilities are increasingly dispersed across the EU, member states and substate levels of government (Hooghe & Marks, 2001; Bach, 2012; Pazos-Vidal, 2019; Schakel, 2020). Marks and Hooghe's study on multi-level governance has been a turning point since the new conceptual tool could explain the increased presence of regions in Brussels and their impact on EU policy (Schakel, 2020, p. 767). Theories of European integration, which were extensively used at the time, such as functionalism, could no longer explicate the new modes of EU governance (p. 767)

Moreover, some authors stress that shared decision-making with numerous stakeholders is beneficial for the Union in the long term. For instance, Schönlau argues that, in practice, multi-level governance is and should go beyond the structures formally foreseen by the EU Treaties to help find common solutions and make the European project resilient to internal and external crises (2020, p. 197). Similar arguments emphasise that increased cooperation between the European Union and local and regional governments has produced effective policies and contributed to the legitimacy of the European integration project (Kokaj, 2023, p. 4; Schönlau, 2020, p. 206).

2. Regional involvement in EU policymaking

One of the reasons why Hooghe and Marks (1996, p. 73) introduced the concept of multi-level governance was to reveal the influence of regions on European Union policymaking. They reveal that sub-national governments have different channels through which they try to have a say in EU governance, including the Committee of the Regions, access to the Council of Ministers and regional lobby offices (Hooghe & Marks, 1996, pp. 75-89). According to the authors, new opportunities have opened for regional mobilisation, and national states are losing control over critical areas of decision-making (p. 91). More recent literature that deals with the regions in the EU agrees that there are increased incentives for regions to be involved in EU affairs but also points out that their primary responsibility is still limited to the implementation and enforcement of top-down EU laws and policies (Waetherill, 2005, p. 3; Loughlin, 2005, p. 166; Kokaj, 2023, p. 41). In other words, regional governments have no access to the negotiating process that potentially generates laws that directly affect them, such as the principle of free movement of

goods, which could take away powers guaranteed under domestic constitutional settlements (Waetherill, 2005, p. 6).

3. The role of EU consultive bodies and the Committee of the Regions

Another approach to evaluate the extent to which regional and local governments can impact EU policymaking is through their representative body at the EU level (Schönlau, 2020). The author argues that, although the Committee of the Regions is formally limited to an advisory role to the European Commission, it has gained political recognition from the other EU institutions (2020, p. 198). The CoR is one of two consultive committees in the Union that are mandatory in many legislative processes according to the ordinary legislative procedure (Hönnige & Panke, 2013, pp. 452- 455). Both the CoR and the European Economic and Social Committee (EESC) are understood by the literature to have a relatively limited role in the formal decision-making process at EU-level, given that they have no formal voting power and due to a lack of awareness of the committees among the other EU institutions (Hönnige & Panke, 2013, 2016).

However, recent studies on the advisory committees refute this perception and prove that the CoR and the EESC are increasingly involved in EU affairs (Schakel, 2020; Schönlau, 2017). For instance, the CoR has expanded its influence beyond the limited consultative task by actively pushing the boundaries and employing strategies to become more visible (Schönlau, 2017, p. 1180). The Committee has been successfully promoting the needs of local and regional authorities at the EU level by organising dialogues with citizens and contacts with local practitioners to assess their difficulties in implementing EU legislation (p. 197). In this regard, the CoR becomes a direct link between the EU member states and sub-national entities, reinforcing the institutionalisation of multi-level governance (p. 206). All things considered, the multi-level governance model is widely accepted, but the extent to which each level of government, especially sub-national authorities, is involved in the policy-making process is still a point of contention.

4. EU health policy in the regions

The introduction mentions that the European Union has become increasingly involved in health governance, especially since the COVID-19 pandemic. The EU seeks to expand its role as a health actor on the European, national, and global levels (Azzopardi-Muscat et al., 2017, p. 1). The institutionalisation and the legal development of EU public health began with the treaty changes of Maastricht 1992 but has ever since significantly expanded, especially with increased integration in other policy areas (Greer & Jarman, 2021, p. 28; Palm & Wismar, 2018, p. 20).

This newly found purpose of the EU was born out of the need to address important health disparities across its member states and globally. According to Holland et al. (1999, p. 2), EU countries' health expenditures per capita differ. However, all face similar health challenges, such as inequalities in health status and health service provision between different geographical regions and social groups (Holland et al., 1999, p. 2; European Commission, 2013, pp. 34-37). For instance, there are geographical and social disparities within countries in health-related behaviours as well as in access to healthcare services and infrastructure (Scholz, 2020, pp. 5-8). Additionally, reports by the World Health Organisation (WHO) and the EU also stress that health improvement is strongly related to environmental and social factors (Holland et al., 1999, p. 2; European Commission, 2013, p. 145).

This relation between the well-being of people and their environmental surroundings or social status has been further analysed. For instance, the authors Mazeikaite, O'Donoghue and Sologan (2021) examine the large cross-country differences in population health in the EU, given that living standards are comparably similar. They find that socio-economic factors, the level of education and the labour market play a significant role in explaining the differences in population health across EU regions (p. 137). Hence, the authors conclude their study by encouraging the Union to increase equal educational attainment and income and fight unemployment across all its regions (p. 137). This idea has many advocates in academia, as the EU-level development to tackle health inequalities through actions on issues beyond public health has broadly been considered to be very effective (Greer et al., 2022; Mazeikatie et al., 2021; Holland et al., 1999).

The EU seeks to address these regional health challenges more directly through the Cohesion Policy funds (Greer et al., 2022, p. 191). The primary funds are the European Regional Development Fund (ERDF) and the European Social Fund Plus (ESF+), which, according to Greer et al. (p. 192), can make an essential contribution to improving health and reducing inequalities. Nevertheless, the authors Védrine and Le Gallo (2021, p. 168), who have examined the effectiveness of the EU Cohesion Policy on local and regional cross-country inequalities, have found that the impact on economic growth and social challenges has been limited. They stress that the effectiveness of the Cohesion policy could be improved by a new governance structure more suitable to the needs of local situations by ensuring that projects are initiated locally and in the responsibility of local governments (p. 168).

In sum, the literature has shown that no governing level in the European Union can claim complete responsibility for health. However, when considering the territorial inequalities of the European Union and the locality of social issues affecting access to health services, the need for

an integrated health policy uniting various EU institutions and regional authorities becomes clear (Palm & Matthias, 2018, p. 22).

5. The gap in the literature

The literature review has shown that extensive research has been done on the involvement of the regions in EU affairs. It has been proven that regional governments have gained importance in the Union's legislative process and EU policy beyond their formal legislative role, primarily through the Committee of the Regions. Additionally, some researchers stress that if the EU wants its health policies to be effective, the initiatives must be tailored to the specific needs of the individual regions.

According to Article 168 in TFEU, the Council and the Commission must consult the Committee of the Regions before making decisions on matters concerning public health (European Parliament, 2024, p. 5). The CoR also issues opinions on its own initiative concerning policies that directly affect the regions, including health (2024, p. 4).

Nevertheless, it has not yet been analysed whether the Committee of the Regions has been trying to shape the EU's health policies or has been able to do so through its consultive role.

Considering the identified gap in the literature and the political relevance of the topic, it would be interesting to analyse how the regions influence EU health policy by answering these questions:

What are the Committee of the Region's health interests? Which interests of the Committee of the Regions are incorporated into the EU health policies?

By answering the sub-research questions above, the response to the following primary inquiry will be assessed:

What influence does the Committee of the Region have on EU health policy?

III. Theoretical Framework

1. Conceptualisation

1.1 Interests

In this paper, interests will be conceptualised as the explicitly expressed preferences of the CoR to change the EU's health policy. Otherwise defined as the CoR's ideal points, they illustrate the committee's perception of a policy that would work in its favour (Tatham, 2015, p. 391; Dür, 2008, p. 11). Considering that the CoR is an essential linkage between sub-national and local authorities and the decision-making process at the EU level, the committee's expressed preferences reflect the region's interests (Schönlau, 2020, p. 197). Hence, the interests

presumably manifest the region's wishes for, for instance, adequate aid in health care provision or more involvement in the EU's newest and already existing health frameworks, such as plans to advance e-health across Europe.

1.2 Influence

As mentioned above, the role of Consultative Committees in the EU is limited. However, they can exercise some influence on the policy-making process by correcting policies or giving advice. The extent of influence of the EU's consultative committees in the decision-making process has been analysed before. Hence, this paper will incorporate some previously defined conceptualisations. For instance, influence can be defined as the CoR's ability to shape the positions of EU decision-makers (immediate effect) or the final policy (mediated effect) according to its opinions and recommendations (Panke et al., 2015, p. 12). To measure the CoR's influence, this paper opts for the second conceptualisation, that is, through European directives and regulations instead of through the positions of the European Parliament, the Commission or member states. Panke and Hönnige (2013, p. 460) also mention that two types of influence can be considered, including the extent of changes brought about by a consultative committee and the quality of those changes. Although analysing both types would be beneficial, this paper's inquiry primarily concerns the quality of changes triggered by the CoR's influence measured through the final policy.

2. Theory

2.1Multi-level governance

The multi-governance model by Hooghe and Marks is the basis of the research project and hypothesis. The theory seeks to explain the increased influence of both supranational and subnational actors in EU governance, but I will focus mainly on the sub-national.

The multi-level governance model is a concept that Hooghe and Marks (2001, p. 1) introduced to create an understanding of the rapid developments the EU has been going through since the 1990s, with the completion of the internal market (1993) and changes in EU decision-making such as the Treaty of Amsterdam (1999). In short, the argument is that European integration has given rise to a process in which authority and policy-making influence are shared across multiple levels of government (p. 3). Political control does not lie solely with the member states anymore. Political arenas are interconnected, with domestic politics extending into the European level since subnational actors increasingly operate in national and supranational arenas. The concept of

multi-level governance is critical to understanding the entire EU-decision-making process because it directs attention to the incentives for regions to be involved in EU affairs and how national governments and EU institutions have come to share some of their authority (Schakel, 2020, p. 772). This perspective that goes beyond formal decision-making by central governments will be necessary to reveal the impact of regions on EU health policymaking (p. 768). Most importantly, the Committee of the Regions is part of this multi-level governance structure because it links the regional and local authorities with EU-level affairs. The regions have three main channels to influence EU decision-making: limited access to the Council of Ministers, regional lobby offices in Brussels, and finally, the Committee of the Regions (p. 768). It has also been proven that the CoR has tried to practice the multi-level governance model in specific policy areas, such as those addressing climate change (Schönlau, 2020, p. 199).

The increased acknowledgement of the multilevel governance model in EU scholarship and the role that the regions and the consultative committees have come to play in it will be considered in formulating the hypothesis. Also, when considering the region's crucial role in implementing health policies on the ground and the EU's multi-level governing process, this paper expects that the opinions of the Committee of the Regions can *influence the Union's health policies according to its interests.* Nevertheless, considering the limited role and previous findings of consultive committee influence, this potential influence is expected to not be of substantial weight.

IV. Methodology

1. Research Design

This paper investigates the European regions' influence on the EU policy-making process, building on previous research on the topic (Waetherill, 2005; Loughlin, 2005; Schönlau, 2020; Kokaj, 2023). An intensive examination of this specific phenomenon will be needed to carry out the investigation. Hence, a single-case study of the Committee of the Regions has been chosen (Halperin & Heath, 2017, pp. 234-237).

Also, the research questions are descriptive and explanatory, and the selected sources for the analysis are textual. Thus, qualitative content analysis is the most functional because it provides detailed descriptions and methods to systematically code large amounts of secondary data (Halperin & Heath, 2020, p. 364; Schreier, 2013, p. 6).

The central inquiry will be broken down into the analysis of two interdependent research questions. The first sub-question will be answered by examining the opinion papers of the Committee of the Regions on the Commission's health Policy proposals. This analysis will be

purely descriptive to create an overview and understanding of the CoR's interests. Then, the focus will shift to qualitatively analysing the final health regulation.
Finally, the preferences expressed by the CoR will be compared with the adopted health policy to detect if the CoR's opinions have encouraged a change from the Commission's initial proposal. By systematically coding and analysing these policy documents and answering the sub-questions, the CoR's role in EU health policy governance will be revealed.

2. Data collection and data analysis

This thesis will use a qualitative data collection method and execute a qualitative content analysis (QCA). The documents under analysis were found and taken from official EU websites managed by the EU's publication office. This paper will examine three types of EU policy documents: the Commission's policy proposals, the CoR's "opinion papers" published at the beginning of the legislative process, and the adopted policy document at the end of the legislative process.

Three health policies covering post-Covid 19 plans have been selected for qualitative analysis. The adopted health policies are EU regulations, binding legislative acts subject to the ordinary legislative procedure. Although health is part of many EU policy areas, only those explicitly targeting public health issues were collected for this analysis (Greer et al., 2022, pp. 121-140). According to the Treaty on the Functioning of the European Union (TFEU), the Commission and the Council must consult the Committee of the Regions on matters concerning Public Health (European Parliament, 2024, p. 4). For this analysis, the EU regulation on serious cross-border threats (2022), the regulation on the role of the European Medicines Agency in preparing for a health crisis (2022) and the regulation on the EU4Health programme (2021) were chosen. The Commission initiated these policies in response to the EU's limited capacity to manage the COVID-19 pandemic. They are supposed to complement each other with the objective of preparing the Union for upcoming public health emergencies (Commission, 2020, p. 1). The European regions were disproportionally affected by the COVID-19 pandemic and have repeatedly and publicly expressed discontent with the shortcomings of the existing legal framework (CoR, 2023). To illustrate this, the president of the CoR, Vascos Alves Cordeiro, has been calling for the EU to put regional authorities at the centre of any new Health policies (2023).

The coding on the opinion papers will be a mix of data-driven and a priori coding. In the opinion papers, the amendments proposed by the CoR are written in bold and italics and are hence directly identifiable. The CoR's amendments, which reflect its interests, will be collected to compare them to the other policy documents. The analysis will go beyond the frequency and number of health interests incorporated to study the potential change in the final policy. Instead, a

change will be assessed if the final health policy has moved closer to the Committee of the Regions' than the initial policy proposal. The health interests that had previously been identified will set the a priori codes for the coding. That is if the wording, phrase, or paragraph was added to a specific part of the proposal, as the CoR had wished. Changes to the policy proposal, which refer to the CoR's proposals less directly as an exact reproduction of the committee's words, are also identified as a change. For each policy, one coding frame will be used to assess the Committee of the region's influence on the content of the final policy. The categories are derived from the CoR's amendments and indicate *what* part of the policy proposal the CoR wants to change. The column with the CoR's correction indicates *how* the committee wants to change the policy.

V. Analysis

1. Overview of findings

Table 1.

Policy 1

Category	**CoR opinion that was incorporated**	**CoR opinion that was *not* incorporated**
Article 6&7: The National Response Plan	• Involvement of regional authorities in the implementation and reporting • Include regional response plans	
Article 5: The Union Response Plan	• ***Should encourage cooperation with regions and local authorities to implement plans***	
Article 9&10: Preparedness and response planning (Coordination and reporting)	• ***HSC should coordinate the activities of interregional, cross-border***	• ***Commission should transmit a report on the state of progress of Union-level plans (also) to the CoR***
Article 13: Epidemiological surveillance	• Monitoring of epidemiological occurrences should be developed territorially through regional statistics	
Article 11: Training of health care staff and public health staff	• Commission should provide targeted training of health care staff to regions	
Article 19: Alert notification		• In a public health emergency, national competent authorities and the Commission should communicate the territorial areas concerned.

Table 2.

Policy 2

Category	**CoR opinion that was incorporated**	**CoR opinion that was *not* incorporated**
Article 3: Executive Steering Group on Shortages and Safety of Medicinal Products	• Working party in contact with local and regional authorities responsible for healthcare	
Article 11: Role of Member States in monitoring and mitigation of shortages of medicinal products		• The member states should have a reasonable timeframe to inform the steering group of shortages and measures taken
Article 12&28: Role of the Commission in monitoring and mitigation of shortages of medicinal product		• The Commission should (also) liaise with the World Health Organisation to mitigate shortages
Article 20 & 35: IT tools and data	• Electronic health data should be exchanged in accordance with Union legislation on personal data protection	
Article 15: Emergency task force		• ***The representatives of local and regional authorities should attend meetings of the Emergency Task Force***
Article 21: Executive Steering Group on Shortages of Medical Devices	• Working party in contact with local and regional authorities responsible for healthcare	
Article 27: Obligations on manufacturers of medical devices, authorised representatives, importers, distributors etc.		• Should inform the Medical Devices Steering Group within a reasonable timeframe of measures taken and medical shortage

Table 3.

Policy 3

Category	**CoR opinion that was incorporated**	**CoR opinion that was *not* incorporated**
Article 4: Specific Objectives	• Use of Stress-tests in Member States	• Health corridors • Support the work of regional authorities
Article 3: General Objectives		• ***Coordination between Member states and regional authorities to improve public health***
Article 5 & Recital 37: Budget and funding		• Higher budget for EU4Health • Better coordination between EU4Health and existing EU instruments
Article 16: Stakeholder consultation and information of the European Parliament	• The Commission should consult national and regional health authorities	
Recital 49: Climate change	• Increased % of programme budget to support climate objectives	
Recital 34: Cross-border health care		• Health corridors between border regions • ***Integrated work among member states and local and regional authorities*** • ***Involve European Groupings of Territorial Cooperation (EGTC)***
Recital 38: Authorities involved in the implementation of the programme	• Regions or other tiers of government involved in drafting health policy	• ***Local and regional authorities should implement the actions of the programme***
Recital 6: Union-level Cooperation and coordination to prevent and control the spread of diseases		• ***Support coordination among member states and regional authorities*** • Promote investment in pharmaceuticals for European sovereignty • Compare data at NUTS 2 level
Recital 14: Protection of vulnerable groups	• Use of telemedicine • Specify obesity	
Recital 21: Health promotion and protection and Union-level		• ***The programme should complement the action of local and regional authorities*** • NUTS 2 regional-level data
Recital 15: Reforms and transformations of health systems across Europe	• Funding of stress tests for Member States	• Health services should not be subject to private-sector thinking

Tables 1, 2 and 3 summarise and present the results of the coding process. The categories are colour-coded depending on whether the final policy has changed according to the CoR's amendments in the opinion papers. If the category is green, the regulation either directly or indirectly adopted the CoR's amendments. The red means that the CoR's amendments were not incorporated into the final policy. Some categories are green and red because one opinion by the committee had elements in the paragraph that were incorporated and some that weren't. The CoR's opinions, written in ***bold and italics*** and highlighted in yellow**,** are those who actively seek to change the role of the local and regional authorities at the *Union level*.

2. Description of findings

2.1 EU regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU

The CoR has amended six articles of the health regulation addressing cross-border health threats to health.

Concerning the National and Union preparedness and response plans (Articles 7, 6), the CoR encourages the participation of regional and local authorities in drawing up, implementing, and reporting the plans. The initial policy proposal did not include regional stakeholders in the national plans' activities. Hence, the observed changes in the final policy are substantial. In the articles "Epidemiological Surveillance" and "Training of Healthcare Staff", similar changes are observed. The CoR's amendments were directly added to the article in question. For instance, the committee wanted to monitor epidemiological occurrences with the help of regional statistics instead of only national ones (Article 13). The final policy adopted this by changing the article so that the member states need to report at the NUTS II level. The NUTS classification is a hierarchical system that divides the economic territory of the EU for socio-economic analyses. The NUTS II is described as "basic regions for the application of regional policies", such as the "Länder" in Germany or the "provinces" in Belgium (European Parliament, 2024).

In contrast, in the articles on "Preparedness and Response Planning" and "The Union Response Plan" (Articles 5, 9, 10), the changes recognised in the final policy are not as directly traceable back to the CoR's opinions paper. For instance, the CoR wants the Union's response plans to add the regional and local authorities to its cooperation and implementation scheme next to the Commission and the member states at the political level. Although this was not fully incorporated, the final policy mentions in a different paragraph of the article that collaboration should be facilitated with Union agencies or bodies to ensure the plan's implementation. The term

"Union Bodies" was added, which, next to the EU institutions, play a specialised role in helping the EU to fulfil its tasks. This includes advisory committees such as the Committee of the Regions. Hence, even though the regions were not granted involvement in the union health plans at a higher political level, they can potentially do so through the Committee of the Regions.

2.2 EU regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

The CoR has amended seven articles of the EU regulation on the European Medicines Agency, of which fewer were directly adopted than in the former policy. However, article 18, which addresses the use of "IT tools and data" for the agency's work, is an exception. The CoR's amendment stresses that when the Agency collects or exchanges electronic health data in the case of a public health emergency, it needs to respect previous EU legislation on the protection of personal data. The CoR's interest in protecting health data differs from most of the other amendments, which specifically concern the needs of local and regional authorities (Articles 20, 35). In the introduction section of the Commission's initial proposal, it is noted that the processing of personal data needs to be done in line with the relevant Union legislation (Commission, 2020, p. 3). However, in the final policy, article 35 is added, which specifically enforces this protection encouraged by the amendment of the CoR. Conversely, the CoR's demand that the working parties supporting the Executive Steering Groups responsible for managing medicinal products should be in contact with local and regional authorities was more indirectly translated into the final policy (Article 3). At the end of both articles 3 and 21, a new paragraph was added in the final regulation, stressing that the working party should consist of representatives of the national competent authorities responsible for shortage monitoring and management of medical devices on a national level. These "national competent authorities" differ per country but often depend on regional authorities' consultations. For example, the Danish authorities ("Danish Medicines Agency") monitor the supply situation in Denmark and collaborate with the Danish regions to minimise the risk of supply and delivery problems in pharmacies and hospitals (Danish Medicines Agency, 2024).

2.3 Regulation establishing a Programme for the Union's action in the field of health ('EU4HealthProgramme') for the period 2021-2027

The regulation on the Union's health programme post-pandemic touches on many public health issues and lays out the priorities that the EU will focus on until 2027, such as cross-border health care and health promotion across Europe. Similar to the previous policies, the CoR's focal

interest is to highlight the importance of local and regional health actors. For instance, in its amendments on the "Authorities involved in the implementation of the programme" (Recitals 31, 42) and in "Stakeholder consultation and information of the European Parliament" (Article 16), the CoR stresses that regional authorities should be consulted on the work plans of the EU4Health programme and be implicated in the drafting and implementing of the health policies. Interestingly, only those amendments demanding the Commission to consult the regional governments were adopted into the final policy. However, even so, the regulation does not directly name regional or local authorities but refers to them as "stakeholders" in health. Other amendments which were incorporated into the final regulation concern more functional issues. The CoR has consistently emphasised the importance of incorporating telemedicine into the programme (Recital 12) and the need for the use of stress tests to assess the weaknesses of national health systems (Articles 4, 15). These practicalities were not raised in the Commission's initial proposal but are mentioned in the final policy in the "specific objectives" of the programme and numerous recitals. Hence, in these cases, the CoR has substantially influenced the regulation with its interests.

The summary table and the brief, more in-depth assessment of specific articles show that incorporating the Committee of the Regions interests in the final policy is volatile and strongly depends on the article in question. The following chapter will further explore the CoR's overall health interests and explain why some are more influential than others.

VI. Conclusion

This thesis aims to determine if the Committee of the Regions can change EU health policies through its limited consultive role. To this end, two sub-research questions were used: *What are the Committee of the Region's health interests? Which interests of the Committee of the Regions are incorporated into the EU health policies?*

First, the amendments made by the CoR to the three policies under inquiry show a clear pattern of interests. Two types of interests could be identified.
On the one hand, the committee advocates that the EU should give more attention to the needs of regions and increase support so they can better prepare for future health emergencies and improve public health services. These amendment measures aim to ameliorate the regulation's efficiency at the regional level. For example, in *Policy 1*, the CoR stresses that National response plans to

cross-border health threats should include subnational response plans and that the Commission's training for healthcare staff should be targeted towards regional needs (Articles 6, 7, 11). Similarly, the amendments also express the CoR's interest in increasing the visibility and developing the role of regional authorities and itself at the political level of the European Union, alongside the other institutions. To illustrate this, article 9 of *Policy 1* demands that the Commission transmit a report on the progress of the preparedness and response planning on the Union level to the Committee of the Regions, next to the European Parliament and the Council. Furthermore, in *Policy 3,* the CoR proposes that the general objectives of the EU4Health Programme should be to coordinate the work of the Member states and regional authorities (Articles 3, 4; Recitals 6, 34). These types of interests aim to highlight the importance of regions in public health and grant them a more influential role in the policymaking and implementation process at the Union level.

On the other hand, the CoR also has more practical and content-related interests. That is, amendments that seek to add or remove words and specify policy aspects to make it more effective and expand its scope. In these cases, the needs of the regions are not the main aim or not mentioned. For instance, in *Policy 2,* the CoR stresses the importance of protecting personal data when exchanging electronic health data (Articles 20, 35). Another example is *Policy 3,* where the Union body emphasises that the EU4Health Programme should protect vulnerable people suffering from non-communicable diseases, especially obesity (Recital 14).

Second, only specific interests are reflected or fully adopted into the final policy.

As mentioned above, two types of interests could be identified.

The amendments focused on content-related issues were more likely to be fully adopted into the final policy. These interests are either incorporated word-by-word, such as Recital 49 in *Policy 3,* or a whole new article is added to the regulation, as with Article 35 in *Policy 2*.

However, those amendments that express an interest in giving regions and the CoR more political say at the Union level are either ignored or strongly diluted and reworded.

In certain cases, as in *Policy 3,* where the proposal initially mentioned the involvement of regional and local levels in actions against cross-border health threats, the subnational was even later removed from the final policy (Recital 10). That is contrary to what the CoR is advocating for.

However, when the interests are incorporated, indirect names such as "Union bodies" and "relevant stakeholders" often occur, or the regions are mentioned in different parts of the policy with less operational weight, such as in the recitals. The recitals in EU legislation are there to describe the purpose of the act and are used to interpret the articles but are nevertheless subject to

policy negotiations (Humphreys et al., 2015; Den et al., 2019). Another point worth mentioning is that the specific interests translated into the final policy principally consider the region's role as consultative.
Policy 1 differs from the others under analysis in that some amendments concerning the role of regions were adopted in the same article with direct naming. However, this was only in the context of national response plans and primarily the role of regions as consultative. A possible explanation is that, in contrast to *Policies 2* and *3*, managing cross-border health threats is a health issue that must be tackled locally.

Finally, the findings from the qualitative analysis and the answers to the previous two sub-research questions resolve the central inquiry of this thesis: *What influence does the Committee of the Regions have on EU health policy?*

In sum, the CoR has a significant influence because, as observed, amendments were fully adopted in the final policies, which have moved closer to the CoR's interests. That is, not the *amount* of amendments adopted but its closeness and quality to the initial recommendation of the CoR. However, some are adopted more directly than others. For example, some were added directly to the article or the recitals, whereas others were ignored. This means that the change that the CoR can bring about firmly depends on the ambition and aim of the amendment. Another aspect to consider when answering this question is that the CoR's role is to link subnational authorities, and in the case of health policies, especially those responsible for public health, to EU-level affairs. The latter is identified as the most critical issue for the CoR because most of the amendments highlight the importance of regions. However, these interests were either ignored or indirectly incorporated into the regulation, which raises questions about the extent of influence the CoR has on EU policy.

VII. Discussion

When the findings of this qualitative analysis are connected to the theory and literature addressed earlier in the thesis, it becomes clear that the CoR is an inherent part of the EU's Multilevel governance and a strengthening force behind it.
The results confirm that the EU's governance and policy-making process is multi-level in that it consults the CoR and adopts some of its interests. Other research projects that analyse the extent of influence have come to similar conclusions.

For instance, Hönnige and Panke's (2013, p. 452) quantitative analysis on the Committee of the Regions and the EESC concluded that they are influential, but only under certain conditions (p. 468). In brief, the consultative committees were most influential when they delivered their opinion papers early in the formal decision-making process (p. 467). Efficiency also depended on the quality of the opinions, persuading the addressee to believe that the committee has superior knowledge on the issue of the policy (p. 467). These conditionalities introduce an interesting nuance to the results of this analysis. For example, in the three cases here, the opinions were published at least five months before the regulation was adopted, potentially reinforcing its influence on the European Parliament, the Council and the final regulation. Also, the opinion paper on cross-border health threats might have successfully adopted amendments because of regional border authorities' expertise in handling disease outbreaks, which would have strengthened its credibility among the EP and the Council.

Furthermore, Schönlau (2017), who published a paper on the expanding role of the CoR, argues that the Union body is trying to "promote its own brand of multi-level governance" (p. 1180). This is also observable in the content of the amendments to the policies analysed here. The CoR repeatedly highlights the importance of involving the regions in the drafting and implementing of EU health policies and actively advocates for more political participation at the Union level. Although not analysed in this paper, the CoR has also, over the years, published many own initiative opinions on health-related issues. For instance, the body recommended an EU strategy on alcohol-related issues (CoR, 2017) and a revised European cancer plan (CoR, 2021), even if EU law does not mandate consultation on these topics. The own-initiative opinion is an instrument used to intervene in the early stages of policy formation. It allows the CoR to communicate its interests unrelated to the other institution's agenda (Schönlau, 2017, p. 1173).
Hence, the CoR has multiple formal ways to promote its own idea of multi-level governance in health, such as through the content of the amendments and its own initiative opinions.

VIII. Future Research

In 19 of the 27 EU Member States, local and regional authorities are primarily responsible for planning, organising, and delivering healthcare services to citizens.
Nevertheless, it is not clear yet if the regions can influence EU health policies, which affect them so directly and dictate their capacity to respond to health emergencies, as the COVID-19 pandemic has shown. The research of this thesis is the first step to resolve this issue.

From one perspective, the findings of this inquiry are encouraging because they prove that the CoR, through its consultative role, can influence the policies, at least in certain health subjects. However, the analysis also proves that the main interest of the CoR and the regions, to get more involved in the policy-making process at the EU level in health matters, is more difficult to achieve. Nevertheless, remembering that the Committee also has other paths of political influence, it is possible that these are more effective in increasing the visibility and active involvement of the regions in EU health policy at the Union level (Schönlau, 2017, p. 1173).

However significant this research project is, the findings are preliminary and should encourage further research.
Due to difficult access to primary sources and a focus on regulations adopted after COVID-19, only limited generalisations can be made of the CoR's influence and involvement in EU governance. Hence, future research should broaden the scope of policies under analysis, including pre-pandemic, enabling a longitudinal study. It is probable that, since COVID-19, when the regions became indispensable in managing the crisis in communities, the importance of local health care has gotten more attention. A different approach to data collection could also result in more rich and instructive findings, such as interviews with CoR members to understand their health interests and activities beyond the content of the opinion papers. Contrary to the policy documents, interviews could reveal CoR strategies behind closed doors or in local communities. These alternative paths of influence will steer the research into new directions that need to be explored and broaden academic and public understanding of the CoR and its sphere of influence.

This paper encourages further research into the political influence of consultive committees and non-governmental bodies at the Union level. Since these findings will expose weaknesses in the EU's governance model, changes can be introduced to make the EU's policy-making process more inclusive. After all, the European Union's integration project firmly depends on its democratic legitimacy.

Bibliography

EU Documents

Committee of the Regions. (2020, June 7). *Bringing Europe closer to people: The political priorities of the European Committee of the Regions 2020-2025.* Retrieved from *https://cor.europa.eu/en/engage/brochures/Documents/Bringing%20Europe%20closer%20to%20people%20%20The%20political%20priorities%20of%20the%20European%20Committee%20of%20the%20Regions%202020-2025/4325%20Political%20Priorities%20Brochure.pdf*

Committee of the Regions. (2023, October 10). *European Health Union: Commissioner Kyriakides and local leaders stress region's and cities' essential role*. Retrieved from https://cor.europa.eu/en/news/Pages/European-Health-Union.aspx

Dijkstra, L. (2022). *The regional impact of Covid-19*. Retrieved from https://cohesiondata.ec.europa.eu/stories/s/The-regional-impact-of-COVID-19-CR8/24gj-n8r2/

European Commission. (2013). *Health inequalities in the EU*. Retrieved from https://health.ec.europa.eu/document/download/0ff103b0-d07c-47df-8b95-49a147ad6b01_en

European Parliament. (2023, November). *Fact sheet on the Committee of the Regions*. Retrieved from https://www.europarl.europa.eu/factsheets/en/sheet/16/the-committee-of-the-regions

European Parliament. (2024, March). *Common classification of territorial units for statistics (NUTS).* Retrieved from https://www.europarl.europa.eu/factsheets/en/sheet/99/common-classification-of-territorial-units-for-statistics-nuts-

Soldi, R. (2020). *Regional health policy responses to the COVID crisis*. Retrieved from https://cor.europa.eu/en/engage/studies/Documents/Regional%20Health%20Policy_Covid.pdf

Scholz, N. (2020). *Addressing health inequalities in the European Union: Concepts, action, state of play.* Retrieved from https://op.europa.eu/en/publication-detail/-/publication/36c99612-6347-11ea-b735-01aa75ed71a1/language-en

Tilindyte, L. (2016 April). *Regional participation in EU decision-making*. Retrieved from https://www.europarl.europa.eu/RegData/etudes/IDAN/2016/580913/EPRS_IDA(2016)580913_EN.pdf

Wassenberg, B. (2020 February 6). *The history of the Committee of the Regions: 25 years of cities and regions furthering European integration*. Retrieved from https://cor.europa.eu/en/engage/brochures/Pages/default.aspx?from=01/01/2020&to=01/01/2021

Opinion of the European Committee of the Regions – EU4Health Programme. (2020). *Official Journal*, C 440, 131-149. CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020AR2917[legislation]

Opinion of the European Committee of the Regions — Cross-border health threats and the mandate of the European Centre for Disease Prevention and Control. (2021). *Official Journal*, C 300, 76-86. CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020AR5624[legislation]

Opinion of the European Committee of the Regions — A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA). (2021). *Official Journal of the European Union*, C 300, 87-92. CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020AR5525[legislation]

Opinion of the European Committee of the Regions — Europe's Beating Cancer Plan. (2022). Official Journal of the European Union, C97, 17-20. CELEX: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52021IR2072&qid=1716394590961

Opinion of the European Committee of the Regions — The need for and way towards an EU strategy on alcohol-related issues. (2017). Official Journal of the European Union, C207, 61-66. CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016IR1831&qid=1716395069341

Proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing decision No 1082/2013/EU. (2020). COM(2020) 727 final 2020/0322 (COD). CELEX: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52020PC0727

Proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. (2020). COM/2020/725 final 2020/0321(COD). CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0725

Proposal for a regulation of the European Parliament and of the Council on the establishment of a programme for the Union's action in the field of health –for the period 2021-2027 and repealing regulation (EU) No 282/2014 ("EU4Health Programme"). (2020). COM(2020) 405 final 2020/0102(COD). CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A0405%3AFIN

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014. PE/69/2020/REV/1. CELEX: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32021R0522

Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. PE/40/2022/REV/1. CELEX: https://eur-lex.europa.eu/eli/reg/2022/2371/oj

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. PE/76/2021/REV/1. CELEX: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123

Zumer, K. & Rittelmeyer, Y. (2020 July). *Linking the levels of governance in the EU. Retrieved from* https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/652034/EPRS_BRI(2020)652034_EN.pdf

Other sources

Bache, I. (2012). Multi-level governance in the European Union. *The Oxford Handbook of Governance* (pp. 628–641). Oxford: Oxford University Press.

Bayerlein, M. (2024). Regional health care in the EU: ESI funds as a means of building the European health union. SWP Research Papers.

Brand, H. & Palm, W. (2014). Health and European integration: Part of the problem or part of the solution?, *Eurohealth*, *20*(3), 5–7.

Dellmuth, L. (2021). Regional well-being, Inclusive growth and EU legitimacy. In *Is Europe Good for You?: EU Spending and Well-Being* (pp. 115–128). Chapter, Bristol University Press.

Den Heijer, M., Abeelen, T. & Maslyka, A. (2019). On the use and misuse of recitals in European Union law. *Amsterdam Law School Research Paper*, *2019*(31), 1-24.

Doyle, L., McCabe, C., Keogh, B., Brady, A., & McCann, M. (2020). An overview of the qualitative descriptive design within nursing research. *Journal of Research in Nursing*, *25*(5), 443–455.

George, A. L., & Bennett, A. (2005). *Case studies and theory development in the social sciences*. MIT Press.

Greer, S., & Kurzer, P. (2013). *European Union public health policy: Regional and global trends*. Oxford: Routledge.

Greer, S. L., Rozenblum, S., Fahy, N., Brooks, E., Jarman, H., de Ruijter, A., Palm, W., & Wismar, M. (2022). *Everything you always wanted to know about European Union health policies but were afraid to ask*. Copenhagen: European Observatory on Health Systems and Policies.

Guy, M. & Kuiper, E. (2022). Forging a European health union: Between subsidiarity and sovereignty? *Eurohealth, 28* (3). 50-52.

Halperin, S., & Heath, O. (2020). *Political research : methods and practical skills* (Third edition.). Oxford University Press.

Hooghe, L., & Marks, G. (1996). "Europe with the regions": Channels of regional representation in the European Union. *Publius*, *26*(1), 73–92.

Hooghe, L. & Marks, G. (2001). Multi-level governance in the European Union. *Multi-level governance and European integration* (pp. 1-33). Lanham, MD: Rowman & Littlefield.

Hönnige, C. & Panke, D. (2013). The Committee of the Regions and the European Economic and Social Committee: How influential are consultative committees in the European Union? *Journal of Common Market Studies, 51*(3), 452-471.

Hönnige, C. & Panke, D. (2016). Is anybody listening? The Committee of the Regions and the European Economic and Social Committee and their quest for awareness. *Journal of European Public Policy, 23*(4), 624-642.

Jeffery, C. (2005). Regions and the European Union: Letting them in and leaving them alone. *Role of Regions and Sub-National Actors in Europe* (pp. 33–45) Oxford: Hart.

Kokaj, A., & Sinani, B. (2023). The multi-level governance of the European Union: the role of the local government. *Juridical Tribune, 13*(1), 32–42. doi:10.24818/TBJ/2023/13/1.03

Loughlin, J. (2005). The regional question, subsidiarity and the future of Europe. *The Role of regions and sub-national actors in Europe* (pp. 157–169). Oxford: Hart.

Mazeikaite, G., O'Donoghue, C., & Sologon, D. M. (2021). What drives cross-country health inequality in the EU? Unpacking the role of socio-economic factors. *Social Indicators Research, 155*(1), 117–155.

McCann, P., Ortega-Argilés, R., & Yuan, P.-Y. (2022). The Covid-19 shock in European regions. *Regional Studies, 56*(7), 1142–1160. Doi:10.1080/00343404.2021.1983164

Palm, W., & Wismar, M. (2018). EU integration and health policy at the crossroads, *Eurohealth, 24* (2), 19 - 22.

Panke, D., Hönnige, C., & Gollub, J. (2015). *Consultative committees in the European Union: No vote - No influence?* Colchester: ECPR Press.

Pazos-Vidal, S. (2019). Introduction: Subsidiarity and EU multilevel governance: Actors, networks and agendas. *Subsidiarity and EU Multilevel Governance*. New York: Routledge.

Rotolo, A. (2015). Mapping recitals to normative provisions in EU legislation to assist legal interpretation. In *Legal Knowledge and Information Systems* (Vol. 279). IOS Press, Incorporated.

Schakel, A. H. (2020). Multi-level governance in a 'Europe with the regions.' *British Journal of Politics & International Relations*, *22*(4), 767–775. doi:10.1177/1369148120937982

Seawright, J., & Gerring, J. (2008). Case selection techniques in case study research: A Menu of qualitative and quantitative options. *Political Research Quarterly, 61*(2), 294–308.

Schönlau, J. (2020). New multi-level governance in the EU? The European committee of the regions and regional diversity. *European Regions* (pp. 195–210). Bielefeld: transcript Verlag.

Schönlau, J. (2017). Beyond mere 'consultation': Expanding the European Committee of the Regions' role. *Journal of Contemporary European Research, 13*(2). 1166–1184.

Schreier, M. (2014). Qualitative content analysis. In U. Flick (Ed.), *The SAGE handbook of qualitative data analysis* (pp. 170–183). Los Angeles: SAGE.

Weatherill, S. (2005). The challenge of the regional dimension in the European Union. *The Role of Regions and Sub-National Actors in Europe* (pp. 1–32). Oxford: Hart.

Vannoni, Matia, & Dür, Andreas. (2017). Studying preference attainment using spatial models. *European Political Science, 16*(3), 369–382. Doi: 10.1057/eps.2016.1

Appendix A: Overview Table

1. *EU regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU*

Categories	Opinion of the Committee of the Regions	Final Policy
The National Response Plan	**Regional and local authorities should be involved** in implementing and reporting the national plans, which should address gaps at subnational levels. The plan should include **subnational response plans from regional and public health authorities**. National plans should establish interregional, cross-border contact groups to coordinate actions on both sides of the border.	The report should cover the plan's implementation (among other things) at the **cross-border regional level**. It should also govern national plans through **regional policies and include coordination between national, regional, and local administrative levels**. Gaps in the plans should be identified through **consultation with relevant partners.**
The Union Response Plan	Union plans should encourage **cooperation between the commission and (among others) regions and local authorities**. Regions should be fully involved at the political level in drawing up and implementing these plans.	Union plans should encourage cooperation between the Commission, the Council, the Member States, the HSC, and the relevant **Union agencies or bodies** to implement the plans.
Preparedness and response planning	The HSC should have a regional territorial component that integrates border regions by **coordinating the activities of interregional, cross-border** contact groups. The commission should transmit a report on the state and	The HSC will monitor the progress of gaps and actions of the **response plan at cross-border regional levels**. The Commission and the Member States should conduct a **dialogue with**

(Coordination and reporting)	progress of the Union-level plans to (among others) the **European Committee of the Regions.**	**stakeholders**, including health and care workers' organisations, etc. (not CoR)
Epidemiological surveillance	The monitoring of epidemiological occurrences should also (apart from national) be developed territorially through **regional statistics**.	The information that the national competent authorities communicate to the European Surveillance Portal for Infectious Diseases (operated by ECDC) should be reported at least at the **NUTS II level**.
Training of health care staff and public health staff	To support subnational capacity-building, the commission should provide **training activities targeted** towards local and regional authorities. Also, the support of programmes for exchanging healthcare staff between Member states in border regions where regional and local authorities have competencies in the field.	To support Member States, they should receive **targeted training** and facilitate the sharing of best practices for healthcare staff. Union plan should also include cross-border elements to share best practices and ensure an exchange of information in crisis.
Alert notification	In case of a public health emergency, the national competent authorities and the Commission should communicate through the EWRS any relevant, helpful information for a coordinated response, such as (among other things) the **territorial areas concerned**.	When notifying an alert, the national competent authorities and the Commission should communicate through the EWRS any helpful information for coordinating the response, such as the type and origin of the agent, etc. (not territorial areas)

2. *EU regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products*

Categories	Opinion of the Committee of the Regions	Final Policy
Executive Steering Group on Shortages and Safety of Medicinal Products	A working party should support the Medicines Steering Group and **maintain contact with local and regional authorities** responsible for healthcare.	A working party consisting of representatives of the **national competent authorities for medicinal products** should support the MSSG. These authorities shall be the single points of contact regarding medicinal product shortages.
Role of Member States in monitoring and mitigation of shortages of medicinal products	The member states should have a **reasonable timeframe** to inform the steering group of shortages and measures taken.	If the member states don't inform the MSSG of shortages and measures (which they should), the reason needs to be shared in a timely manner.
Role of the Commission in monitoring and mitigation of shortages of medicinal product	The commission should liaise with international organisations (among others), particularly the World Health Organisation (WHO), to mitigate the shortages of medical devices.	The commission should liaise with third countries and relevant international organisations to mitigate shortages of medicinal products.
IT tools and data	The European Medicines Agency should facilitate access to and exchange of electronic health data in accordance with **Union legislation on protecting personal data.**	The transfer and **exchange of personal data under this regulation should be subject to Regulations** (EU) 2016/679 and (EU) 2018/1725.

Emergency task force	The chair of the Emergency Task Force may invite (among others) **representatives of local and regional authorities to attend its meetings.**	The co-chairs of the ETF may invite other representatives of Member States, members of scientific committees, and working parties of the Agency, etc. (not local and regional authorities)
Executive Steering Group on Shortages of Medical Devices	A working party should support the Executive medical devices steering group and be in **contact with local and regional authorities responsible for healthcare**.	A working party consisting of **representatives of national competent authorities** responsible for monitoring and managing medical device shortages should support the MDSSG**.**
Obligations on manufacturers of medical devices, authorised representatives, importers, distributors etc.	Should inform the Medical Devices Steering Group within a **reasonable timeframe** of measures taken and medical shortage.	Should inform the Medical Devices Steering Group in a timely manner/or at an appropriate time considering the emergency. The relevant notified bodies need to communicate the date.

Appendix B

Full Coding List

Red= the CoR's amendment was not incorporated into the article itself or the final policy; ignored

Blue= A weakened version of the CoR's amendment was indirectly incorporated into the policy, or the article has changed but not clearly in the direction of the CoR's preference

Green= the CoR's amendment was directly adopted into the article or other parts of the policy, the exact wording

BLACK AND IN ITALICS: HOW the CoR wants to change the policy according to its interests

1. *Regulation on serious cross-border threats (2022)*

Health Policy topic	**Categories**	**Opinion of the Committee of the regions**	**Commission proposal**	**Final Policy**
Cross-border health threats	National response plan	1. Amendment 3 Article 7: (c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resist	1. Article 7: 1.Member States shall by the end of November 2021 and every 2 years thereafter	1. Article 7: 1.By 27 December 2023 and every three years thereafter, Member States shall provide the Commission and relevant Union agencies and bodies with an updated report on prevention,

		ance, healthcare associated infection, ***territorial statistics*** and other specific issues. The report shall include, whenever relevant, interregional ***and cross-border*** preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions ***Regional and local authorities should be involved in preparing reports on matters relating to their area of responsibility, particularly those mentioned in subpoint (c) above.***	provide the Commission with a report on their preparedness and response planning and implementation at national level. That report shall cover the following: (a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR; (b) elements of emergency preparedness, in particular: (i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response	preparedness and response planning and implementation at national level and, where appropriate, cross-border interregional levels. That report shall be succinct, based on agreed common indicators, shall give an overview of the actions implemented in the Member States, and shall cover the following: (a) identification of, and an update on, the status of the implementation of the capacity standards for prevention, preparedness and response planning as determined at national and, where appropriate, cross-border interregional level for the health sector, as provided to the WHO in accordance with

		The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national or ***subnational*** *level.* 2. Amendment 2 Article 6: 1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.	and recovery; coordination mechanisms; (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness; (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential	the IHR, as well as, where available, the interoperability arrangements between the health sector and other critical sectors in emergency situations; (b) an update, where necessary, on the elements of emergency prevention, preparedness and response planning, in particular: (i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency and preparedness actions; plans for emergency prevention, preparedness, response and recovery; coordination mechanisms, including, where relevant, among national,

		If applicable, where local and regional authorities have significant public health responsibilities in the national health system, national plans should include subnational preparedness and response plans. ***2.*** ***National preparedness and response plans should specify that inter-regional, cross-border contact groups can or should be set up in border areas to prepare and coordinate actions in regions on both sides of the border in the event of a health threat emerging.***	supplies for health; and dedicated, trained and equipped human resources for emergencies; and (c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues. The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing	regional or local administrative levels and in terms of multi-sectoral collaboration; (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; business continuity measures and arrangements aimed at ensuring continuous access to diagnostic services, tools and medicinal products during emergencies, where available; basic and safe gender-sensitive health and emergency services; an overview of the impact of serious cross-border threats to health on the provision and continuity of

			capacities, resources and coordination mechanisms across neighbouring regions. 2. Article 6: 1.When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.	healthcare services for other diseases and conditions during public health emergencies; risk communications; research development and evaluations to inform and accelerate emergency preparedness; and (iii) resources: including financial resources for emergency preparedness and contingency funding for response; essential supplies for health; logistics mechanisms, including for the storage of medical countermeasures; dedicated, trained and equipped human resources for emergencies;

				(c) implementation of national prevention, preparedness and response plans, including where relevant implementation at the regional and, if appropriate, local levels, covering epidemic response; antimicrobial resistance, healthcare-associated infection, and the other serious cross-border threats to health as referred to in Article 2; (d) where applicable, consultation with relevant partners on risk assessment and national prevention, preparedness and response plans; and (e) actions taken to improve gaps found in the implementation of

				national prevention, preparedness and response plans The report shall include, where relevant, cross-border interregional and intersectoral prevention, preparedness and response elements involving neighbouring regions. Such elements shall include coordination mechanisms for the relevant elements of Union and national prevention, preparedness and response plans, including cross-border training and sharing of best practices for healthcare staff and public health staff, and coordination mechanisms for the medical transfer of Patients.

				Added: ***(d) where applicable, consultation with relevant partners on risk assessment and national prevention, preparedness and response plans; and*** ***(e) actions taken to improve gaps found in the implementation of national prevention, preparedness and response pla***ns. 2. Article 6 1. Without prejudice to Member States' competences in this area,

				when preparing national prevention, preparedness and response plans, Member States shall liaise with each other within the HSC and coordinate with the Commission in order to seek coherence with the Union prevention, preparedness and response plan to the largest possible extent. 2. **Added:** National prevention, preparedness and response plans may include elements relating to governance, capacities and resources laid down in the Union prevention, preparedness and response plan as referred to in Article 5.

	Union Response plan	1.Amendment 1 Article 5: 2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6. 3.The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for: (a) the timely cooperation between the Commission, the Member States, ***their regions and local authorities and*** the Union agencies; (b) the secure exchange of information between the	1.Article 5: 2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6. 3.The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for: (a)the timely cooperation between the Commission, the Member States and the Union agencies; (b) the secure exchange of information between the Commission, Union agencies and the Member States;	2.Article 5: 2. The Union prevention, preparedness and response plan shall complement the national prevention, preparedness and response plans established in accordance with Article 6, and shall promote effective synergies between the Member States, the Commission, the European Centre for Disease Prevention and Control (ECDC) and other relevant Union agencies or bodies. 3.The Union prevention, preparedness and response plan shall, in particular, include provisions on joint arrangements

		Commission, Union agencies and the Member States; (c) the epidemiological surveillance and monitoring; (d) the early warning and risk assessment; (e) the risk and crisis communication; (f) the health preparedness and response and intersectoral collaboration; (g) the management of the plan. 4.The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. ***Regions shall be fully involved at political level***	(c) the epidemiological surveillance and monitoring; (d) the early warning and risk assessment; (e) the risk and crisis communication; (f) the health preparedness and response and intersectoral collaboration; (g) the management of the plan. 4.The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the	for governance, capacities and resources for: (a) the timely cooperation between the Commission, the Council, the Member States, the HSC and the relevant Union agencies or bodies. The Union prevention, preparedness and response plan shall take into account the services and support potentially available under the Union Civil Protection Mechanism, and, in particular, the capacities under the rescEU stockpile as laid down in Commission Implementing Decision (EU) 2019/570 (30) or other mechanisms, the capacities and resources made available for its purposes by the

		in drawing up and implementing these plans. The plans shall include preparedness and response means to address the situation of those citizens with higher risks. 5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary	situation of those citizens with higher risks. 5.In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. (24) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation. Article 7:	Union and the Member States, and the cooperation with the WHO for cross-border threats to health; (b) the secure exchange of information between the Commission, the Member States, in particular the competent authorities or designated bodies responsible at national level, the HSC and the relevant Union agencies or bodies; (c) the epidemiological surveillance and monitoring; (d) the early warning and risk assessment, especially regarding cross-border interregional preparedness and response; (e) the risk and crisis communication, including to health professionals and citizens;

			(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues.	(f) the health preparedness and response and multi-sectoral collaboration, such as identifying risk factors for disease transmission and the associated disease burden, including social, economic and environmental determinants, following the One Health approach for zoonotic, food and waterborne diseases and relevant other diseases and related special health issues; (g) the drawing up of an overview of the production capacities for relevant critical medical countermeasures in the Union as a whole to address serious cross-border threats to health as referred to in Article 2;

				(h) emergency research and innovation; (i) the management of the plan; and (j) support to Member States for the monitoring of the impact of a serious cross-border threat to health on the provision and continuity of healthcare services, including for other diseases and conditions during health emergencies. 4.The Union prevention, preparedness and response plan shall include cross-border interregional preparedness elements to support aligned, multi-sectoral, cross-border public health measures, in particular considering capacities for

				surveillance, testing, contact tracing, laboratories, training of healthcare staff and specialised treatment or intensive care across neighbouring regions. The Union prevention, preparedness and response plan shall take into account national respective circumstances and include preparedness and response means to address the situation of citizens with higher risks. 5. In order to ensure the implementation of the Union prevention, preparedness and response plan, the Commission shall facilitate, in collaboration with Member States and, when applicable, with relevant Union agencies or bodies or with

				international organisations, stress tests, simulation exercises and in-action and after-action reviews with Member States, and update the plan as necessary. Recitals: (11) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' prevention, preparedness and response plans so as to ensure

				they are compatible within the regional level structures. It is crucial that those Union and national plans be prepared with particular attention paid to cross-border regions in order to enhance their health cooperation. Where appropriate, regional authorities should be able to participate in the drawing up of such national plans. To support Member States in this endeavour, the Commission and the relevant Union agencies and bodies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to

				improve their knowledge and necessary skills. Cross-border elements should also, where relevant, be included in the Union plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised treatment and intensive care across neighbouring regions. To ensure the implementation of the Union plan, the Commission should facilitate stress tests, simulation exercises and in-action and after-action reviews with Member States. The Union plan should be functional and updated, and have

				sufficient resources for its operationalisation. Following reviews of the national plans, proposed recommendations should be addressed in an action plan and the Commission should be kept informed of any substantial revision of the national plans. (12) Member States should provide the Commission with an update on the latest situation with regard to their prevention, preparedness and response planning and implementation at national level, and where applicable at regional level. Information provided by the Member States

				to the Commission should include the elements that Member States are obliged to report to the WHO in the context of the IHR. Access to timely and complete data is a precondition for prompt risk assessments and crisis mitigation. T (31)? (42) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.

➔ Amendment mostly ignored, but present in recitals				
	preparedness and response planning • Coordination • Reporting	1. Amendment 5 Article 10: ***(f) supporting CoR amendment Regional cross-border cooperation on health in regions potentially or already at risk and coordinating the activities of inter-regional, cross-border contact groups.*** (A regional territorial component in the work of the HSC will allow for seamless integration of border regions in the crisis response and prevent the lack of communication experienced on many occasions during the COVID-19 outbreak in 2020)	1. Article 10 1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health. The coordination shall, in particular, be aimed at: (a) sharing best practice and experience in preparedness and response planning;	1. Article 10: (d) support the development of the prevention, preparedness and response plans referred to in Articles 5 and 6; (e) monitor and discuss progress for gaps identified and actions to strengthen prevention, preparedness and response planning, including in the field of research**, at cross-border regional, national and Union levels; and** **(f) facilitate the exchange, outside the** joint procurement procedure laid down in Article 12, of information on medical

		2. Amendment 4 Article 9: 1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament, the Council ***and the European Committee of the Regions*** a report on the state of play and progress on preparedness and response planning at Union Level.	(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level; (c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR; (d) developing the preparedness plans referred to in Articles 5 and 6; (e) monitoring progress identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels. Article 7:	countermeasures, including, where appropriate, on pricing and delivery dates. 2.**The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations.** **3**. The HSC shall also coordinate, where relevant, response to public health emergencies with the Health Crisis Board, where it is established in accordance with Regulation (EU) 2022/2372, and contribute

			Reporting on preparedness and response planning 1. Member States shall by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level. That report shall cover the following: (a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;	accordingly to the coordination and information exchange within that body. Article 7: 1. By 27 December 2023 and every three years thereafter, Member States shall provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness and response planning and implementation at national level and, where appropriate, cross-border interregional levels. That report shall be succinct, based on agreed common indicators, shall give an overview of the actions implemented in the

			(b) elements of emergency preparedness, in particular: (i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms; (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to	Member States, and shall cover the following: (a) identification of, and an update on, the status of the implementation of the capacity standards for prevention, preparedness and response planning as determined at national and, where appropriate, cross-border interregional level for the health sector, as provided to the WHO in accordance with the IHR, as well as, where available, the interoperability arrangements between the health sector and other critical sectors in emergency situations; (b) an update, where necessary, on the elements of emergency

			inform and accelerate emergency preparedness; (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and (c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues.	prevention, preparedness and response planning, in particular: (i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency and preparedness actions; plans for emergency prevention, preparedness, response and recovery; coordination mechanisms, including, where relevant, among national, regional or local administrative levels and in terms of multi-sectoral collaboration; (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness;

			The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions. Recitals: (7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the	surveillance and early warning, information management; business continuity measures and arrangements aimed at ensuring continuous access to diagnostic services, tools and medicinal products during emergencies, where available; basic and safe gender-sensitive health and emergency services; an overview of the impact of serious cross-border threats to health on the provision and continuity of healthcare services for other diseases and conditions during public health emergencies; risk communications; research development and evaluations to

			Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-	inform and accelerate emergency preparedness; and (iii) resources: including financial resources for emergency preparedness and contingency funding for response; essential supplies for health; logistics mechanisms, including for the storage of medical countermeasures; dedicated, trained and equipped human resources for emergencies; (c) implementation of national prevention, preparedness and response plans, including where relevant implementation at the regional and, if appropriate, local levels, covering epidemic

			action and after-action reviews with Member States. 1. Article 9 1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level. 2.	response; antimicrobial resistance, healthcare-associated infection, and the other serious cross-border threats to health as referred to in Article 2; (d) where applicable, consultation with relevant partners on risk assessment and national prevention, preparedness and response plans; and (e) actions taken to improve gaps found in the implementation of national prevention, preparedness and response plans. The report shall include, where relevant, cross-border interregional and intersectoral prevention, preparedness and

			The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. <u>Article 7:</u> 1.Member States shall by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level.	response elements involving neighbouring regions. Such elements shall include coordination mechanisms for the relevant elements of Union and national prevention, preparedness and response plans, including cross-border training and sharing of best practices for healthcare staff and public health staff, and coordination mechanisms for the medical transfer of patients. Recitals: (11) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and

				combatting serious cross-border threats to health. As such, a Union health crisis and pandemic plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' prevention, preparedness and response plans so as to ensure they are compatible within the regional level structures. It is crucial that those Union and national plans be prepared with particular attention paid to cross-border regions in order to enhance their health cooperation. Where appropriate, regional authorities should be able

				to participate in the drawing up of such national plans. To support Member States in this endeavour, the Commission and the relevant Union agencies and bodies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to improve their knowledge and necessary skills. Cross-border elements should also, where relevant, be included in the Union plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised

				treatment and intensive care across neighbouring regions. To ensure the implementation of the Union plan, the Commission should facilitate stress tests, simulation exercises and in-action and after-action reviews with Member States. The Union plan should be functional and updated, and have sufficient resources for its operationalisation. Following reviews of the national plans, proposed recommendations should be addressed in an action plan and the Commission should be kept informed of any substantial revision of the national plans.

				(34) Inconsistent communication with the public and stakeholders, such as healthcare and public health professionals, can have a negative impact on the effectiveness of the response from a public health perspective, as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and address communication challenges with a view to coordinating risk and crisis communication, based on holistic, robust and

				independent evaluation of public health risks, to be adapted to national and regional needs and circumstances where relevant. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. To that end, relevant public institutions should contribute to sharing verified information and fighting disinformation. Given the cross-sectoral nature of health-related crises, coordination should also be ensured with other relevant constituencies, such as the EU Civil Protection Community.

				2. Article 9: 1. On the basis of the information provided by the Member States in accordance with Article 7 and the results of the assessment referred to in Article 8, the Commission shall by 27 December 2023 and every three years thereafter, transmit to the European Parliament and to the Council a report on the state of play and progress on prevention, preparedness and response planning at Union level. 2. The Commission report shall include, where applicable, cross-border preparedness and response elements in neighbouring regions.

				3. Based on its report, the Commission may support the action of the Member States through the adoption of general recommendations on prevention, preparedness and response planning. <u>Article 7:</u> 1.By 27 December 2023 and every three years thereafter, Member States shall provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness and response planning and implementation at national level and, where appropriate, cross-

				border interregional levels.
1. Amendment 1: → full incorporation of amendment 2. Amendment 2: → no incorporation of amendment				
	Epidemiological surveillance	1. Amendment 7 Article 13(8): 8.Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1. ***This monitoring shall be developed also territorially, notably through regional statistics.***	1. Article 13: 8.Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1. 3.The national competent authorities referred to in paragraph 1 shall communicate the	1. Article 13: 9.Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1. 3. The national competent authorities referred to in paragraph 1 shall communicate the following information, based

			following information to the participating authorities of the epidemiological surveillance network: (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1); (b)relevant information concerning the progression of epidemic situations, including for modelling and scenario development; relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;	on agreed indicators and standards, to the participating authorities of the network for epidemiological surveillance: (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in Article 2(1), points (a)(i) and (a)(ii); (b) relevant information concerning the progression of epidemic situations, including for modelling and scenario development; (c) relevant information concerning unusual epidemic phenomena or new

			(d) molecular pathogen data, if required for detecting or investigating cross-border health threats; (e) health systems system data required for managing cross-border health threats; and (f) information about contract tracing monitoring systems developed at national level. 4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with	communicable diseases of unknown origin, including those in third countries; (d) molecular pathogen data, if required for detecting or investigating serious cross-border threats to health; (e) health systems data required for managing serious cross-border threats to health; and (f) information about contact-tracing monitoring systems developed at national level. 4. The information communicated by the national competent authorities referred to in paragraph 3, point (a), may be, when available, reported at least at ***NUTS II level to the European Surveillance Portal***

			paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.	***for Infectious*** Diseases operated by the ECDC, on a timely basis
➔ Amendment ignored in paragraph, but reporting should be done at NUTS II Level				
	Training of health care staff and public health staff	1. Amendment 6 Article 11: 2.The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis pre preparedness and surveillance capacities including the use of digital tools. ***Training activities shall also be targeted***	1. Article 11: 2.The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.	1. Article 11: 2.The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with the knowledge and skills necessary, in particular, to develop and implement the national prevention, preparedness and response plans, and implement activities to strengthen crisis preparedness and surveillance capacities, especially regarding the gaps identified, including in relation to the use of digital tools,

		towards local and regional authorities with competences in healthcare in order to support capacity-building at subnational level. 5.The Commission may support organising pro grammes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. ***Such actions should be carried out particularly in border regions where regional and local authorities have***	5.The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. Recital (7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the	and shall be consistent with the One Health approach. 5. The Commission and relevant Union agencies and bodies may support the organisation of programmes, in cooperation with the Member States and Union candidate countries, for the exchange of healthcare staff and public health staff, as well as for the temporary secondment of staff between Member States, Union candidate countries or Union agencies and bodies. In organising those programmes, account shall be taken of the contribution made by professional

		significant competences in the field of healthcare, not least through the training of people who work for interregional, cross-border contact groups. (While the division of powers may vary in different Member States, local and regional authorities are often involved both in the management of municipal hospitals and civil protection, but lack specific training or capacity. Targeted training is very much needed for often understaffed municipal services and would allow faster response times and more efficient action)	Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-	health organisations in each of the Member States. BUT: IN RECITAL 11 (11) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' prevention, preparedness and response plans so as to ensure they are compatible within the regional level

			action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates. <u>Article 5:</u> 4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures,	structures. It is crucial that those Union and national plans be prepared with particular attention paid to cross-border regions in order to enhance their health cooperation. Where appropriate, regional authorities should be able to participate in the drawing up of such national plans. To support Member States in this endeavour, the Commission and the relevant Union agencies and bodies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to improve their knowledge and necessary skills. Cross-

			in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.	border elements should also, where relevant, be included in the Union plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised treatment and intensive care across neighbouring regions. To ensure the implementation of the Union plan, the Commission should facilitate stress tests, simulation exercises and in-action and after-action reviews with Member States. The Union plan should be functional and updated, and have sufficient resources for its operationalisation.

				Following reviews of the national plans, proposed recommendations should be addressed in an action plan and the Commission should be kept informed of any substantial revision of the national plans. <u>Article 5:</u> 4. The Union prevention, preparedness and response plan shall include cross-border interregional preparedness elements to support aligned, multi-sectoral, cross-border public health measures, in particular considering capacities for

				surveillance, testing, contact tracing, laboratories, training of healthcare staff and specialised treatment or intensive care across neighbouring regions. The Union prevention, preparedness and response plan shall take into account national respective circumstances and include preparedness and response means to address the situation of citizens with higher risks.
1. Amendment 6: → indirectly incorporation of amendment in the article but full translation in recitals and article 5				
	Alert notification	1. Amendment 8 Article 19(3): When notifying an alert, the national competent authorities	1. Article 19: 3. When notifying an alert, the national competent authorities and the	1. Article 19: 3. When notifying an alert, the national competent authorities

		and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as: (a) the type and origin of the agent; (b) the date and place of the incident or outbreak; ***(c) the territorial areas concerned;*** (d) means of transmission or dissemination; (e) toxicological data; (f) detection and confirmation methods; (g) public health risks; (h) public health measures implemented or intended to be taken at national level; (i) measures other than public health measures;	Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as: (a) the type and origin of the agent; (b) the date and place of the incident or outbreak; (c) means of transmission or dissemination; (d) toxicological data; (e) detection and confirmation methods; (f) public health risks; (g) public health measures implemented or intended to be taken at national level;	and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as: (a) the type and origin of the agent; (b) the date and place of the incident or outbreak; (c) means of transmission or dissemination; (d) toxicological data; (e) detection and confirmation methods; (f) public health risks; (g) public health measures implemented or intended to be taken at national level;

		(j) urgent need or shortage of medical countermeasures; (k) requests and offers for cross-border emergency assistance; (l) personal data necessary for the purpose of contact tracing in accordance with Article 26; (m) any other information relevant to the serious crossborder threat to health in question.	(h) measures other than public health measures, including multi-sectoral measures; (i) whether there is an urgent need for or shortage of medical countermeasures; (j) requests and offers for cross-border emergency assistance, such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions; (k) personal data necessary for the purpose of contact tracing in accordance with Article 28; (l) any other information relevant to the serious cross-border threat to health in question.	(h) measures other than public health measures, including multi-sectoral measures; (i) whether there is an urgent need for or shortage of medical countermeasures; (j) requests and offers for cross-border emergency assistance, such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions; (k) personal data necessary for the purpose of contact tracing in accordance with Article 28; (l) any other information relevant to the serious cross-border threat to health in question.
➔ Ignored in Article and in rest of policy				

2. Regulation a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (2022)

Health Policy	Categories	Opinion of the Committee of the regions	Commission proposal	Final Policy
European Medicines Agency & medicinal products and medical devices	1.Executive Steering Group on Shortages and Safety of Medicinal Products	1. Amendmet 2 Article 3(5): The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1). ***The working party shall, where appropriate, maintain contact with local and***	2. Article 3(5) 3.The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings. 5.The Medicines Steering Group shall be supported in its work by a working partycomprised of single points of contact related to shortages from national competent authorities for	1. Article 3 3. The MSSG shall be co-chaired by the representative of the Agency and by one of the representatives of the Member States, who shall be elected by and from among the representatives of the Member States in the MSSG. The co-chairs of the MSSG, on their own initiative or at the request of one or more members of the MSSG, may invite, as observers and to provide expert advice, representatives of national competent authorities for veterinary medicinal

		regional authorities with responsibility for healthcare. (In 19 out of 27 Member States, the local and regional level is responsible for healthcare. If the monitoring of medicine shortages is to work properly and add value, this level of government needs to be involved in the process.)	medicinal products established in accordance with Article 9(1).	products, representatives of other relevant competent authorities and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actor in the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, to attend its meetings, as necessary. 6. The MSSG shall be supported in its work by a working party established in accordance with Article 9(1), point (d). ***Added: The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities for medicinal products, who shall be the single points of contact in relation to shortages of medicinal products***.

➔ More stakeholders included, including "national competent authorities" but not regional/local authorities as such				
	2.Role of Member States in the monitoring and mitigation of shortages of medicinal products	1. Amendment 3 Article 11(4)(b): b) inform the Medicines Steering Group ***within a reasonable timefram***e of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage. (Member States need to have a reasonable period of time to inform the steering group, as compiling the information may impose an administrative burden on the healthcare system when it is under pressure in a crisis.)	1. Article 11(4) Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall: (a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12; (b) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on	1. Article 11 4. Following the reporting on the results of the monitoring referred to in Article 7 and any recommendations on preventive or mitigating measures provided in accordance with Article 8(3) and (4), Member States shall: (a) take into account any recommendations and guidelines referred to in Article 12, point (c), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a); (b) inform the MSSG of any measures taken and report on the results of the actions referred to in point (a), including providing information on

			the resolution of the potential or actual shortage.	the resolution of the actual or potential shortage of medicinal products. ***For the purposes of the first subparagraph, points (a) and (b), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MSSG in a timely manner.***
➔ Timely manner → refers to as quickly as possible → not considerate of CoR amendment (Vague → polite way to say hurry up)				
	3.Role of the Commission regarding the monitoring and mitigation of shortages of medicinal product	1.amendment 9 Article 26(e): e) liaise with third countries and relevant international organisations, ***in particular the World Health Organization (WHO),*** as appropriate, [...] 2. Amendment 4 Article 12(f):	1. Article 26(e) e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices included on the critical	1. Article 28 (e) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medical devices included on the public health emergency critical devices list or their component parts,

		f) liaise with third countries and relevant international organisations, in particular the World Health Organization (WHO), as appropriate, [...	devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications. 2.Article 12(f) (f)liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or	where those devices or parts of such devices are imported into the Union, and where such actual or potential shortages have international implications, and report on any related actions as well as the results of those actions to the MDSSG, where relevant. 2.Article 12 g) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medicinal products included on the critical medicines lists or their active substances, where those medicinal products or active substances are imported into the Union and where such actual or potential shortages

			ingredients are imported into the Union and where such potential or actual shortages have international implications.	have international implications, and report on any related actions as well as the results of those actions to the MSSG, where relevant
1.Amendment is ignored, policy only mentions the WHO in relation to the organisations cooperation with the Emergency Task Force 2. “				
	4.IT tools and data	1. Amendment 6 Article 18(c): c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of	1.Article 18 To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall: (a) develop and maintain electronic tools for the submission of information and data,	1.Article 20: In preparation for and to support the work of the ETF during public health emergencies, the Agency shall: (a) develop and maintain IT tools, including an interoperable IT platform, for the submission of information and data,

		such data between Member States, the Agency, and other Union bodies, ***in accordance with applicable Union legislation on the protection of personal data;*** (The importance of secure data sharing and protection of personal data needs to be highlighted.)	including electronic health data generated outside the scope of clinical studies; (b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform; (c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of	including electronic health data generated outside of clinical studies, that facilitate interoperability with other existing IT tools and with IT tools under development, and provide adequate support to national competent authorities; (b) coordinate independent monitoring studies on the use, effectiveness and safety of medicinal products intended to treat, prevent or diagnose diseases related to the public health emergency, using relevant data, including, where relevant, data held by public authorities; (c) as part of its regulatory tasks, make use of digital infrastructures or IT tools in order to facilitate rapid access to or analysis of available electronic health data generated outside of clinical studies and to facilitate the exchange of such data between Member States, the Agency and other Union bodies;

			available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies; (d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to which the Agency has access. <u>Context of the proposal: Consistency with other Union policies (p. 3)</u>	(d) provide the ETF with access to external sources of electronic health data to which the Agency has access, including health data generated outside of clinical studies. For the purposes of the first paragraph, point (b), coordination as regards vaccines shall be conducted in conjunction with the ECDC, in particular, through a new vaccine monitoring IT platform. <u>Recital:</u> (48) Due to the sensitive nature of health data, the Agency should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is

			The proposal contributes to achieving a high level of human health protection and is thus consistent with the Charter of Fundamental Rights in this regard. Where personal data is processed to fulfil the provisions of the proposed Regulation, this will be done in line with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/17254 and Regulation (EU) 2016/6795 (the General Data Protection Regulation (GDPR)) and build on existing procedures and processes within the Agency which are used to meet such requirements.	necessary for the purposes of this Regulation, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation should take place in accordance with Regulations (EU) 2016/679 (14) and (EU) 2018/1725 (15) of the European Parliament and of the Council. Article 35: Personal data protection 1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable. 2.As regards transfers of personal data to a third country, in the absence of an adequacy decision or appropriate

				safeguards as referred to in Article 46 of Regulation (EU) 2016/679 and Article 48 of Regulation (EU) 2018/1725 respectively, the Commission, the Agency, and Member States may carry out certain transfers of personal data to regulatory authorities of third countries with which they have put in place confidentiality arrangements where those transfers are necessary for important reasons of public interest, such as the protection of public health. Such transfers shall be made in conformity with the conditions laid down in Article 49 of Regulation (EU) 2016/679 and Article 50 of Regulation (EU) 2018/1725
➔ The amendment is not adopted in the actual article but a whole new article on the subject of personal data was created ➔ Already in the proposal there was mentioning of personal data protection but not in the article → the CoR might have contributed to that				
	5.Emergency task force	1. Amendment 5 Article 14(5):	1.Article 14(5)	1.Article 15 2.

		The Chair may invite representatives of Member States ***and local and regional authorities***, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	2. During public health emergencies, the Emergency Task Force shall undertake the following tasks: (f)cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary. 5.The Chair may invite representatives of Member States, members of scientific	During public health emergencies, the ETF shall undertake the following tasks: (f) **cooperating with national competent authorities, Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations, on** scientific and technical issues that relate to the public health emergency and to medicinal products which have the potential to address public health emergencies, as necessary. 5.The co-chairs of the ETF may invite other representatives of Member States, members of scientific committees and working parties of the Agency, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial

		(In many Member States, local and regional authorities are responsible for healthcare.)	committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	experts and researchers, and representatives of healthcare professionals and of patients to attend its meetings.
➔ More stakeholders included, including "national competent authorities" but not regional/local authorities as such ➔ The national competent authorities can be local or regional authorities.				
	6. Executive Steering Group on Shortages of Medical Devices	1. Amendment 7 Article 19(5): The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for	1.Article 19(5) 5. The Medical Devices Steering Group shall be supported in its work by a working	1. Article 21 5. The MDSSG shall be supported in its work by a working party established in accordance with Article 25(1).

		medical devices established in accordance with Article 23(1). ***The working party shall, where appropriate, maintain contact with local and regional authorities with responsibility for healthcare.*** (In 19 out of 27 Member States, the local and regional level is responsible for healthcare. If the monitoring of critical medical devices is to work properly and add value, this level needs to be involved in the process.)	party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).	***Added: The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities responsible for shortage monitoring and management of medical devices, who shall be the single points of contact in relation to shortages of medical devices.***
➔ Added: national competent authorities: possibly regional, local				
	7.Obligations on manufacturers of medical devices, authorised representatives, importers,	1. amendment 8 Article 25(4)(d): d) inform the Medical Devices Steering Group ***within a reasonable timeframe*** of any measures taken and report on the results of	2. Article 25 4. Following the reporting on the results of the monitoring and any recommendations	1.Article 27 4.Following the reporting on the results of the monitoring referred to in Article 23 and any recommendations on

	distributors and notified bodies	those measures, including information on the resolution of the potential or actual shortage.	on preventive or mitigating measures in accordance with Article 22, Member States shall: (b) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list; (c)take into account any recommendations and guidelines and comply with any	preventive or mitigating measures provided in accordance with Article 24, Member States shall: (a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating actual or potential shortages of medical devices included on the public health emergency critical devices list while ensuring a high level of patient and product safety; (b) take into account any recommendations referred to in Article 24(3) and any guidelines referred to in Article 28, point (b), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a);

			measures taken at Union-level pursuant to Article 26; (d) inform the Medical Devices Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage. Article 23: 1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency shall: (a) specify the procedures for establishing the public health emergency critical devices list;	(c) inform the MDSSG of any measures taken and report on the results of the actions referred to in point (b), including providing information on the resolution of the actual or potential shortage of medical devices concerned. For the purposes of the first subparagraph, points (b) and (c), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MDSSG. The recommendations, guidelines and actions referred to in the first subparagraph, point (b), of this paragraph, and a summary report of the lessons learned shall be made publicly available via the web portal referred to in Article 29. Article 25:

			(b) develop streamlined electronic monitoring and reporting systems; (c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities for medical devices; (d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies; (e) specify the methods for the provision of recommendations and coordination of	1. In order to prepare for the fulfilment of the tasks referred to in Articles 22, 23 and 24, the Agency shall: (a) specify the procedures and criteria for establishing and reviewing the public health emergency critical devices list.; 1 (b) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with existing IT tools and Eudamed, once it is fully functional, and provide the adequate support to national competent authorities for monitoring and reporting; (c) establish the working party referred to in Article 21(5) and ensure that each Member State is represented on that working party;

			measures provided for in Article 22. 2. Following the recognition of a public health emergency the Agency shall: (a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list; (b) (c) request information from the points of contact included in the sub-network	(d) specify the methods for the provision of recommendations referred to in Article 24(3) and (4) and for the coordination of measures referred to in Article 24. For the purposes of the first subparagraph, point (a), the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and consumers may be consulted as necessary. 2. Following the recognition of a public health emergency, the Agency shall: (a) establish a list of single points of contact for the manufacturers of medical devices, or their authorised representatives,

			based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission; request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission. 3. The information referred to in point (b) of paragraph 2 shall include at least: (a)	importers and notified bodies, for the medical devices included on the public health emergency critical devices list; (b) maintain the list of single points of contact referred to in point (a) for the duration of the public health emergency; (c) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in point (a) on the basis of the set of information adopted by the MDSSG and set a deadline for the submission of that information; (d) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in Article 21(5), second subparagraph, on the basis of the set of information

			the name of the manufacturer and, if applicable, the name of the authorised representative; (b) (c) identification of the medical device and the intended purpose; if applicable, the name and number of the notified body and information on the relevant certificate or certificates; (d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause; (e) sales and market share data;	adopted by the MDSSG in accordance with Article 22(2) and set a deadline for the submission of that information. The Agency may use sources other than those referred to in the first subparagraph, including existing databases and databases in development, to gather information required under paragraph 3. For the purposes of the first subparagraph, point (a), where it is considered relevant, national or Union databases, including Eudamed, once it is fully functional, or medical device associations may be used as sources of information. 3. The information referred to in paragraph 2, point (c), shall include at least: (a) the name of the manufacturer of the medical device and, if applicable, the name of its authorised representative;

			(f) mitigation plans including production and supply capacity; (g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list; (h) <u>information on the number of</u> applications received by concerned notified bodies in relation to medical devices included in the public health emergency	(b) the information identifying the medical device and the intended purpose and where necessary, specific characteristics of the medical device; (c) if applicable, the name and number of the notified body and information regarding the relevant certificate or certificates; (d) details of the actual or potential shortage of the medical device, such as actual or estimated start and end dates and the suspected or known cause; (e) sales and market share data of the medical device; (f) available stocks of the medical device; (g) the forecast of supply of the medical device, including information on the potential vulnerabilities in the supply chain; (h) quantities already delivered and projected deliveries of the medical device;

			critical devices list and relevant conformity assessment procedures; (i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues which need to be resolved in order to complete the conformity assessment process.	(i) the demand forecasts for the medical device; (j) shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity; ***(k) information from relevant notified bodies regarding their capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list, within an appropriate period of time considering the emergency;*** (l) information on the number of applications received by relevant notified bodies in relation to medical devices included in the public health emergency critical devices list and on the relevant conformity assessment procedures;

				(m) where conformity assessments are ongoing, the status of the conformity assessment by the relevant notified bodies in relation to medical devices included in the public health emergency critical devices list and possible critical issues on the final outcome of the assessment and which need to be considered in order to complete the conformity assessment process. For the purposes of the first subparagraph, point (k), the relevant notified bodies shall communicate the date by which the assessment is expected to be completed. In that regard, notified bodies shall prioritise conformity assessments of medical devices included in the public health emergency critical devices list.
➔ Ignored				

3. *Regulation establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014*

Health Policy	**Categories**	**Opinion of the Committee of the regions**	**Commission proposal**	**Final Policy**
Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027	1."Specific objectives"	1. Amendment 14 Article 4 The general objectives referred to in Article 3 shall be pursued through the following specific objectives in keeping with the 'One Health' approach where relevant: (1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises,	1. Article 4: The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the "One Health" approach where relevant: (1)strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through	1. Article 4: The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities in keeping with the One Health approach, where applicable: (a) in synergy with other relevant Union actions, supporting actions for disease prevention, for health promotion and for

		including through coordination, provision and deployment of emergency health care capacity, data gathering, the ***establishment of health corridors*** and surveillance; (2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis; (3) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies; (4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by ***organis-ing the coordination and funding of stress tests for***	coordination, provision and deployment of emergency health care capacity, data gathering and surveillance; (2) ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, healthcare and support staff to be mobilised in case of a crisis; (3) support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies; (4)strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital	addressing health determinants, including through the reduction of damage to health resulting from illicit drug use and addiction, supporting actions to address inequalities in health, to improve health literacy, to improve patient rights, patient safety, quality of care and cross-border healthcare, and supporting actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer, as well as supporting actions to improve mental health, with special attention given to new care models and the challenges of long term care, in order to strengthen the resilience of the health systems in the Union; (b) strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-

		pandemics, taking into consideration how the Member States organise their health systems, supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health; (5) support actions aimed at strengthening health system's ability to foster disease prevention and health promo-tion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals;	transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health; (5) support actions aimed at strengthening health system's ability to foster disease prevention and health promotion, patient rights and cross-border healthcare, and promote the excellence of medical and healthcare professionals; (6)support action for the surveillance, prevention, diagnosis and treatment and	border threats to health in accordance with relevant Union legislation, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, the coordination of voluntary stress testing of national healthcare systems, and the development of quality healthcare standards at national level; (c) supporting actions to enhance the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union, while supporting the prudent and efficient use of medicinal products, in particular antimicrobials, and actions to support

		(6) support action for the surveillance, prevention, diag- nosis and treatment and care of non-communicable diseases, and notably of cancer; (7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices; (8) support the development, implementation and enforce- ment of Union health legislation and provide high- quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;	care of non-communicable diseases, and notably of cancer; (7)foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices; (8)support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;	the development of medicinal products that are less harmful for the environment, as well as the environmentally friendly production and disposal of medicinal products and medical devices; (d) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences, and in close cooperation with relevant Union bodies, supporting actions complementing national stockpiling of essential crisis-relevant products, at Union level, where needed; (e) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences and in close cooperation with the ECDC, establishing a structure and training

		(9) support integrated work among Member States ***and local and regional authorities***, and in particular their health systems, including the implementation ***of a European health emergency response mechanism to respond to all types of health crisis*** and scaling up networking through the European Reference Networks and other transnational networks; (10) support the Union's contribution to international and global health initiatives.	(9)support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks; (10) support the Union's contribution to international and global health initiatives.	resources for a reserve of medical, healthcare and support staff allocated voluntarily by Member States for its mobilisation in the event of a health crisis; (f) strengthening the use and re-use of health data for the provision of healthcare and for research and innovation, promoting the uptake of digital tools and services, as well as the digital transformation of healthcare systems, including by supporting the creation of a European health data space; (g) enhancing access to quality, patient-centred, outcome-based healthcare and related care services, with the aim of achieving universal health coverage; (h) supporting the development, implementation and enforcement and, where necessary, the revision of Union health

				legislation and supporting the provision of valid, reliable and comparable high-quality data for evidence-based decision-making and monitoring, and promoting the use of health impact assessments of other relevant Union policies; (i) supporting integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, supporting work on HTA, and strengthening and scaling up networking through ERNs and other transnational networks, including in relation to diseases other than rare diseases, to increase the coverage of patients and improve the response to low prevalence and complex communicable and non-communicable diseases;

				(j) supporting global commitments and health initiatives by reinforcing the Union's support for actions by international organisations, in particular actions by the WHO, and fostering cooperation with third countries.
	2."General objectives"	1. Amendment 13 Article 3(3) Strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States ***and the local and regional authorities with competences in*** ***the field of public health, through the*** coordination of health and social care actors in areas that match	1. Article 3: The Programme shall pursue the following general objectives, in keeping with the "One Health" approach where relevant: (1) protect people in the Union from serious cross-border threats to health; (2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their	1. Article 3: The Programme shall have a Union added value and complement the policies of the Member States, in order to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities. It shall pursue the following general objectives in keeping with the One Health approach, where applicable: (a) improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases,

		population centres, through the sustained implementation of best practice and data sharing, to increase the general level of public health. (Reason Highlights the importance of the responsible local health actors.)	affordability, and support innovation; (3)strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.	by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare; (b) protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health; (c) improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products; (d) strengthening health systems by improving their resilience and resource efficiency, in particular through: (i) supporting integrated and coordinated work between Member States;

				(ii) promoting the implementation of best practices and promoting data sharing; (iii) reinforcing the healthcare workforce; (iv) tackling the implications of demographic challenges; and (v) advancing digital transformation.
	3.Budget and funding	1. Amendment 15 Article 5 1.The financial envelope for the implementation of the Programme for the period 2021-27 shall be ***10 398 000 000*** in current prices (***EUR 9 370 000 000 in constant prices)*** 2. Amendment 9 Recital 30 ***In order to ensure that all of these objectives are implemented at Union level, the European Commission should strengthen the budget and mandate of the various***	1. Article 5 1.The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR 1 946 614 000 in current prices. 2.The amount referred to in paragraph 1 may be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation	1. Article 5: 1.The financial envelope for the implementation of the Programme for the period 2021 - 2027 shall be EUR 2 446 000 000 in current prices. 2.As a result of the Programme-specific adjustment provided for in Article 5 of Council Regulation (EU, Euratom) 2020/2093 (27), the amount referred to in paragraph 1 of this Article shall be increased by an additional allocation of EUR 2 900 000 000 in 2018 prices as specified in Annex II to that Regulation.

		European agencies responsible for health, such as the European Centre for Disease Prevention and Control, the European Medicines Agency, the European Food Safety Authority, the European Chemicals Agency and the European Agency for Safety and Health at Work. Further-more, the work of these agencies should be better coordinated so that they can more effectively contribute to achieving the objectives of the EU4Health programme, and their role in the governance of this programme should be strengthened.	activities including corporate information technology systems. 3. Appropriations deriving from activities under point (c) of Article 10 of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3 and paragraph 5 of Article 21 of Regulation (EU, Euratom) 2018/1046. 4. The budgetary commitments extending over more than one financial year, may be broken down over several years into annual instalments. 5. Without prejudice to the Regulation (EU, Euratom) 2018/1046, expenditure for	3.The amounts referred to in paragraphs 1 and 2 may also be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems. 4.The distribution of the amounts referred to in paragraphs 1 and 2 shall comply with the following: (a) a minimum of 20 % of the amounts shall be reserved for health promotion and disease prevention actions as referred to in point (a) of Article 4; (b) a maximum of 12,5 % of the amounts shall be reserved for procurement complementing national stockpiling of essential crisis-relevant products at Union level as referred to in point (d) of Article 4;

		(Reason: The European Union already has many instruments in place. They need to be strengthened and better coordinated in order to increase the EU's capacity to respond to health crises, and to improve the health of Europeans.)	actions resulting from projects included in the first work programme may be eligible as from 1 January 2021. 6.If necessary, appropriations may be entered in the budget beyond 2027 to cover the expenses provided for in paragraph (2) to enable the management of actions not completed by 31 December 2027. 2. Recital 30: In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between	(c) a maximum of 12,5 % of the amounts shall be reserved for supporting global commitments and health initiatives as referred to in point (j) of Article 4; (d) a maximum of 8 % of the amounts shall be reserved for covering administrative expenses as referred to in paragraph 3. 5.Appropriations related to activities under point (c) of Article 9(1) of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3, and paragraph 5, of Article 21 of the Financial Regulation. 6.Budgetary commitments extending over more than one financial year may be broken down over several years into annual instalments. 7.In accordance with point (a) of the second subparagraph of Article 193(2) of the Financial Regulation, for a limited

			the Programme for the Union's action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union's action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or	period in duly justified cases specified in the financing decision, activities supported under this Regulation and their underlying costs may be considered eligible as of 1 January 2021, even if those activities were implemented and those costs were incurred before the grant application was submitted. 8.If necessary, appropriations may be entered in the budget beyond 31 December 2027 to cover the expenses referred to in paragraph 3 to enable the management of actions not completed by 31 December 2027. 2. Recital 37: In order to optimise the added value and impact from investments funded wholly or in part through the budget of

			expenditure on a pro-rata basis to Programme for the Union's action in the field of health and another Union programme.	the Union, synergies should be sought in particular between the Programme and other Union programmes, including those under shared-management. To maximise those synergies, and avoid duplications, appropriate mechanisms should be provided for, including cumulative funding in an action from the Programme and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility of declaring the same cost or expenditure on a pro-rata basis under the Programme and another Union programme, in order to ensure that there is detailed and transparent reporting.

	4.Stakeholder consultation and information of the European Parliament (governance)	1. Amendment 16 Article 16: The Commission shall consult, ***at the national or — where competences are shared — at the regional and local level,*** the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation. ***This will ensure that local and regional authorities that are responsible for health policies are involved in this exercise.*** (Reason Highlights the role of local and regional authorities in the field of health.)	1.Article 16: Joint policy implementation The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.	1.Article 16: The Commission shall consult with ***relevant stakeholders, including representatives of civil society and patient organisations,*** to seek their views on: (a) the priorities and strategic orientation of the annual work programme; (b) the needs to be addressed through the annual work programme and the results achieved through it. 2. L 107/19 ***For the purposes of paragraph 1, the Commission shall organise the consultation and information of stakeholders at least once a year, in the six months preceding the presentation of the draft work programme to the committee referred to in***

				Article 23(1). ***3.*** ***The Commission may at any time seek the views of relevant decentralised agencies and of independent experts in the field of health on technical or scientific matters of relevance for the implementation of the Programme.*** ***4.*** ***Each year, prior to the last meeting of the EU4Health Steering Group, the Commission shall present to the European Parliament the outcomes of the proceedings of the EU4Health Steering Group and the consultation of stakeholders referred to in paragraphs 1 and 2***.
	5.Climate change	1. Amendment 11 Recital 40:	1. Recital 40:	1. Recital 49: Reflecting the importance of tackling climate change in line with the Union's

		Reflecting the importance of tackling climate change in line with the Union’s commitments to implement the Paris Agreement and the United Nations Sustainable Develop-ment Goals, this Programme will contribute to mainstream climate action in the Union’s policies and to the achieve-ment of an overall target of ***30 %*** of the EU budget expenditures supporting climate objectives. Relevant ac-tions will be identified during the Programme’s preparation and implementation, and reassessed in the context of its mid-term evaluation.	Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of 25 % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.	commitments to implement the Paris Agreement adopted under the United Nations Framework Convention on Climate Change and the UN Agenda 2030 Sustainable Development Goals, the Programme should contribute to mainstreaming climate action in the Union’s policies and to the achievement of an overall target of at least ***30 %*** of the total amount of the Union budget and the European Union Recovery Instrument, established by Council Regulation (EU) 2020/2094 (24), expenditures, supporting climate objectives. The Programme should support activities that would respect the climate and environmental standards and priorities of the Union and the ‘do no harm’ principle of the European Green Deal.

				Relevant actions should be identified during the Programme's preparation and implementation, and reassessed in the context of its interim evaluation.
➔ Fully incorporated				
	6.Cross-border health care	1. Amendment 8 Recital 26: Cross-border cooperation in the provision of healthcare to patients moving between Member States or ***European Groupings of Territorial Cooperation (EGTCs***), collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States ***and local and regional authorities*** has shown to have strong added value	1. Recital 26: Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase	1. Recital 34: ERNs and cross-border cooperation in the provision of healthcare to patients moving between Member States are examples of areas where integrated work between Member States has been shown to have strong added value and great potential to increase the efficiency of health systems and thus to improve public health in general. Collaboration as regards HTA is another area that is bringing added value to Member States. The Programme should

		and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore support activities to enable such integrated and coordinated work, which also serves to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact. ***For example, as recommended by the European Committee of the Regions in its opinion on cross-border healthcare, the programme should set up***	the efficiency of health systems and thus health in general. The Programme should therefore support activities to enable such integrated and coordinated work, which also serves to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the concerned population and areas so as to maximise their impact.	therefore support activities that enable integrated and sustained coordinated work, thereby also serving to foster the implementation of best practices that are aimed at distributing the available resources to the population and areas concerned in the most effective way so as to maximise their impact.

		'health corridors' between the border regions, making it possible for patients and health professionals to continue moving across the border during the lockdown to guarantee access to and provision of care.		
	7.Authorities involved in the implementation of the programme	1. Amendment 10 Recital 31: Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member ***States and local and regional authorities with competences in the field of public health*** are best placed in some cases to implement the related	1. Recital 31: Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States	1. Recital 38: Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States will be best placed, in some cases, to implement actions related to the Programme. Those authorities, designated by the Member States, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial

		activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals. (Reason Highlights the role of local and regional authorities with competences in the field of health.) 2. Amendment 12 Recital 42: The implementation of the Programme should be such that the responsibilities of the Member States ***and, if necessary,***	themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals. 2. Recital 42: The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.	Regulation and grants should therefore be awarded to those authorities without the prior publication of calls for proposals. Investments under the Programme should be implemented in close cooperation with Member States. 2. Recital 43: The implementation of the Programme should be supported by extensive outreach activities to ensure that the views and needs of civil society are duly represented and taken into account. To this end, the Commission should seek feedback on the Programme's priorities and strategic orientations and on the needs to be addressed through its

		the regions or other tiers of government involved in drafting health policy, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected. (Reason The aim is to target the different stakeholders involved in drafting health policies.)		actions from relevant stakeholders once a year, including from representatives of civil society and patients' associations, academics and organisations of healthcare professionals. Each year, before the end of the preparatory work for the work programmes, the Commission should also inform the European Parliament about the progress regarding such preparatory work and on the outcome of its outreach activities towards stakeholders.
	8.Cooperation and coordination to prevent and control the spread of diseases	1. Amendment 1 Recital 6: While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity, ***as also provided for in Article 222***	1. Recital 6: While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity8.	1. Recital 6: While Member States are responsible for their health policies, they should protect public health in a spirit of European solidarity, as called for in the communication of the Commission of 13 March 2020 on coordinated

		TFEU, which stipulates that the Union and its Member States shall act in a spirit of solidarity. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States ***and local and regional authorities and, where necessary, public institutions***, in order to improve the prevention and control of the spread of severe human diseases across borders, ***to support the development of and make available the products needed to prevent and treat disease,*** to	Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States in order to improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union. 2. Recital 10: Due to the serious nature of cross-border health threats, the Programme should support	economic response to the COVID-19 outbreak. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further action at Union level to support cooperation and coordination among the Member States. That cooperation should improve preparedness for, and the prevention and control of, the spread of severe human infections and diseases across borders in order to combat other serious cross-border threats to health and to safeguard and improve the health and well-being of all people in the Union. Preparedness is the key to improving resilience to future threats. In that regard, Member States should be given the possibility of carrying out stress tests on a voluntary basis to improve preparedness and increase resilience.

		combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union. (Reason It is important to highlight the spirit of solidarity among Member States in the field of health.) 2. Amendment 2 Recital 10 Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis	coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health crisis the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council10 and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies or capacity building in crisis response,	2. Recital 11: Due to the serious nature of cross-border threats to health, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage any future health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council (9) and other relevant mechanisms and structures referred to in the communication of the Commission of 11 November 2020 entitled ‘Building a European Health Union: Reinforcing

		the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council and other relevant mechanisms and structures established at Union level. This could include strategic stockpiling of essential medical supplies, ***promoting investment in the production of devices and pharmaceutical products to combat pandemics and other public health scourges in order to ensure European sovereignty***, capacity building in crisis response,	preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the "One Health" approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis - prevention,	the EU's resilience for cross-border health threats', including actions directed at strengthening preparedness planning and response capacity at national and Union level, at reinforcing the role of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and at establishing a health emergency preparedness and response authority. Such actions could include building capacity for responding to health crises, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, provision of health information, and platforms to share best practices. In this context, the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness and surveillance, and the management capacity and response

		or support for the development by Member States of a statistical protocol making it possible to compare data on the impact of pandemics at NUTS 2 level, preventive measures related to vaccination and immunisation, or strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the 'One Health'	preparedness and response.	capacity of actors at Union and Member State levels, including contingency planning and preparedness exercises, in keeping with the 'One Health' and 'Health in All Policies' approaches. The Programme should facilitate the setting up of an integrated cross-cutting risk communication framework for all phases of a health crisis, namely prevention, preparedness and response.

		approach. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis — prevention, preparedness and response.		
	9.Protection of vulnerable groups	1. Amendment 3 Recital 12: With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases ***(including obesity),*** the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. ***In order to ensure high standards for essential health***	1. Recital 12: With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.	1. Recital 14: With a view to protecting people in vulnerable situations, including those suffering from mental illness and those living with or most affected by communicable or non-communicable diseases and chronic diseases, the Programme should also promote actions which address and prevent the collateral impact of health crises on people belonging to such vulnerable groups and actions which improve mental health

		services, the Programme should encourage, particularly in times of crisis and pandemic, the use of telemedicine. (Reason Telemedicine must be further developed, so that it becomes an effective tool in times of crisis and pandemic. C 440/133)		<u>However:</u> Annex I, 6. Actions meeting the objective laid down in point (f) of Article 4: d) Supporting the optimal use of telemedicine and telehealth, including through satellite communication for remote areas, fostering digitally-driven organisational innovation in healthcare facilities and promoting digital tools to support citizen empowerment and patient-centred care; (i) Actions to support e-health, such as the transition to telemedicine and at-home administration of medication;
	10.Health promotion and protection at Union level	1. <u>Amendment 5 Recital 18</u> The Programme therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing	1. <u>Recital 18:</u> The Programme therefore should contribute to disease prevention throughout the	1. <u>Recital 21:</u> The Programme therefore should support health promotion and disease prevention and improve mental health

		health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement	lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of illicit drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits and physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also	throughout the lifetime of an individual by addressing health risk factors, and health determinants, which would also contribute to the attainment of Goal 3 of the UN 2030 Agenda Sustainable Development Goals. The Programme should also therefore contribute to the objectives set out in the Commission communication of 11 December 2019 entitled 'The European Green Deal' (the 'European Green Deal'). 2. <u>Recital 32:</u> Union health legislation has an immediate impact on public health, on the lives of people, on the efficiency and resilience of health systems and on the proper functioning of the internal market. The regulatory framework for

		the action of Member States ***and local and regional*** ***authorities*** in these areas. The Programme should also therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy. (Reason: Highlights the role of local and regional authorities.) 2. Amendment 7 Recital 25 The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of	therefore contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy. 2. Recital 25: The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for	medical products and technologies, including medicinal products, medical devices and substances of human origin, and the regulatory frameworks for tobacco, patients' rights in cross-border healthcare and serious cross-border threats to health, are essential to the protection of health in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and, in conjunction with relevant bodies such as EMA and ECDC, should provide high-quality, comparable and reliable data, including real-world healthcare data, to support policymaking and monitoring, set targets and develop tools to measure progress.

		the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border health- care and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high	tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.	

		quality, comparable and reliable ***NUTS 2 regional-level*** data to underpin policymaking and monitoring. (Reason: Specifies the NUTS 2 regional level.)		
	11.Reforms and transformations of health systems across Europe	1. Amendment 4 Recital 15: Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. ***These reforms, in the context of a revamped*** ***European Semester, need to strengthen the specific***	1. Recital 15: Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the	1. No recitals or articles on reforms However: Rectal 6: While Member States are responsible for their health policies, they should protect public health in a spirit of European solidarity, as called for in the communication of the Commission of 13 March 2020 on coordinated economic response to the COVID-19 outbreak. Experience from the ongoing COVID-19 crisis has demonstrated

		features of European health systems based on strong ***public services and substantial public investment. Health*** ***services are services of general interest intended to*** ***strengthen the European Pillar of Social Rights, which*** ***cannot be made subject to private-sector thinking***. In the context of such transformation and reforms, the Pro- gramme should, taking into consideration how the Member States organise their health systems**,** ***organise the coordina-***	Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems,	that there is a need for further action at Union level to support cooperation and coordination among the Member States. That cooperation should improve preparedness for, and the prevention and control of, the spread of severe human infections and diseases across borders in order to combat other serious cross-border threats to health and to safeguard and improve the health and well-being of all people in the Union. Preparedness is the key to improving resilience to future threats. In that regard, Member States should be given the possibility of carrying ***out stress tests*** on a voluntary basis to improve preparedness and increase resilience. Article 4

		tion and funding of stress tests in the Member States in ***order to identify weaknesses and to assess their ability to*** ***respond to pandemics. The programme should further-*** ***more*** promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide	researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 200612 the Programme should support actions ensuring the universality and inclusivity of health care,	b) strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross- border threats to health in accordance with relevant Union legislation, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, ***the coordination of voluntary stress testing of national healthcare systems***, and the development of quality healthcare standards at national level; <u>Annex I:</u> 2. Actions meeting the objective laid down in point (b) of Article 4 b) Supporting actions to foster Union-wide health crisis prevention and preparedness, and the management capacity

		new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the	meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.	and response capacity of actors at Union and national level, ***including voluntary stress tests, contingency planning and preparedness exercises***; supporting the development of quality health standards at national level, mechanisms for the efficient coordination of preparedness and response, and the coordination of those actions at Union level; (j) Supporting upwards convergence of national systems' performance through health indicator development, analysis and knowledge brokering and the organisation of ***voluntary stress tests of national healthcare system***s;

		fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 (12) the Programme should support actions ensuring the universality and inclusivity of health care,		

		meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.		
➔ Completely deleted and ignored but incorporated in other recitals and articles				