

TOWARDS A COMPREHENSIVE EU HEALTH POLICY? THE EUROPEANISATION OF THE FIGHT AGAINST COVID-19 AND REFLECTIONS ON THE FIRST YEAR OF THE PANDEMIC

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Abstract

In winter 2020 it was roughly one year since the first cases of Covid-19 disease were reported in China and soon the virus spread all over the world. The main aim of this article is to analyse the response of the EU which was hit by the virus in early 2020 and quickly responded to the pandemic. This response may be best analysed in the context of the Europeanisation concept which offers a suitable analytical framework allowing a systematic analysis of the impact on EU policy, politics and polity. The application of the concept will explore EU activities and contribute to both: a better understanding of the response of the EU and verification of the usability of the concept. How might the response of the EU be interpreted in the context of Europeanisation? And what were the key differences in the Europeanisation between the first and second wave?

Key words: *Pandemic, Covid-19, Health Policy, Europeanisation, Response*

INTRODUCTION

The Covid-19 pandemic changed the World and penetrated the life of billions of citizens. All states were forced to adopt restrictive measures and so did international organisations, transnational companies and other non-state actors. This article focuses on the reaction of the European union which is undergoing a process of significant transformation: at the end of 2019 EU institutions were still under pressure over the migration crisis, Brexit negotiations were stuck leaving future ties uncertain, Russia continued its hybrid warfare in order to destabilize EU countries and its neighbours and some countries in the EU (mainly Poland and Hungary) adopted more illiberal policies. It seems that the Covid-19 pandemic of Covid-19 hit the European union at a bad time and soon overshadowed other challenges. Despite the plans of the newly formed Commission led by Ursula von der Leyen, it became a key agenda of the EU which quickly materialised in the form of new programmes, new tools and new institutional settings. In this sense Covid-19 brought to the EU and its institutions a new content which may be best analysed in the context of Europeanisation.

This article deals with the response of the EU towards the spread of Covid-19. Because the response was very complex and is related to all areas including the single market, this article will focus mainly on health policy measures without considering the economic dimension of the crisis. Issues such as Brexit, the Multiannual Financial Framework, the Recovery Fund, EU help to third countries or other topics – and their response to Covid are not assessed in this article. The article focuses on the EU's internal response which is analysed in the context of the Europeanisation concept in all three domains including *polity*, *politics* and *policy*. It analyses roughly the period of the first year starting with the initial reaction of the EU on the new situation (approximately since January 2020) until the end of 2020. Europeanisation provides an analytical framework which will be used to analyse all of the three above mentioned domains where politics might be considered as an independent variable which led to the policy changes. Polity – is understood mainly as a legal and institutional setting – stands for a stable environment in which politics influences policy outcomes. The above understanding of the variables' interaction suggests that the article is mainly oriented towards policy analysis. However, because policy outcomes are fully dependent on the remaining two domains equal space is dedicated to all three domains.

There are two principal research questions: 1) *How the response of the EU in the area of health and healthcare might be interpreted in the context of Europeanisation?* 2) *What were the key differences in Europeanisation in the area of health and healthcare between the first and second wave?* To answer these principal questions the following analysis will focus on placing changes at the EU level within the context of Europeanisation. Research will help to provide a complex picture about legal margins for the competences of the EU in the area of health, put the fight against Covid-19 in the context of existing policy measures and provide an overview on the activities of the

EU institutions regarding this issue, including policy proposals.

The research design also determined the structure of the article which is divided into four parts. The first part introduces the Europeanisation concept. Due to the great variability of the concept and limited space in this article only the most important parts and usable concepts which are later applied are introduced. The second part is dedicated to the domain of politics where special emphasis will be put on the role of European Council and European Commission. The third part will deal with policy outcomes at the EU level and the individual fourth part will focus on polity – changes in the legal and institutional aspects of the EU.

The literature on EU activities over Covid-19 is not rich, as the topic is novel. However, it might be expected that new articles will appear soon, using various perspectives employing various theories (notably the application of the new institutionalism, constructivist approaches, liberal intergovernmentalism or even post-modernist approaches might be very fruitful). The article uses the concept of Europeanisation which has been well known in EU studies for more than two decades. Hopefully, this article will contribute to a better understanding of the EU, its reactions and development, and will also highlight the usability and functionality of the Europeanisation concept which is increasingly popular among scholars. Moreover, this study, with its exploratory character, may provide a certain correction of the EUs image, which is increasingly depicted as too bureaucratic, passive, “ossified” or even “evildoing” from the populist and illiberal positions.

THE CONCEPT OF EUROPEANISATION

Europeanisation is a well-established concept within European studies. For this reason this part is not dedicated to a full exploration of the concept but rather to the introduction of basic parts of the concepts which will be later used as a framework for analysis. However those who are interested in other aspects of the concepts are advised to read the “classical works” by people who greatly contributed to the development of Europeanisation within European studies [Ladrech 2004: 69; Bulmer & Burch 1998: 602; Börzel 1999: 574; Buller & Gamble 2002: 17; Risse & Cowles & Caparoso 2001: 3; Radaelli 2004: 5; Ladrech 2010: 2; and many others]. After almost three decades of usage of the term Europeanisation in the areas of European studies there are probably hundreds of significantly varying definitions. Despite that there is no universally acknowledged definition they all have one aspect in common as they all deal with the process of change which leads to the involvement or inclusion of some European element. The process of change implies that there are at least two states: the original state with no or a lesser degree of Europeanisation and subsequent state where a stronger European element is present. The EU or Europe is playing some part in this change as it might be the actor or a subject. However, the logics behind Europeanisation vary.

It was Johan P. Olsen who distinguished between five types of different logic. The

first, Europeanisation might be understood as an ongoing process of EU enlargement and change in the external boundaries of the EU. Second, a different understanding of the logic is to view Europeanisation as the development of institutions at the EU level. This logic is also useful for this article as, from the perspective of social institutionalism, a policy development to fight Covid-19 fits in. Third, Europeanisation might be considered as an opposite process when the EU agenda penetrates national and sub-national levels of governance and, as a result, the EU norm becomes part of the national legal order. This understanding is also applicable for this article as decision-making at the EU level regarding Covid-19 may have further implications for member states when adopting some policy measures. The fourth logic mentioned by Olsen is export of the EU norms and forms of political organisation beyond EU borders. Thus, it is very similar to the “EU enlargement logic” but focuses on softer tools than employed in direct accession talks and adaptation to *Acquis Communautaire*. Lastly, Olsen mentions Europeanisation as the synonymous construction of the EU unification project [Olsen 2002: 923-924]. As mentioned above, this article understands Europeanisation predominantly as the second and third type of logic summarized by Olsen which is to a certain degree limiting.

These limits lie in restricting Europeanisation on two levels: between a state level and the level of the EU, without relation to the external dimension of the EU (the first and fourth logic) or the more general context (the fifth logic). However, to understand Europeanisation as a development of institutions (including policies) at the EU level or the penetration of the EU agenda (including processes and values) is not mutually exclusive as cooperation between states may lead to the development of the EU level and then subsequently have implications for member states. In this sense Europeanisation may be understood as an interactive two-way process. This approach is summarised in the definition of Claudio Radaelli as follows: “Europeanisation consists of processes of a) construction, b) diffusion and c) institutionalisation of formal and informal rules, procedures, policy paradigms, styles, “ways of doing things” and shared beliefs and norms which are first defined and consolidated in the EU policy process and then incorporated in the logic of domestic (national and sub-national) discourse, political structures and public policies” [Radaelli 2004: 5]. This is also the case of the fight against Covid-19 where cooperation resulted in policy measures adapted by EU institutions with subsequent implications for the member states. The following chapters will explore and analyse this process. Moreover, there are other theoretical tools which might improve the framework.

Simon Bulmer in his chapter developed Europeanisation in the context of institutionalism which might enrich this concept with new aspects [Bulmer 2008: 51]. For example rational choice institutionalism may highlight an emphasis on decision-making and the role of rationality as the main driver for Europeanisation. Similarly, historical institutionalism offers a focus on time, timing and tempo. With the employment of historical institutionalism the rationale of Europeanisation may be explained in rela-

tion to a historical context, the issue of timing and factors resulting in a different tempo. This is also very applicable in the case of Covid-19. The unprecedented and fast development of measures within health policy would not have been possible without the pandemic and the urgent nature of the crisis. Lastly, sociological institutionalism allows us to analyse Europeanisation in the context of culture, ideas and attitudes and switch from the logic of consequences (rational institutionalism) to the logic of appropriateness, which is also close to social constructivism.

Europeanisation led to the changes in politics, policy and polity as it influences the interests and behaviour of political actors and the results of the policy-making process which ought to be implemented and which have implications for legal and institutional settings in which the processes took place. All three domains were influenced by the agenda of the pandemic and will be explored in further parts by employing the framework designed above.

EUROPEANISATION OF POLITY

The Lisbon treaty placed protection and the improvement of human health among supporting competences (Article 6 TFEU) where “the EU can only intervene to support, coordinate or complement the action of EU countries. Legally binding EU acts must not require the harmonisation of EU countries’ laws or regulations”. However, common safety concerns in public health matters for the aspects defined in the TFEU may fall also under shared competences under Article 4(k). The above short demarcation of competences has been further limited within title XIV of the SFEU which is fully dedicated to public health. The limits might be visible in three domains: 1) the areas of competence; 2) actors and procedural practices; and 3) restrictions on implementation.

The TFEU stresses that the Union shall direct its complementary activities towards the improvement of public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Notably such actions shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, including health information and education, and monitoring, early warning and combating serious cross-border threats to health (see article 168(1)). The reference to cross-border threats to health is applicable also to Covid-19 disease. Moreover, the Union shall also explicitly complement member states in reducing drugs-related health damage, including information and prevention.

Regarding procedural practices, the TFEU limits the outputs of EU activities at “informing”, “educating”, “monitoring” and “early warning” while harder competence – “fighting” or “encourage competence” is directed in the area of cross-border cooperation in order to improve the quality of services. The TFEU also stresses the obligation for member states activities and policies in the above-mentioned areas and that the EU shall act in improving coordination among member states. This coordination

support may involve the establishment of guidelines and indicators, the -exchange of best practices and the establishment of mechanisms for long-term monitoring and evaluation. The TFEU clearly states that in these areas the European Parliament and Council acts in accordance with the ordinary legislative procedure involving obligatory consultation of the Economic and Social Committee and the Committee of Regions. There are also limits in the area of implementation where several “checks” demonstrate the sovereignty of member states in the area of health. For example, paragraph 7 of the article 168 stresses that: “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.” In other words, the management of health services and medical care are fully in the hands of member states. Moreover, article 168(7) should be put into context together with article 114 SFEU. It provides that when a Member state raises a specific problem in the area of public health which was previously the subject of prior harmonisation, then it shall be brought to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council. This provision might be interpreted as a defensive stance of the European Commission, which is in any case required to act in a sense to ensure a high level of human health protection in defining EU policies and activities – which is a binding principle for all actors (see 168(1)).

Due to the legal status of health policy the pre-pandemic activities of the EU were mainly aimed at setting standards for health products or services or funding various health projects improving healthcare infrastructure. The EU also promoted research and conducted a project to improve public health, prevent diseases or address threats to health, mainly associated with lifestyle. The EU does not have an official health policy despite activities in many areas directly touching on health such as pharmaceuticals, consumer safety, regulation of chemicals or endocrine disruptors, cross-border healthcare (e. g. European insurance card), food safety, worker’s protection etc. Due to its lack of competence in this area, the EU focused on soft tools including various programmes¹, plans² and strategies³. These “soft tools” are mainly in the forms of Communications, Green Papers (e.g. Green Paper on Mental Health), White papers (e. g. Together for Health) or Recommendations from the Commission, Commission Reports, Council Conclusions or Council Resolutions. Rarely does the

¹ For example: Information programmes of the Community Tobacco Fund (2002); Programme of Community action in the field of public health (2003-2008); Second programme of Community action in the field of health (2008-2013); Health for Growth: EU health programme (2014-20).

² For example: Environment and Health Action Plan 2004-2010 or Action plan on Organ Donation and Transplantation (2009-2015).

³ For example: New Community health strategy (2000); Community strategy against antimicrobial resistance (2001); Environment and health strategy (2003); EU Drugs strategy (2000-2004); A new strategic approach to health for the EU (2008-2013); Economic crisis and healthcare: European health strategy; Nutrition, overweight and obesity – EU strategy, EU alcohol strategy and others.

Commission adopt decisions or other legally binding acts.⁴ This is, for example, the case for security and safety standards, e. g. in the areas of blood, tissues and organs where standards are set for blood establishments or human tissues and cells for transplantation.⁵

As expected the majority of measures are not legally binding and thus voluntary. However, legally binding measures are present in the areas requiring risk regulation and risk assessment, especially in the areas of technical norms and minimal standards aimed at occupational safety where the legitimacy of legally binding measures (e. g. directives and decisions) might be derived from the necessity to regulate the common market and ensure safe conditions for workers. Despite a lack of official EU health policy, various strategies and plans support the view of the EU being a very influential normative actor. Nonetheless, EU institutions also play a very real role in health as there are at least two EU agencies in the area of health policy which are supportive to member states on health issues and significantly intervenes in the health policy of the member states due to its expert capacity or regulatory powers. Both agencies – the European Medicines Agency (EMA) and the European Centre for Disease prevention & Control (ECDC) – played an important role in the fight against Covid-19 and might be considered as important agents of Europeanisation. The EMA almost immediately adopted several measures aimed at fighting disease. Regarding a noticeable institutional adaptation is the establishment of the EMA pandemic Task Force aimed at quick and coordinated action on the development, authorisation and safety monitoring of the treatments and vaccines intended to treat and prevent Covid-19 [European Medicines Agency 2020a]. The EMA also established a Covid-19 Steering Group aimed at rapid response to evolving scientific and regulatory challenges [European Medicines Agency 2020b]. The ECDC supplied the member states and institutions with data regarding risk assessment on Covid-19, situation updates and weekly maps in support of the Council Recommendation on a coordinated approach to the restriction of free movement in response to the Covid-19 pandemic [European Commission 2020a]. Apart from the agencies, the Joint European Research Centre (JRC) also contributed to the management of the crisis by the development of the new control material which helped to prevent coronavirus test failures [European Commission 2020b]. In other words, the JRC provided the benchmark for analytical laboratories to deliver accurate results ensuring that the methods used are able to

⁴ A good example might be acts establishing EU agencies or directives focusing on worker's protection such as Directive 2012/11/EU of the European Parliament and of the Council of 19 April 2012 amending Directive 2004/40/EC on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) or Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

⁵ Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

detect the virus. In this sense the European Commission also published guidelines to ensure reliable testing, which were part of the European Roadmap towards lifting coronavirus containment measures. By providing testing methodologies the European Commission contributed to the sharing of a best practice [European Commission 2020c].

The pandemic also influenced the approach of the citizens. Approximately 69 % of EU citizens agree that the EU should have more competences to deal with crisis such as the Coronavirus pandemic. However, the rates significantly vary from big supporters to that idea in Portugal (87 %), Ireland (81 %), Romania (79 %), Bulgaria (78 %), Italy (77 %), Greece (77 %) and Spain (76 %) to countries with the lowest support such as the Czech Republic (43 %), Sweden (48 %), Croatia (51 %) or Austria (55 %) [European Parliament 2020a: 4-15]. Despite clear answers it is questionable whether people know about the scope of the EU competences and whether they rely on truthful information, despite the majority (74 %) having answered that they have heard, seen or read about measures or actions taken by the EU. Despite the interest of citizens, it seems that Covid-19 has not led to significant changes in the EU competences, institutional or legal setting of the EU, except a minor strengthening of the mandate for the EMA and ECDC which will be discussed below. As expected, the pandemic entered the agenda of all institutions which became platforms for the management of the crisis.

EUROPEANISATION OF POLITICS

The first case of confirmed Covid-19 infection in Europe was on 24th of January 2020 in France. However, EU institutions had already reacted before that date. At the beginning of January the European Commission (Directorate General for Health and Safety – DG SANTE) opened an alert notification on the Early Warning Response System (EWRS) where some of the members states already shared information about the spread of the disease. On 17th of January – a week before the first case in the EU, there was the first meeting of the Health Security Committee (HSC) which met four times by the end of the month [European Commission 2020d]. Soon the HSC became an important meeting platform bringing together representatives of member states and important agencies or organisations including the EMA, ECDC or WHO which debated first policy responses, which are analysed in the following section.

The spread of coronavirus was dealt with by all EU institutions and was the most important issue on the political agenda. In 2020 there were 68 ministerial meetings in all 10 configurations of the Council of Ministers, whilst in addition since March, Ministers of Health were in daily contact. However, the main input was provided by the European Council. In 2020 13 meetings of the European Council took place within 21 days, including 8 video conferences and two regular meetings between 15th and 16th of October and 10th and 11th December. The Covid agenda was dealt with at 10 meetings of the European Council which took place from March 2020. Next to this

intergovernmental institution, Covid was also dealt with at 9 international summits (e.g. EU-Western Balkans, EU-Japan, EU-China), 2 ministerial meetings of the European Economic Area and 9 meetings of the Eurogroup. It is out of the scope of this article to provide the detailed positions of the countries. Nonetheless, it is possible to reveal the interaction between the European Council and the European Commission whose president Ursula von der Leyen participated in all sessions.

The first extraordinary meeting of the European Council in February was still dominated by the EU Multiannual Financial Framework for the years 2021-2027 which would be the normal priority. However, Covid-19 soon entered the agenda and, at the March meeting, the crisis was addressed. The meeting had high level participation including the President of the Commission, and the High Representative, the meeting was accompanied by the president of the European Central Bank and President of the Eurogroup. States agreed that health ministers should be in contact to discuss issues on a daily basis. Charles Michel summarised the priorities of the Council including 1) to develop measures to limit the spread of virus, 2) ensuring medical equipment, 3) stimulate research support aimed at the development of a vaccine and 4) dealing with the socio-economic effects of the virus. The European Commission was entrusted to conduct an analysis of needs and submit proposals for how to avoid a shortage of medical equipment [European Council 2020a]. However, in some regards the European Commission envisaged the intentions of the Member States and acted in advance. Tasks given to the Commission are summarised in Table 1 which provides an insight into the scope of activities requested. It is very interesting to compare policy initiatives by the European Commission which might help to understand the degree by which the European Commission acted alone and the degree by which the Commission reacted to the requests of the member states.

Table 1: Commission Activities Requested or Supported by the European Council

Date	Activities Requested or Supported
10.3.2020 Video Conference	<p>Stressed the need for a joint European approach and a close coordination with the EC.</p> <p>EC will closely monitor economic developments in the EU and take all necessary initiatives.</p>
17. 3. 2020 Video Conference	<p>Endorsed guidelines proposed by the EC on border management.</p> <p>Welcomed the decision taken by the EC to adopt a prior authorisation for the export of medical equipment.</p> <p>Supported the EC effort to (1) engage with the industry; (2) to run joint public procurements that had been recently launched and those which were to be shortly finalised to provide sufficient protective equipment; (3) and the purchase of protective equipment through the Civil Protection Framework.</p> <p>Supported the various initiatives taken by the EC in the areas of the Single Market, such as the adaptation of the State Aid rules, and the use of the flexibilities provided for in the Stability and Growth Pact and the recourse to the EU budget.</p>

26. 3. 2020 Video Confer- ence	<p>Leaders called on the EC to continue and accelerate its efforts to help in this respect (fight against Covid-19).</p> <p>Leaders asked the EC to explore ways to speed up procedures concerning joint procurement initiatives for personal protective equipment, ventilators and testing supplies.</p> <p>The EC will increase the initial budget for the strategic rescEU stockpile of medical equipment, including for intensive care, and vaccines and therapeutics.</p> <p>Leaders welcomed the initiatives taken by the EC, the European Innovation Council and the European Investment Bank (EIB) Group to provide financial support for the clinical and public health response to the Covid-19 disease.</p> <p>The EC Temporary Framework for state aid measures to support the economy in the current Covid-19 outbreak constitutes a major step forward.</p> <p>Leaders welcomed the EC guidelines on the screening of foreign direct investment.</p> <p>The EC will put forward an addendum to the border management guidelines to facilitate transit arrangements for repatriated EU citizens.</p>
23. 4. 2020 Video Confer- ence	<p>We have therefore tasked the Commission to analyse the exact needs and to urgently come up with a proposal that is commensurate with the challenge we are facing (unprecedented economic crisis).</p> <p>The EC proposal should clarify the link with the MFF, which in any event will need to be adjusted to deal with the current crisis and its aftermath.</p>
19. 6. Video Conference	Debates with the EC on MFF and Recovery Fund.
17.-21. 7. 2020 Special Meeting	Approval of Next Generation EU, Recovery Fund and MFF.
15.-16. 10. 2020 Regular Meeting	It calls on the Council, the EC and the Member States to continue the overall coordination effort based on the best available science, notably regarding quarantine regulations, cross-border contact tracing, testing strategies, the joint assessment of testing methods, the mutual recognition of tests, and the temporary restriction on non-essential travel into the EU.
29. 10. 2020 Video Confer- ence	<p>Leaders will work on the basis of the EC recommendation on testing strategies presented on 28 October.</p> <p>On tracing, EU leaders discussed the initiative on interoperability between apps tabled by the EC and work on a common passenger locator form, which would likewise facilitate tracing.</p>

19. 11. 2020 Video Confer- ence	We welcome that Member States and the EC have already finalised sev- eral Advance Purchase Agreements.
10.-11.12. 2020 Regular Meeting	The European Council welcomes the recent positive announcements on the development of effective vaccines against Covid-19 and the conclu- sion of advance purchase agreements by the EC. Invites the EC to present a proposal for a Council recommendation on a common framework for rapid antigen tests and for the mutual recogni- tion of test results.

Source: Author, based on Council Conclusions and Remarks by President Charles Michel

From Table 1 it is evident that the Commission received a broad political mandate to manage the Covid-19 crisis. Already on 10th March 2020 there was a mandate to “take all necessary initiatives”. In the following months, the Commission functioned as the implementor of the will of the European Council, utilised its expert role (with the great contribution of advisory experts) and acted as “the engine of integration”. The efforts of the Commission were directed by “invitations” to submit proposals which might be associated with the will of member states to delegate responsibility over solutions to the Commission and utilisation of its expert potential. Nonetheless, the Commission used an inclusive approach to enhance an objective attitude and also consulted external experts.

At the beginning of March Ursula von der Leyen established at the political level a “Coronavirus Response Team” with the aim of covering various areas (or dimensions) of the pandemic, including medical, economic, transport etc. The new Coronavirus Response Team was based on three pillars: the first medical pillar (areas of prevention, procurement, foresight and relief information); the second pillar based on mobility involving transport and Schengen-related issues; and the third pillar – aimed at the economy with reference to tourism, transport, trade etc. Ursula von der Leyen put individual Commissioners in charge including Janez Lenarčič (in charge of crisis management), Stella Kyriakides (health issues), Ylva Johansson (border issues), Adina Vălean (mobility) and Paolo Gentiloni (macroeconomic aspects) [European Commission 2020e]. It is important to note that the European Commission was seeking advice for its political steps including new legislation.

On 17th March 2020, a new group of experts was established to advise the European Commission. The so called “Commission’s Advisory Panel on Covid-19” had quite a broad mandate to cover Covid-19 related issues and to complement and capitalise on the work of the ECDC. The group was composed of 12 experts: 9 national experts⁶ type A (Individual expert appointed in his/her capacity) and 3 type E observing experts (Other public entity) representing the Emergency Response Coordination Centre, the ECDC and the EMA. National experts were recognised authorities, mainly professors with research experience, some also with political experience. Among them there were 3 epidemiologists, 3 virologists, 1 specialist on microbiology, a vet

⁶ Representing France, Germany, Spain, Denmark, Germany, Italy, Netherlands, Hungary and Belgium.

doctor and a former Minister of Health. The expert group met on average ever three weeks with varying intensity. For example, there were six meetings in March, but no meetings in June, August or September, which probably reflects the development of the intensity of the pandemics. In mid-November 2020 there was the first meeting of the Covid-19 national scientific advice platform, whose aim was to ensure and facilitate more co-ordinated scientific advice on health measures in the EU. It was a platform for peer exchange and coordination among scientific advisors to national governors which also complemented the President's Covid-19 advisory panel and the work of the ECDC. Moreover, it also complemented the advisory panel created by the European Commission in March 2020. By the end of 2020, there were three meetings (13th November, 20th November and 3rd December) [European Commission 2020f].

On many occasions the European Commission acted in its own capacity including drafts of the new legislation or amending existing ones. For example, at the beginning of April the European Commission proposed to activate the Emergency Support Instrument which basically meant providing direct help to the healthcare sector from the EU budget. Within 12 days, on 14th April 2020, the Council approved a Euro 2,7 billion Instrument. Via the Instrument, the European Commission funded the purchase of 10 million protective masks with the first batch (1,5 million) arriving at the beginning of May and distributed in 17 member states [European Commission 2020g]. States were invited to apply for funding transport operations via the Emergency Support Instrument to transport goods, medical teams or patients. One of the pilot operations was the delivery of over half a million protective masks to Bulgaria [European Commission 2020h]. Later in 2020 the instrument was used to finance the purchase of 20 million rapid antigen tests from Abbott and Roche companies, which will be available from early 2021 to all member states [European Commission 2020i]. At the end of April the European Parliament and the Council adopted amendments to the Medical Devices Regulation guaranteeing patient health and safety and the availability of medical devices.⁷ However, directives and decisions were rarely used as management tools. The European Commission frequently relied on guidelines (issued as communications) and recommendations: they contributed to the sharing of good practice and provided strategies. For example on 16th of June the European Commission published an EU vaccines strategy, to stimulate the development, manufacture and deployment of vaccines across the EU. It is interesting that the Commission talked about a timeframe between 12 and 18 months to develop safe and available vaccines [European Commission 2020j]. Retrospectively, the frame was very precise and matched reality as an effective vaccine was approved at the end of 2020 and distributed in December 2020. In July, the Commission presented immediate short-term measures for strengthening EU health preparedness in the case of future Covid-19 outbreaks where derived “lessons learned” were presented, including a plan

⁷ Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (Text with EEA relevance)

of actions to be taken [European Commission 2020k.] In mid-October, it published another communication aimed at national vaccination strategies including recommendations to consider for priority groups and assured states that the vaccine would be available for all states at the same time [European Commission 2020l]. When the situation worsened the Commission presented additional actions aimed at prevention and an effective response, especially in the areas of testing, contact tracing and preparation for vaccination campaigns [European Commission 2020o]. One of the recommendations issued was aimed at the use of antigen tests [European Commission 2020p]. Antigen tests were also the subject of harmonisation as the Commission adopted a proposal establishing a common framework for the use, validation and mutual recognition of rapid antigen tests [European Commission 2020q]. Before Christmas, the Commission adopted a strategy for the sustainable management of the pandemic during the winter period and announced that further guidance would follow [European Commission 2020r].

During the crisis, the Commission used its politico-administrative hybridity and this active approach was soon transferred into an ambitious plan. On 11th November, the European Commission published a proposal to create a “European Health Union”. It was primarily a set of actions to enhance the health security framework, to enhance EU crisis preparedness and the response role of the relevant EU agencies. The Commission proposed to declare emergency situations at an EU level, take risk management decisions at an EU level, harmonise EU, national and regional preparedness plans, conduct regular audit and stress-tests preparedness plans and to monitor supply of medicine and mitigate shortages. In relation to these aims the ECDC and EMA received a stronger mandate “to monitor” or “to coordinate” the relevant activities ensuring the required outputs. Moreover, the Commission opened a debate to create a new authority which would work on EU health emergency preparedness and response – an authority which would support the capacity to respond to cross-border chemical, biological and nuclear threats, epidemics, emerging diseases and pandemic influenza. It is important to note that both proposals⁸ had a legal basis consistent with the existing regulations (Article 168 TFEU), they were in line with subsidiarity, proportionality and did not supersede competences of member states, despite being developed in the area of non-exclusive competences. To sum up, despite the ambitious term “European Health Union” the content of the notion is of a functional and relatively specific nature, rather than a political project with ill-defined contours. However, as expected, the European Commission used the crisis to improve the specification of competences and extend the supranational level of the EU governance, which was fully in line with the nature of the threat. The following section explores the development of measures introduced in all policy areas relevant to healthcare.

⁸ Proposal for a Regulation of The European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control and 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.

EUROPEANISATION OF POLICY

During the pandemic there were two categories of policy measures. First, there were instant short-term measures at the beginning of the pandemic (such as the activation of the EU Civil Protection mechanism to repatriate EU citizens and provide consular support to EU citizens in Wuhan) [European Commission 2020s]. Activation of the EU Civil Protection Mechanism allowed the sending of EU medical teams to areas. Doctors and nurses from Romania and Norway were working in Milan and Bergamo to reduce pressures on Italian hospitals. The mechanism was often used for the transfer of aid. For example, when the situation in Italy was severe [La Foresta 2020, 73], Austria sent 3 thousand litres of disinfectant and Slovakia provided gloves [European Commission 2020t]. The mechanism was coordinated and co-financed by the European Commission. The EU Civil Protection mechanism was linked to material aid. In the second half of March the Commission decided to create a RescEU stockpile – a strategic stockpile of medical equipment including ventilators, protective masks and later this included vaccines, therapeutics and laboratory supplies. RescEU was put under the authority of the Emergency Response Coordination Centre while supplies would be hosted by member states with 90 % financial coverage by the European Commission [European Commission 2020u]. Among the first countries to host RescEU equipment were Germany and Romania. Four other member states soon followed: Denmark, Hungary, Greece and Sweden. In May, 330 thousand FFP2 masks from the RescEU reserves were transferred to Italy, Spain and Croatia [European Commission 2020v]. Later aid was also delivered to Montenegro and North Macedonia [European Commission 2020w]. In October 30 RescEU ventilators arrived in Czechia [European Commission 2020x].

Second, there were long-term policy measures which had an impact over a longer time horizon. Among many, on 31st January the EU mobilised the first 10 million Euro for the area of research and innovation under the Horizon 2020 scheme to support research of the novel coronavirus. As a result, the Commission launched an emergency call to stimulate new projects in this area [Single Electronic Data Exchange Area 2020]. It is important to note that Research was one of the key policy outcomes during Covid-19 with increasing significance over time. That is why by March the European Commission had scaled up the emergency call. At the end of March there were 18 funded projects worth Euro 48,5 million from Horizon 2020 which employed 140 research teams [European Commission 2020y]. However, it is important to mention that the European Commission also financially supported individual companies. For example, during March the EC offered up to Euro 80 million to CureVac – a German vaccine developer [European Commission 2020z]. As of July, a Euro 75 million loan agreement was signed to stimulate development.

Later, during May 2020, in total 8 large scale research projects (5 focusing on diagnostics and 3 on treatment) were selected for further funding via Innovative Medicines Initiative (a public-private partnership). Moreover, a new call for expression of inter-

est was opened up and Horizon 2020 was boosted by an additional Euro 122 million [European Commission 2020i]. Research was also boosted in June when another 166 million were provided to 36 companies via the European Innovation Council Accelerator Pilot and to another 36 companies via Horizon 2020 [European Commission 2020aa]. However, in many cases the companies were cross financed from various public and private resources. For example, an immunotherapy company BioNTech Se received Euro 100 billion funding via the European Investment Bank, backed by Horizon2020, InnovFin and the European Fund for Strategic Investments [European Commission 2020ab]. Another boost came in August, when the Commission supported another 23 research projects including 347 research teams with Euro 128 million under Horizon 2020. Research was one of the most important pillars of the EU response: next to the finance of the projects and their own contribution through the Joint Research Centre, the European Commission supported science in information exchange. In mid-April 2020 the European Commission launched the European Covid-19 Data Platform to support research, networking and the sharing of available data [Covid-19 Data Portal 2020]. At the end of 2020 there were over 260 thousand publications, 174 000 records on viral sequences, 5 400 records on host sequences, 2700 records on biochemistry regarding Covid-19 pathways, interactions, complexes, targets or compounds and a lot of other data.

However, the most important pillar was the support of the economy. Already on 10th March 2020 the Commission received a mandate from the health ministers to strengthen its response to the Coronavirus. As a result the “Corona Investment Initiative” was launched. The initiative was worth Euro 60 billion of unused money dedicated to the cohesion policy. The sum was aimed at helping the health care systems, small and medium size enterprises, labour markets and other parts of the economy [European Commission 2020ac]. Later on, almost all economic tools including structural funds, the multiannual financial framework and other measures including the Recovery Fund were targeted in the fight against Covid-19. It is out of the scope of this article to deal with the economic dimension which is related to EU trade policy, the common market and its regulatory aspects or for support for individual economic areas including agriculture, tourism, transport, small and medium sized enterprises etc.

For example, when states started to apply restrictive measures on their borders the European Commission started to worry about free movement. That is why guidelines for member states were published to ensure free movement of goods, services and persons. Guidelines distinguished between border control checks and health checks and promoted the rule that entry of the ill should not be refused but access to healthcare should be provided [European Commission 2020ad]. In late March 2020, the European Commission published guidelines to ensure free movement of workers in critical occupations including health and associate professionals, child and elderly care workers, scientists in health-related industries or technicians able to in-

stall medical devices [European Commission 2020ae]. The approach of the European Commission resulted at the beginning of April in the issuing of practical guidelines to support cross-border healthcare cooperation with the aim of transferring patients from overburdened hospitals or qualified personnel across borders [European Commission 2020af].

To ensure sufficient numbers of personal protective equipment, at the best price, the EU Commission initiated joint procurements. Producers of protective equipment were asked to make offers. Within three weeks producers had to submit offers covering the needs of the EU. Moreover, in mid-March 2020, the European Commission also adopted restrictive measures and exporters of personal protective equipment had to ask for export authorisation approved by member states [Official Journal of the European Union 2020]. While exports were restricted, imports of medical equipment was eased when the Commission temporarily waived custom duties and VAT [European Commission 2020ag]. When the situation developed and medical companies were close to successfully passing all of the requirements for introducing a vaccine, the Commission also decided to exempt the vaccine from VAT.

A very important element was the stimulation of the development and production of new medical supplies and their placement on the European market while ensuring high safety standards. For that reason, the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation made standards freely available to all interested parties. As a result in total 11 standards (e. g. respiratory protective devices, medical face masks, personal eye-protection, protective and surgical clothing and medical gloves) were provided and producers were not required to purchase those standards and use them in accordance with intellectual property rights [European Commission 2020ah].

Along with protective equipment, the Commission also worried about the availability of medicines. For that purpose it issued guidelines for member states how to optimize supply and ensure the availability of medicines [European Commission 2020ai]. Some medicines got special attention. For example at the end of July the Commission signed a contract with the company Gilead to gain treatment doses of Remdesivir (Veklury). It was the first medicine authorised at EU level for the treatment of Covid-19, and the European Commission secured deliveries starting from early August [European Commission 2020aj]. Medication and treatment was of immediate importance, however, from a longer perspective, it was necessary to focus on a vaccine.

The European Commission was in negotiation with several companies to ensure sufficient quantity of vaccine. One of the first negotiations took place with Sanofi-GSK to buy 300 million doses on behalf of all EU Member states [European Commission 2020aj]. Positive talks were also conducted with companies Johnson & Johnson, Moderna, CureVac and AstraZeneca to buy potential vaccine. On 27 August, the European Commission concluded its first contract with AstraZeneca to buy 300

million doses of vaccine available to the member states, distributed on a population based pro-rata basis. The sixth company which concluded exploratory talks with the Commission was BioNTech-Pfizer. On 18th September, 3 weeks after the contact with AstraZeneca, the European Commission signed a second contract to buy 300 million doses of the Sanofi-GSK vaccine [European Commission 2020al]. In about another three weeks, on 8th October 2020 the European Commission concluded its third contract for 200 million doses of vaccine with Janssen Pharmaceutica NV – a company from the Johnson & Johnson family [European Commission 2020am]. The fourth contract for 200 million doses was approved on 11th November with companies BioNTech and Pfizer [European Commission 2020an]. The fifth contract was concluded on 17th November with the CureVac company for 225 million doses [European Commission 2020ao]. The Commission signed the sixth contract on 25th December with the Moderna company for an initial purchase of 80 million doses [European Commission 2020ap]. After all six contracts were signed, the European Commission opened new talks with a seventh potential company – Novavax – and envisaged a contract to purchase another 100 million doses [European Commission 2020aq]. However, the virtual race for vaccine was won three days before Christmas by BioNTech and Pfizer, who succeeded in getting authorisation for conditional marketing.

The European Commission also joined the Covid-19 Vaccine Global Access Facility (COVAX) with the aim to ensure equitable access to Covid-19 vaccines for all who need them and pledged a contribution of Euro 400 million in guarantees [European Commission 2020ar]. The Commission was also active in collaboration with WHO. In September, the first High Level Facilitation Council took place composed of governmental and non-governmental actors (BMGF and Wellcome Trust) which served as a political umbrella for roughly 200 vaccine candidates, 1700 clinical trials and 80 diagnostics. During November 2020, the EU's contribution to the COVAX Facility was increased by Euro 100 million [European Commission 2020as].

Some of the policy measures had an impact on third countries. For example at the beginning of February, EU member states mobilised and delivered in total 12 tons of protective equipment to China. The response of the states were coordinated via the EU's Emergency Response Coordination Centre [European Commission 2020at]. As of the end of February, the number of protective devices sent to China doubled [European Commission 2020au]. However, soon after the first deliveries to China the European Commission announced a new aid package to boost global preparedness, prevention and containment of the coronavirus. The package was worth Euro 232 million. Half of the sum was allocated to the WHO and another 90 million into the Innovative Initiative – a partnership initiative involving the pharmaceutical industry. However, the remaining 15 million were sent to provide help in Africa and 3 million for the repatriation of EU citizens [European Commission 2020av]. Special emphasis was put on the Eastern dimension of the EU: the European Commission relocated Euro 140 million for the Eastern Neighbourhood countries to cover immediate needs

and another 38 million to cover the health emergency in the Western Balkans [European Commission 2020aw]. Later at the end of April 2020 the EU announced it was providing financial support of Euro 3,3 billion to the Western Balkans as a part of special package [European Commission 2020ax]. Support of Euro 105,5 million was provided to the Horn of Africa [European Commission 2020i]. As well as aid to other regions (for example considerable help also went to ASEAN), help was also pledged to initiatives. For example, in June the European Commission pledged Euro 300 million to the Gavi – Vaccination Alliance which will, in the period 2021 and 2025, help with the vaccination of over 300 million children around the world [European Commission 2020ay].

Another noteworthy activity was the launch of the Coronavirus Global Response to help all around the World and a “pledging summit” organised by the European Commission which succeeded in generating Euro 6,15 billion to ensure access to tests, treatments and vaccines. All together the EU raised almost Euro 16 billion where the majority was provided by the member states, the Commission and the European Investment Bank [European Union 2020]. The Commission also established a humanitarian air-bridge to transfer humanitarian workers and emergency supplies all around the world (e.g. Afghanistan, Iraq, Yemen, Somalia, Haiti, Congo, Sudan, Central African Republic, Sao Tomé e Príncipe, Venezuela, Peru and many others) [European Commission 2020az]. The above-mentioned activities may be considered as the contribution by the EU to a relatively rare global solidarism [see Widłak 2020]. The above-mentioned response is a summary of the main EU activities which might be supported by a variety of others – less material or “soft” measures. For example, the Commission recommended steps and measures to develop mobile applications which might be used to deal with the pandemic [European Commission 2020aaa]. Such applications might include ones informing their users that they were in contact with a person who tested positive for Covid-19. A special emphasis was put on personal data protection which was the subject of the individual guidelines [European Commission 2020aab]. In October, the first results were delivered, and the EU wide system “Gateway” was put into operation integrating national applications including the German Corona-Warn-App, the Irish “Covid tracker” and the Italian “Immuni” [European Commission 2020ak]. Considerable activities were continuing online. The Coronavirus became a valuable topic for disinformation and hostile foreign propaganda, which in many cases switched from migration related conspiracies to the Covid-19 [Ižák 2020, 93]. The 2020 EUvsDisinfo database (a flagship of the European External Action Service’s East StratCom Task Force) recorded 693 instances of disinformation regarding coronavirus, most with clear anti-western and pro-Russian narrative [EUvsDisinfo 2020]. Disinformation slowly turned from blaming the West (USA, NATO) for the creation of the virus to supporting opposition against vaccination in the West and glorifying the Russian Sputnik V vaccine with the aim to alienate the western population against their governments and the EU. As pointed out by Ark-

adiusz Modrzejewski, the Covid-19 crisis is providing a unique opportunity to look at the value of truth “without any adjectives” [Modrzejewski 2020, 236], which has important implications for public life. Moreover, it is a unique opportunity to improve public policies.⁹

CONCLUSION

This article has considered the response of the EU towards the spread of Covid-19 in the context of Europeanisation. The main aim of the article was to discover what the EU response was in relation to the EU *polity*, *politics* and *policy*. After the introduction of the Europeanisation concept and the broader political and legal context, further analysis was aimed at providing answers to the two principal research questions: 1) *How the response of the EU in the area of health and healthcare might be interpreted in the context of Europeanisation?* 2) *What were the key differences in Europeanisation in the area of health and healthcare between the first and second wave?*

The response of the EU in the area of health and healthcare reflects its competences as defined in article 6 TFEU. However, due to the inter-sectoral nature of the pandemic the response of the EU varied. In the area of the single market the Commission acted more authoritatively, though nonetheless in line with the needs and expectations of member states which instructed the Commission via the European Council and various intergovernmental bodies including the Council of Ministers. The above analysis showed that most of the measures were in the form of recommendations and guidelines. Moreover, in many aspects, member states invited the Commission to prepare proposals and offer solutions. This might be put in the context of the Commission’s expert nature. In this regard some sort of top down Europeanisation might be observed.

The Covid crisis also resulted in a bottom-up Europeanisation, or some sort of Europeanisation development at the EU level without a transfer of competences. In the case of strengthening the mandate of the European Medicines Agency and the European Centre for Disease Prevention and Control, the Commission used the existing legal basis to clarify and extend the tasks of the agencies without intervening with the powers of member states. Similarly, the Commission used various expert advisory bodies, which were created for the purpose. Overall, the Commission utilised its role as a “politico-administrative” hybrid and motor of integration with proposing initiatives filling the gaps. This might be the case for RescEU or various measures aimed at better crisis management. Similarly to other crisis situations (economic or migration), the EU reacted with the development of institutions, tools and policies to deal with the crisis and fill the gaps by utilising a supranational form of cooperation. This cooperation became vital as it would hardly have been possible to secure best practices and ensure the availability of sufficient number of vaccines without the

⁹ A very interesting debate is present in Dyomkin, D. (2021), *Pandemic Lessons for Democracies: High Time To Provide Journalism as Essential Service with a Final Lifeline*. In *European Studies – The Review of European Law, Economics and Politics*, Vol. 8, No. 1, 2021.

help of the Commission. Despite the fact that daily management was carried out by the member states, EU institutions supplied leaders and decision-makers with the best information available.

There are several differences between the first and second wave or between the first and second half of the year with a hardly recognisable transition period. During the first period most of the activities focused on short term measures and immediate help in order to secure the return of citizens from abroad, provision of help via the activated EU Civil Protection Mechanism and providing initial funds to cover immediate costs caused by the outbreak of the pandemic. The EU worked to ensure the free movement of persons necessary for fighting the pandemic and avoid unnecessary restrictions introduced by member states, worked to secure protection devices by offering commercial stimulus (VAT and import reductions, export restriction, providing standards) and capacity development (RescEU).

In the long-term perspective the EU succeeded in stimulating research funding and later negotiated with prospective medical companies to ensure enough doses of vaccine were available at a reasonable price. In line with this progress, the EU provided guidelines and strategic recommendations for member states to prepare vaccination and ensure the availability of medicines. Because of the multi-sectoral impact of the pandemic, it was necessary to adopt a Next Generation EU package, Recovery fund and adapt the Multiannual Financial Framework. In the following years billions of Euros will be invested into the economies of member states to deal with the subsequent economic crisis caused by the virus. Due to the clear transboundary and multi-dimensional nature of the pandemics, the EU provided added value to national approaches by giving expert guidance, resources and the maximization of opportunities. However, despite the multi-dimensional impact of Covid-19, the agenda within health policy is just one segment. Treatment of heart attacks, strokes, cancer, obesity, the effects of tobacco and alcohol consumption, mental health and many other relevant policy areas were somehow lagging. On the other side, the fight against the Covid-19 pandemics clearly uncovered the potential and possibilities for deeper cooperation regarding medical supplies, vaccination strategies, cross-border care, health related research, emergency response and capacity building which might in the future lead to a comprehensive EU health policy. On 28 May 2020, the European Commission presented a new proposal for reinforcing the EU health programme for the period 2021-2027 called the “EU4Health Programme” [European Council 2020b]. It is expected that this new strengthened programme will result in a considerable four-fold increase in funding) and will strengthen the role of the EU to complement and support the health policy of the member states. It is no doubt that this strengthening would not happen without the common experience of Covid-19.

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