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EUROPEAN UNION COMPETENCES IN THE AREA OF COMMUNICABLE DISEASES – EXPERIENCES AND LESSONS LEARNED FROM THE COVID-19 CRISIS**

Abstract

In the European Union, healthcare and public health are mostly within the competence of Member States. Still, in a number of sub-domains, coordination between Member States led to the adoption of legislation that formed the healthcare *acquis*, together with a whole set of programs and initiatives aimed at improving public health within the Union. The European Centre for Disease Prevention and Control (ECDC) was formed in 2004 to help EU institutions and Member States identify and assess the risk of current and emerging threats to human health from communicable diseases. At the end of July 2020, Member States reached a general agreement on the recovery plan, but the final agreement had not been adopted by the end of the year. On the other hand, in the spring of 2020, EU launched a global action for universal access to tests, treatments and vaccines against coronavirus and for global recovery, while in October 2020, it presented the strate-

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gies on vaccine allocation and additional Covid-19 response measures. In November 2020, a new framework was proposed for the improvement of the response to cross-border health threats, as well as for the expansion of the role of EU agencies – ECDC and the European Medicines Agency, related to coordination of preparedness measures and response to public health threats. This initiative came within a wider proposal entitled "European Health Union". Hence, soon after the crisis broke out, different initiatives were launched to improve the institutional system for communicable disease control in Europe and assistance provided to the Member States. Still, these changes remain within the framework prescribed in the contracts and keep the responsibility, for the most part, at the level of Member States with the possibility of EU assisting, coordinating and helping the Member States in the situations that exceed their capacities; they also emphasize that the main role of the Union can and should be in the field of economic assistance, which is what the unique proposed assistance package has shown.

Keywords: Covid-19 crisis, European Union, public health, competencies, ECDC

INTRODUCTION

The Covid-19 outbreak in March 2020 put the public health policy of the EU in the spotlight. Usually outside of the main focus in the studies of European law and policy, in the context of the greatest international crisis since World War II (Guterres, 2020), the field of public health showed many weaknesses of the EU governance, becoming a top priority issue. Union competencies in this field are relatively limited and classified as coordinative, bearing in mind the tendency of the Member States to keep the issues of healthcare and, particularly, of its funding, in the national domain. Still, considering the level of integration in the EU and the importance of free movement of people and goods, a significant number of issues is encompassed in the acts and initiatives at the community level. This is particularly the case in the domain of cross-border communicable disease control. As pointed out by Greer and Jarman, the Covid 19 crisis "not only led to a strengthening of EU public health but also showed that the EU is one of the

many political systems in which the legal and bureaucratic domain of public health is far smaller than the actual issues affecting the public's health" " (Greer & Jarman, 2021). At the very beginning, in the period from January to March 2020, we saw the consequences of poor coordination at the Union level, within a domain where policies are dominantly kept at the national level, combined with inadequate global action. In addition, the crisis demonstrated that Member States were not prepared to handle a public health threat (Herszenhorn&Wheaton, 2020). This can also be analysed in the context of long-term austerity policy promoted among EU Member States, which left its mark on their healthcare systems (Greer, 2014). With the scope of the crisis in mind, numerous challenges can be observed, such as the (lack of a) proclaimed and assumed solidarity among Member States in the context of a health crisis, fragmentation of the health crisis management system and the consequences it had in the context of the pandemic, as well as numerous important health law issues that came to the forefront during the pandemic, such as the protection of health data and resource distribution.[1] This article examines the EU legal framework in the field of infectious disease, as well as the institutional setup and its limits. The EU experience in the joint Covid-19 response from the perspective of health law and the possibilities for further action at the community level are also analysed.

EUROPEAN UNION COMPETENCE AND CONTROL OF COMMUNICABLE DISEASES

The field of healthcare, i.e., public health, for the most part, lies within the competencies of the individual EU Member States, which sets it apart from many other domains of EU policy and law. Still, bearing in mind the high level of integration, as well as the movement of people and goods between EU Member States, legislation was adopted through coordinated efforts of the Member States in a number of sub-domains, to make up the health *acquis*, with a whole set of programs and initiatives aimed at improving public health within the EU (Sjeničić&Milenković, 2019; Sjeničić et al., 2016).

1 See: Powell, A, 2020; Holmes, E, 2020; Politico, 2020; World Health Organisation, Joint Statement on Data Protection and Privacy in the COVID-19 Response.

The EU competencies in the public health domain

Division of competencies between the European Union and its Member States, in line with the founding treaties, is made of exclusive (those where the EU has the sole competence, of which there are five), shared (in most areas) and coordinative, where the Union, in line with Art. 6 of the Treaty on the Functioning of the European Union, supports, coordinates and substitutes the actions of Member States (see further: Rossi, 2012). This last group of competencies also includes the protection and improvement of human health, i.e., public health – the field which, for the most part, remained in the national domain of the Member States, for the Union Member States to manage in line with their constitutional and cultural traditions (De Ruijter, 2016; Neergaard, 2011; Harvey, 2010). In addition, due to the intense movement of people, a number of issues related to healthcare, and especially healthcare workers and their status, in the context of the principle of free movement within the EU, have been regulated by the relevant EU legislation (Guy&Sauter, 2016; Greer et al., 2013). In line with Article 168 of the Treaty on the functioning of European Union, it is prescribed that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health." The Treaty envisages *...the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.* It is also envisaged that the Union shall complement the actions taken by Member States in reducing drugs-related health damage, including information and prevention. In line with the nature of its competencies, *the Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.* Article 168 also envisages that the Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators,

the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. In line with the nature of competencies in this field, it is envisaged that the European Parliament would be kept thoroughly informed. In line with the Treaty, the Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health. In exceptional cases, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in Article 168 through adopting in order to meet common safety concerns: a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures); b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and ***in particular to combat the major cross-border health scourges***, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States. The Council, on a proposal from the Commission, may also adopt recommendations for the above purposes. Union action shall respect 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. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

EU may adopt healthcare legislation on the basis of the Treaty on the Functioning of the European Union, i.e., Art. 168 (public health), Article 114 (approximation of laws) and Article 153 (social policy). The fields in which the EU adopts legislation include: rights of patients in cross-border healthcare, medicines and medical devices (pharmacovigilance, counterfeit medicines, clinical trials), tobacco, organs, blood, tissues and cells, as well as serious cross-border threats, which shall be discussed in greater detail in the next section. In the field of infectious disease, in 2004, the European Centre for Disease Prevention and Control (ECDC) was established, as shall be discussed in the third section of this paper. Finally, in addition to the European Commission, the European Medicines Agency (EMA) also plays an important role with regards to authorisation of medicines.

As can be concluded, although limited, the coordination competencies of the European Union in this field are entwined in numerous domains of human health and health-related activities, taking place at different administrative levels and in the interaction of many sub-sectors – healthcare, social protection, education, police, defence, civil protection etc.[2], with cross-border control of infectious disease being particularly relevant.

European Union and the communicable disease challenge

Bearing in mind the level of integration of the member states economies and the intensity of (free) movement of people and goods in the European Union, the question of controlling the spread of infectious disease has been a major and significant part of EU action in the public health domain for decades. As pointed out by Greer and Mätzke, the control of infectious disease is one of the oldest and most important functions of a modern state, but is given surprisingly little attention (Greer, Mätzke, 2012: 887). Individual sources of European health law in the field of cross-border health threats, i.e., communicable diseases, are: Decision 2119/98/EC

2 Despite significant limitations to its competencies, the European Union has developed numerous programmes in the field of public health. the implementation of which is entrusted to the Consumer, Health and Food Executive Agency. For further detail on the Agency, see: European Commission, Consumers, Health, Agriculture and Food Executive Agency.

(later updated in other Decisions) of the European Parliament and of the Council, setting up a network for the epidemiological surveillance and control of communicable diseases in the Community; Decision 2000/96/EC and its Annex I on the communicable diseases to be covered by the EU network; Decision 2002/253/EC and its Annex on reporting on communicable diseases to the European network and Decision 2012/506/EU supplementing Decision 2002/253/EC; Decision 1082/2013/EU on serious cross-border health threats and the repeal of the Decision 2119/98/EC; Regulation 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data; Council Recommendation 2009/1019/EU on seasonal influenza vaccination; Council Conclusion on the immunization of children 2011/S202/02.

Decision no. 1082/2013/EU of the European Parliament and of the Council from 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC is particularly relevant, as it *sets up the rules of epidemiological surveillance, monitoring, early warning and combating serious cross-border threats to health*, including preparedness and response planning related to these activities, with the aim of coordinating and supplementing the national policies. After adoption of the Treaty of Lisbon, as well as this decision, analyses aimed at the link between public health and security begin to appear in literature (Dijkstra, De Ruijter, 2017).

Commission Decision no. 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network comprises Annex 1 with the *List of communicable diseases and special health issues* to be covered by the Community network. Annex 2 of the Decision contains *Criteria for selection of communicable diseases of special areas to be covered by epidemiological surveillance within the network.*

Commission Decision from 19 March 2002 setting up the definition of cases for reporting communicable diseases to the Community network, under Decision no. 2119/98/EC of the European Parliament and of the Council – 2002/253/EC, prescribes the definition of a case for the purposes of epidemiological surveil-

lance and communicable disease control, to be implemented by the Member States. These definitions are aimed at facilitating the reporting of diseases and special health issues and are founded on a combination of clinical, laboratory and epidemiological criteria (Sjeničić et al., 2016).

In Serbia, the Law on the protection of the population from communicable diseases was adopted in 2016, and it has been harmonised, to a large extent, with EU legislation.[3] After adoption of the Law, for the purposes of concrete implementation of the Law and detailed harmonisation with EU legislation, work began on the elaboration and adoption of a series of by-laws/regulations for its implementation. In the Serbian Progress Report in the process of EU integrations for 2020, it is stated that the "capacities for surveillance and response are still limited and need to be modernised. No centralised healthcare information and communication system has been established as of yet" (European Commission 2020: 121), so more efforts are needed in that respect.

POSITION AND ROLE OF THE EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)

As it is the case in many other EU policy areas, a specialised agency has been formed in the domain of communicable disease control. Ideas on the development of such an agency appeared at the end of 1990-ies (Greer&Mätzke 2012: 1009). The European Centre for Disease Prevention and Control (hereinafter: the Centre) was founded in 2004 by Regulation 851/2004, to assist in identifying and assessing risks from current and emerging threats to human health, posed by communicable diseases. It began operations in 2005, in Stockholm. The Centre has a classical organisational structure and role, like many other decentralised European Union agencies, created for the purpose of gathering experts at the EU level, processing information, networking and providing opinions to the Commission and other Union institutions.[4] The Centre's organisational structure is comprised of a Management Board, Advisory Forum and Director, who represents the Agency and manages the work of expert services. The Managing Board is com-

3 For more, see: Sjeničić, M., Miljuš, D., Milenković, M., 2016.

4 For more, see: Decentralised agencies, European Union.

prised of one member appointed by each of the Member States, two members appointed by the European Parliament and three members representing the Commission, appointed by the Commission; the members are appointed in such a way that ensures "the highest standards of competence and a broad range of relevant expertise" (Article 14). The Advisory Forum is comprised of members from technical competent bodies in Member States, which perform tasks similar to those of the Centre, but again respecting the principle of representation of EU Member States. Each Member State appoints one member based on their recognised scientific expertise. Three members with no voting rights are appointed by the Commission, and they represent the stakeholders at the European level.

Article 3 of the Regulation prescribes that the Centre's mission is to identify, assess and communicate current and emerging threats to human health from communicable diseases. In the case of other outbreaks of illness of unknown origin which may spread within or to the Community, the Centre shall act on its own initiative until the source of the outbreak is known.[5] Like the majority of decentralised EU agencies, the Centre also plays a role in *coordinating the network of relevant national bodies*. In line with the Regulation (Article 5), the Centre, through the operation of the dedicated surveillance networks and the provision of technical and

5 Within the field of its mission, the Centre shall: (a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data; (b) provide scientific opinions and scientific and technical assistance including training; (c) provide timely information to the Commission, the Member States, Community agencies and international organisations active within the field of public health; (d) coordinate the European networking of bodies operating in the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated surveillance networks; and (e) exchange information, expertise and best practices, and facilitate the development and implementation of joint actions. On the other hand, the Member States are obliged to: (a) provide to the Centre in a timely manner available scientific and technical data relevant to its mission; (b) communicate to the Centre any messages forwarded to the Community network via the early warning and response system; (c) identify, within the field of operation of the mission of the Centre, recognised competent bodies and public health experts who could be made available to assist in Community responses to health threats, such as field investigations in the event of disease clusters or outbreaks (Article 4 of the Regulation). From this perspective, it is impossible to have a complete view of how this cooperation functioned during the Covid crisis, but the fact that amendments to the Regulation are being proposed indicates that there are potential shortcomings.

scientific expertise to the Commission and Member States, supports the networking activities of the competent bodies recognised by the Member States. In addition, it plays a role in capacity building and supporting the cooperation between expert and reference laboratories for the purpose of the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health. In addition, the Centre also *provides independent scientific opinions, expert advice, data and information* (Article 6), upon a request from the Commission, European Parliament, Member States but also of its own initiative (Article 7), which, to a large extent, ensures the Centre's independence from the Commission.[6]

The Regulation also envisages the existence of a *System for early warning and response* for which the Centre assists to the Commission. In addition, in line with the Regulation, the Centre provides to the Member States, the Commission and other EU agencies the scientific and technical expertise in the elaboration, regular review and updating of the preparedness plans, as well as in the elaboration of intervention strategies in the areas relevant to its mission. In addition, the Commission, Member States, *third countries and international organisations (particularly WHO)* may request from the Centre to provide scientific or technical assistance in any field within its mission. Furthermore, the Centre identifies, in any field within its mission and in cooperation with Member States, *procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging health threats* which may have mental as well as physical health consequences and which could affect the Community, and *informs the Commission and Member States as soon as possible about findings which require their immediate attention.* Finally, the Centre coordinates data collection, validation, analysis and dissemination at the EU level, including on vaccination strategies. The Centre elaborates rapid risk assessments at the request of the European Commission, EU Member State or based on an internal decision (ECDC, Health Security and Infectious Diseases). In that sense, during the Covid-19 pandemic, a Rapid Risk

6 For more information on the relationship between the Commission and the decentralised agencies, as well as on its impact on their work, in terms of their provision of information, opinions or preparation of individual acts, see: Milenković, 2019.

Assessment on increased Covid-19 transmission was undertaken and regularly updated (ECDC, Rapid Risk Assessment, 2020). The Centre played an important role since the beginning of the Covid-19 crisis. The Centre collects data on the number of people infected with Covid-19 virus from around the world, on a daily basis. It also publishes regular reports on threats from communicable diseases (ECDC, Communicable Disease Threat Report).

The Regulation also contains a clause on external evaluation of the results (Article 31). The first such evaluation was performed in 2007 and included, *inter alia*, geographic extension of the Centre's activities in cooperation with agencies outside of the EU, but the proposals for amendments to the legislation came about only with the Covid crisis. Within the wider proposal designed under the title "European Health Union", the Commission proposed to the Council and the Parliament the amendments to the founding regulation of the Centre based on the experiences from the first months of the Covid-19 crisis (EC, Proposal for a Regulation of the European Parliament and of the Council amending Regulation no. 851/2004). This proposal focuses on strengthening the capacities and the mandate of the Centre, specifically including: epidemiological surveillance via integrated systems enabling real-time surveillance; preparedness and response planning, reporting and auditing; provision of non-binding recommendations and options for risk management capacity to mobilise and deploy EU Health Task Force to assist local response in Member States; building a network of EU reference laboratories and a network for substances of human origin. (EC, Building a European Health Union: Stronger crisis preparedness and response for Europe).

It can be concluded that the proposed amendments represent useful steps to improve the system of communicable disease control and cooperation at EU level, but do not bring about crucial changes to the system. This is also expected, bearing in mind that management of such a crisis primarily remains at the national and lower levels of government, while the EU maintains its coordination and support role, in line with the founding treaties.

EU EXPERIENCES IN COVID-19 CRISIS – TOWARDS THE ESTABLISHMENT OF THE EUROPEAN HEALTH UNION

The Covid-19 pandemic undoubtedly represents the greatest crisis faced by the European Union in its history. Already in February 2020, the governments introduced different types of restrictions and measures in response to the outbreak (EAHL newsletter, 2020). With regards to the Covid-19 response, in the first wave of the outbreak in Europe, the countries that were hit the hardest were Italy and Spain, according to the data (WHO, Coronavirus disease (COVID-19) Weekly Epidemiological Update and Weekly Operational Update). At the beginning of March 2020, the Italian Prime Minister turned to European Union, asking it "not to make tragic mistakes" in its management of the coronavirus crisis, and warning that if it does, and if it fails to help during COVID-19 crisis "the whole EU project will lose its raison d'être" (Euronews a), 2020). At that time, Italy proposed the establishment and implementation of a recovery plan , that would support the entire European economy. In its address to the EU in March, the Italian Prime Minister stated that Italy had suffered over 9000 victims and was being forced to make many hard decisions. The Italian PM warned the EU leaders that such decisions must be avoided in the future and that, if Europe didn't show that it was up to the task, the Italian citizens would see no further reason for the existence of the European project (Euronews a), 2020). After the appeal from Spain ensued, the EU state aid rules were relaxed, and Brussels announced the formation of stocks of medical supplies, such as ventilators, masks and laboratory equipment (Euronews b), 2020).

Following the Spanish and Italian call for greater solidarity, in the first weeks, the EU leaders failed to achieve an agreement on a joint financial response, i.e., on financial instruments that would help Member States facing crises. Member States only achieved a general agreement at the end of July 2020, on a recovery plan and European long-term budget 2021-2027, with a generous assistance plan for the Member States exceeding 750 billion euros and, for the first time in history, the EU took out a direct loan to finance this endeavour. This was a new recovery instrument – the Next-

GEneration EU, which was to support the EU budget with new funding sources from the financial markets, in the period 2021-2024 (EC, Recovery Plan for Europe). The mechanisms envisaged to provide for the recovery of Member States can be classified into three pillars: Supporting Member States to recover, Kick-starting the economy and helping private investment as well as Learning the lessons from the crisis. Each of these groups contains different instruments of support (EC, The EU budget powering the recovery plan for Europe). Still, until the very end of 2020, during the new wave of the pandemic and more than eight months from the beginning of the crisis, final agreement had not been reached.

On the other hand, in the spring of 2020, EU launched a global action for a universal access to tests, treatments and vaccines against the coronavirus, and for the global recovery (Coronavirus Global Response), as well as for the collection of about 16 billion Euros for this initiative. It invested 400 million Euros to accelerate the development, production and administration of vaccines against Covid-19 (EC, Health-EU newsletter 259 – Focus). In addition, on 15 October 2020, the European Commission presented a document – Communication from the Commission to the European Parliament and the Council Preparedness for COVID-19 vaccination strategies and vaccine deployment. This document defined the basic elements of vaccination strategies of Member States and activities that would ensure that the vaccines are effectively distributed across the EU (EC, Health-EU newsletter 259 – Focus). This document also proposed the method of accelerating the development and production of vaccines by providing advance financing, and for assisting Member States to procure them under the best possible conditions. Until October 2020, three contracts were signed with vaccine manufacturers for almost one billion doses (EC, Health-EU newsletter 259 – Focus).

In addition, in October 2020 the European Commission concluded that "relaxation of applied measures during the summer months was not always accompanied by steps to build up sufficient response capacity. This means that urgent steps are needed now at both national and EU level". (EC, Communication from the Commission to the European Parliament, European Council and the Council on additional COVID-19 response measures). This

Communication defines several objectives and steps for the next phase of EU crisis response measures. Firstly, ensuring *the flow of information to allow for informed decision-making*. The steps in achieving this goal would cover two aspects: Member States would submit all relevant data to the Centre and the Commission using common criteria, and an improved internet portal of the Centre would be launched to host all key data in one place, at the latest by April 2021. Secondly, *efficient and rapid testing*, with mobilisation of EU funds for the procurement of tests, as well as joint public procurements. The *use of contact-tracing apps* represents the third measure. Steps to ensure this goal would include the Commission supporting Member States in developing national contact tracing apps and their linking via the *European Federation Gateway Service*, while all Member States should set up efficient and compatible applications to ensure the functioning of the system at the EU level. As pointed out in the document, currently available apps may and will be used for providing information, checking symptoms and for telemedicine, as well as for contact tracing and warning. To ensure a coherent, joint European approach, the European Commission issued Guidelines for support to Member State governments and app programmers in implementing apps to combat the Covid-19 pandemic (European Data Protection Board) on 16 April 2020. On the 21 April 2020, the European Data Protection Board issued Guidelines on using location data and contact tracing tools in the context of Covid-19 outbreak, to develop the joint European approach to win the trust of the citizens. The Board outlined that "contact tracing apps should be used to empower, and not to control, stigmatize or repress individuals, and to clarify the conditions and principles for proportional use of the location data and contact tracing mechanisms" (European Data Protection Board, 2020). The Board also took the position that the use of contact tracing apps should be voluntary and that "one should not have to choose between an efficient response to the current crisis and the protection of our fundamental rights." The Board also underlined that it must be kept in mind that data and technology can be useful tools to fight Covid-19, but their use requires a case-by-case approach and they need to be managed under the control of the competent public health authorities. It should be noted that the large scope and sensitivity of data to be processed require

stringent privacy protection and cyber security measures, in order to decrease the risk of data security breaches, as such breaches can have a negative effect on the public's trust in the use of such solutions (Olivi et al., 2020).

Communication on additional Covid-19 response measures emphasizes, as the fourth aspect, *efficient vaccination,* with the establishment of a platform to monitor the efficiency of vaccination strategy during its implementation as well as *efficient communication with the population,* and *ensuring their access to basic provisions.* Finally, the Communication lists, as the fifth priority, *facilitating safe travels*, which is of special importance, considering the traveling restrictions to/outside the Union, as well as within the Union itself, since the beginning of the Covid crisis. This relates to, for example, extension of the so-called "green lanes" to "*to ensure that more than 90% of border crossing points continue to be permanently fluid with under 15 min crossing time*" (EC, Communication from the Commission to the European Parliament, European Council and the Council on additional COVID-19 response measures). The conclusion of this Communication is that Member States must acknowledge and respond to their own call to a more coordinated, more consistent approach. A package of measures is also planned, *establishing the first building blocks of a European Health Union* (EC, Communication from the Commission to the European Parliament, European Council and the Council on additional COVID-19 response measures).

Based on the lessons learned from the fight with the Coronavirus, the European Commission proposed, on 11 November 2020, a new framework to improve the response in case of cross-border threats to health, as well as to expand the role of EU agencies - European Centre for Disease Prevention and Control (EC, Proposal for a Regulation of the European Parliament and of the Council amending Regulation No 851/2004) and European Medicines Agency (EC, 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) in the field of coordinating preparedness measures and response to public health threats (EC, Health Security and Infectious Diseases). In that regard, the idea of the

aforementioned European Health Union was also promoted (European Commission, Building a European Health Union). To create and receive a stronger mandate for the coordination between the Commission and the EU agencies, the Commission *proposed a new Regulation on serious cross-border threats to health* (EC, 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). As the European Commission announced, the proposed new legislative and organisational framework should: strengthen preparedness, intensify surveillance, improve reporting and the possibilities of proclaiming the state of alert in the EU. With regards to reinforcing preparedness, plans and recommendations for the adoption of plans at the national level are to be developed, as are reporting mechanisms. According to the proposal, preparation of the national plans would be supported by the European Centre for Disease Prevention and Control and other EU agencies. The Commission and EU agencies would also supervise these plans. Member States will be asked to increase reporting on quality indicators of their healthcare systems (i.e., availability of beds, specialised treatments and ICU capacities, number of medically trained staff etc.). Finally, it is emphasized that the "declaration of an EU emergency situation" would activate increased coordination and enable the development, stocking, procurement of products relevant for the crisis at hand (EC, Building a European Health Union). It can be concluded that, despite its attractive name, the formation of a European Health Union, at a level similar to other integration fields is not what is actually being planned, but that concrete steps are being made to ensure that EU functions better in similar epidemiological situations in the future.

CONCLUDING REMARKS

The competence in the field of public health, and especially sustainability and adequacy of the healthcare system to withstand non-standard pressures, primarily is in the domain of EU Member States. The coordinative role of the Union in the area of communicable diseases and the developed institutional arrangements and procedures primarily facilitate the functioning of the single market in standard conditions, when public health challenges remain within

the limits of the usual problems that all societies face from time to time. Although the institutional system for the control of the spread of communicable diseases in Europe and the assistance it provides to the Member States can be assessed as generally adequate, it has shown numerous shortcomings; in that regard, initiatives have been launched to improve this system, a few months after the outbreak of the pandemic. It can be concluded that these changes remain within the limits defined in the treaties and keep the responsibility primarily at the level of Member States, with the possibility for the EU to coordinate actions and assist Member States when their capacities are insufficient. The COVID crises has demonstrated that more profound issues, such as the lack of solidarity between Member States, represent a far more fundamental challenge for the integration project. However, it can also be concluded that the area of economic assistance can and should be the main role of the Union, as the proposed assistance package has shown. Finally, it can be concluded that the level of inter-dependence between Member States does point to need to further discuss aspects of the Union actions in fields that were considered to be (almost) exclusively in the national domain.

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