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WHAT IS THE ROLE OF THE EUROPEAN UNION IN THE COVID-19 PANDEMIC?

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Abstract: Whereas the heart of the purpose and activity of the European Union is concerned with economic harmonisation, its internal market, and the freedom of movement of people, goods, services, and capital, necessarily require public health measures. The EU is committed to both human rights and to "Health in All Policies". This paper considers how that agenda has been confronted by the COVID-19 pandemic. It considers how the EU Treaties limit the possible scope of that response. The paper considers responses in relation to freedom of movement, the work of the European Centre for Disease Prevention and Control, issues relating to the operation of the General Data Protection Regulation, and the Clinical Trials Directive

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and Medical Devices Directive. It concludes with a brief examination of the economic responses of the EU to the COVID-19 pandemic. An Appendix gives a brief introduction to EU (health) law and history.

Keywords: EU; COVID-19; Public Health; ECDC; GDPR

Introduction

The European Union (EU), with its central objective of creating an internal market, with free movement of people, goods, services and capital across the Member States' borders,[1] and, with its Treaty-based competence to bind its 27 Member States through legislation and coordinated soft-law responses,[2] is where one might expect to see robust, harmonised, collective action in the face of the current global COVID-19 pandemic. With its broader commitment to human rights, especially in the Charter of Fundamental Rights of the EU, one might expect to see measures to ensure equality of access to health care for all the EU citizens. Elements of the EU response to COVID-19 have worked well, particularly the European Centre for Disease Prevention and Control (ECDC) Early Warning and Response System (EWRS), with the ECDC alerting the Member States to the threat, on the basis of aggregated information.[3] The EU took measures to ensure the availability of medical equipment through the rescEU programme, within the EU Civil Protection Mechanism,[4] and measures to ensure the supply of medical equipment.[5] In February and March 2020, the EU response was limited, as the infection and death rates rose in the different Member States.

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1 Article 3(2) Treaty of European Union (TEU), and Article 26 Treaty on the Functioning of the European Union (TFEU).

2 TEU and TFEU

3 The European Early Warning and Response System EWRS opened an alert notification on January 9 2020 informing ECDC and all member countries; on January 28 the EU Civil Protection Mechanism was activated; this compares to the official notification of China to the WHO China Country Office on Dec 31on increased numbers of cases of pneumonia of unknown etiology; WHO reported on Jan 5 a disease outbreak news. See, https://www.ecdc.europa.eu/en/early-warning-and-response-system-ewrs; https://www.ecdc.europa.eu/en/covid-19/data-collection. Indeed, the EWRS worked so well, that (Brexit) UK wants to stay connected: https://www.theguardian.com/politics/2020/may/02/uk-seeks-access-to-eu-health-cooperation-in-light-of-coronavirus. (Each last visited 13 June 2020.)

4 https://ec.europa.eu/echo/what/civil-protection/resceu_en (last visited 13 June 2020.).

5 https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en#health-crisis-management (last visited 13 June 2020.).

The impact of COVID-19, so named by the World Health Organisation (WHO) on 11 February 2020, and characterised as a pandemic by the same on 11 March 2020,[6] has been relatively rapid; it emerged in China in late 2019 and spread globally in the early months of 2020. This virus and disease are part of a family of Severe Acute Respiratory Syndrome (SARS) that has long cast a global shadow and produced particular incidents for years.[7] The pandemic tested the preparedness of established policies and provision. This paper, written in the midst of the pandemic in Europe, considers elements of the preparedness of the 27 EU Member States in the collective, harmonising action of their Union. It addresses what is in place and answers why other things, one might expect to see, are not (yet) in place. It differs from the papers that explain the responses of individual nation States, since the Member States of the EU do not cede all their sovereignty to the EU and its political institutions; the EU is not a single, sovereign State. As public health and "*health in all policies and activities*" (HiAP) are key concepts in the EU and in its Treaties,[8] it is legitimate to ask - as many EU citizens may well do - where is the EU response in the COVID-19 pandemic?

The paper considers the place of health in the concept of the EU. The EU has limited legal competence in relation to health, which explains the limits on the response to the pandemic.[9] It evaluates where the EU has acted in relation to the pandemic. It examines freedom of movement, the ECDC and the regulatory regimes for the protection of personal data, clinical trials and medical devices. It relates these to the Charter on Fundamental Rights of the European Union,[10], in the face of the pandemic, rights to free movement, to access medicines and devices and to privacy. Rights to life and health care require an economic base and the final part of the paper briefly considers the EU's efforts to protect the future economic life of the Union.

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6 See, for example, World Health Organisation Regional Office for Europe, 'WHO announced COVID-19 outbreak a pandemic' (WHO: 12 March 2020) available via http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic (last visited 13 June 2020.).

7 Cheng, V. C., Lau, S. K., Woo, P. C., & Yuen, K. Y. (2007). Severe acute respiratory syndrome coronavirus as an agent of emerging and reemerging infection. Clinical microbiology reviews, 20(4), 660-694.

8 Articles 9 and 168(1) TFEU.

9 We include a short appendix on EU history and law, which may be useful to contextualise this first part of the paper.

10 See in particular Article 6(1) TEU.

Understanding the Mandate for (Public) Health in the EU

The EU is not equipped or legally competent to deliver frontline health care or to address systemic differences in health care delivery between its Member States. The EU pursues the Treaty-based duty to ensure "*Health in All Policies*". Whereas Article 168 creates EU competence in relation to public health responses, the responses are limited because, by Article 168(7), the Member States have retained sovereignty for the organisation and delivery of their national health systems:

> "*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.*"

This is in line with the right to health care, created in Article 35 of the Charter of Fundamental Rights of the European Union: "*Everyone has the right of access to preventive health care and the right to benefit from medical treatment* ***under the conditions established by national laws and practices****. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*" (emphasis added).

This means two important things, in relation to the EU response to the COVID-19 pandemic: the EU has no authority to centralise the response; and it has no infrastructure to centralise the response. The EU cannot command the Member States' healthcare professionals or infrastructure (such as doctors, nurses and hospitals) to produce a harmonised response. EU participation in relation to health is about facilitating cooperation and promoting health amongst the Member States.[11] Its focus is in soft-law measures, rather than in creating major legislation to create centralised healthcare provision.[12]

This is demonstrated in the legislation that relates to the availability of healthcare in relation to the exercise of freedom of movement within the

11 On the basis of Article 6(a) TFEU, the EU has a competence to perform actions to support, coordinate or supplement the action of the Member States, and the areas of such action shall at European level be 'protection and improvement of human health'. There are also several opportunities in Article 168(2) and 168(3) TFEU.

12 See, for example, European Commission, "Communication from the Commission. Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis" (2020/OJ C 111 I) 3.4.2020.

EU. Regulation (EC) No. 883/2004 which coordinates entitlement to social security benefits accrued in Member States, by citizens moving between Member States, enables citizens to gain emergency healthcare whenever they are temporarily staying in another Member State from that where they reside. Provided that a prior authorisation is granted by the competent institutions, Regulation (EC) No. 883/2004 also allows citizens to seek planned healthcare in another Member State, from the one in which they have accrued entitlement to the care where it cannot be provided in a timely manner.[13] Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, enables citizens to seek planned healthcare in Member States other than the one in which they have affiliation in the health system (namely where they have purchased their health insurance). The Directive makes this a matter of right for out-patient care and a rebuttable presumption of permission for in-patient care. For both the Regulation and the Directive, the care that is sought outside the Member State where one is linked by insurance contract can only be what one is entitled to by that insurance (it has to be in the basket of goods that you have purchased). It is subject to the broader issues of the restriction of free movement to ensure a "*lockdown*" and that is determined individually by each of the 27 Member States, as a matter of their sovereignty. These instruments also indicate that non-medical, social care is largely beyond the purview of the EU. This lack of decisive legal competence for the EU is particularly difficult in the face of human rights concerns. Older people and people with disabilities may be discriminated against by new Covid-19 intensive care guidelines, suggesting that their rights, as patients, may be at risk of violation.[14] One might have hoped that the EU would be a place to challenge these national policies.

Whereas the EU Treaties and policies have created soft-law mechanisms of guidelines and health promotions that operate to ensure a smooth functioning, freely moving citizenry in the general life of the EU, in the extraordinary emergency situation of this pandemic, the EU has very little authority or infrastructure to operate at the frontline of healthcare. This explains the scope of the response.

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13 Regulation (EC) 883/2004, Articles 19 and 20, respectively.

14 See, for example, https://blogs.bmj.com/medical-ethics/2020/03/26/dont-let-the-ethics-of-despair-infect-the-intensive-care-unit/; https://www.hja.net/press-releases/nice-amends-covid-19-critical-care-guideline-after-judicial-review-challenge/; http://www.edf-feph.org/newsroom/news/international-disability-alliance-urges-who-condemn-discrimination-treatment-covid19; https://theconversation.com/coronavirus-allocating-icu-beds-and-ventilators-based-on-age-is-discriminatory-136459 (each last visited 13 June 2020.).

The Immediate, Direct Response.

There are a number of direct measures that the EU has taken in response to the pandemic. One set relate to the freedom of movement, the other to the surveillance, control and prevention of the disease.

The Freedom of Movement

From March 2020, the EU put in place a number of measures concerning the modification of freedom of movement to respond to the Coronavirus and Covid-19. This was not about locking everything down and ensured the continued movement of goods, including Personal Protection Equipment (PPE), between the Member States. The continued possibility of movement of healthcare professionals between Member States to meet local needs is desirable.[15] The EU acted to repatriate citizens. However, non-essential travel was restricted, largely by the actions of the Member States.[16]

The freedom of movement of individuals is a challenge to their fundamental rights. Free movement of EU citizens is a right, under Article 45 of the Charter of Rights of the European Union. This is not an absolute right: under Article 52, Charter rights can be limited in their scope, proportionately, to meet "*the need to protect the rights and freedoms of others*". The temporary closure of external borders, in an acute international health crisis that has been declared by the respective international competent authority, does not necessarily constitute a serious conflict with fundamental rights, especially as the EU supported actively, and in collaboration with Member States, the repatriation of stranded citizens, both it's own (EU) as well as ex-pats. EU law allows the restriction of entry into the EU to respond to public health threats, linked to the International Health Regulations (IHR) definition of epidemic.[17] Signatories of the IHR[18] have agreed to the common criteria, process and procedures to keep

15 Free movement of professionals in relation to health is somewhat tempered by the Member State's residual right to ask about the content of the studies undertaken to achieve the professional qualifications in relation to healthcare. See Directive 2005/36/EC as amended by Directive 2013/55/EU. The response during the pandemic has been to encourage the acceleration of this process.

16 For the European Commission's timeline of its response, see https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response_en#borders-and-mobility (last visited 13 June 2020.).

17 See Reg. (EU) 2016/399, particularly Article 2(21); Directive 2004/38/EC, particularly Articles 1 and 29.

18 WHO, 2005. https://www.who.int/ihr/about/en/ (last visited 13 June 2020)

the consequences of the containment measures to the absolutely necessary limits. It is the nature of an "unknown" pathogen for which, in the early state of an outbreak, many mechanisms are unclear and precautions might be more rigid, than one would apply in the later stage, with better knowledge. The current reality of excess mortality is an indication that there was, and is, a severe health threat that falls under the IHR. Is this an unjustified infringement of individuals' rights? Were the measures limited to the absolutely unavoidable restrictions (being proportionate) or were they in excess? It is too early to answer this question comprehensively.

The temporary closure of *internal* borders is a different issue and would need to be seen against the EU's principal of free movement. The restriction of free movement of people is allowed under EU law,[19] but this is more complex. This is not the first time that some of the internal borders were closed and some preceding events had less plausible justifications. The same view applies regarding the IHR as the Member States are the signatories and have not delegated the health authority to the EU. Through the entire process, the EU has pressed Member States to allow cross-border workers to commute to their workplaces, to find solutions for seasonal workers and to allow the movement of goods - to keep the restrictions at the lower limit.

Another question is the consequences of individual Member States restricting cross-border movements for the EU cross-border mechanisms and regional cross-border collaborations. The decisions to close borders have overruled regional agreements on cross-border collaboration (such as, the joint hospital at the Spanish-French border; pooling inter-hospital-tranfer resources and use of intensive care units (ICUs) in the Aachen-Maastricht-Liege region; sharing infrastructure by communities on either side of the German-French border). Some of these cross-border agreements were especially intended to improve resilience of the regions in crisis situations but, in a real crisis, these agreements are not robust and the decisions relating to closure of borders (especially in

19 See Reg. (EU) 2016/399, particularly Article 2(21); Directive 2004/38/EC, particularly Articles 1 and 29. See DG Internal Policies, Policy Department C: Citizens' Rights and Constitutional Affairs. 2016 Obstacles to the right of free movement and residence for EU citizens and their families: Comparative Analysis PE 571.375 European Commission. http://publications.europa.eu/resource/cellar/29524abc-9ad1-11e6-868c-01aa75ed71a1.0001.03/DOC_1 (last visited 13 June 2020). It is worth noting that there is also a possibility to restrict the movement of goods (at the external or internal borders) to respond to public health threats under the TFEU, Article 36. It is clear that the right to freedom of movement is not an absolute right in EU law.

areas with cross-border arrangements) will have to be judged on the basis of the proportionality of the response to the risk. The same reflection will be required for the restriction of the right to move across borders to receive health care that is not provided in a timely manner (relative to the prognosis and condition of the patient) under Article 20 of Regulation 883/2004.

The European Centre for Disease Prevention and Control

The ECDC and EWRS are important parts of the EU response to the pandemic.[20] ECDC started operating in 2005.[21] It is an independent Centre, but it does not have the higher legal status of the European Medicines Agency or the European Food Safety Authority. The mandate for the ECDC is "*to enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease, the mission of the Centre shall be to identify, assess and communicate current and emerging threats to human health from communicable diseases*."[22] In terms of the current COVID-19 pandemic, it is important to see the scope of the work of the ECDC.

"*Within the field of its mission, the Centre shall:*[23]

(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

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20 See, generally, A. de Ruijter, EU Health Law & Policy. The Expansion of EU Power in Public Health and Health Care, Oxford: Oxford University Press 2019.

21 Regulation (EC) 851/2004. The work had started under the 1998 Decision 2119/98/EC of the European Parliament and the Council "setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, which requires timely scientific analysis in order for effective Community action to be undertaken." (Recital 3, 851/2004.)

22 Article 3(1), Regulation (EC) 851/2004.

23 Article 3(2), Regulation (EC) 851/2004.

> *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 de*velopment and implementation of joint actions."

Member States have obligations to provide information to the ECDC on relevant technical and scientific matters, information provided to "the Community network via the early warning and response network", and identify "recognised competent bodies and public health experts" who could contribute to the work of the ECDC.[24]

ECDC has duties in relation to the surveillance networks of the Member States' Competent Bodies, and the Network created by the EU in 1998. These extend to quality control, cataloguing activities, communicating results of analyses, and creating harmonised methodologies.[25] Article 5(3) is particularly telling about the nature of the ECDC:

> *"By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes."*

The ECDC provides "*independent scientific opinions, expert advice, data and information*"[26], the "*early warning and response system*" (EWRS),[27] and "*scientific and technical assistance and training*."[28] The Centre also has a duty to report on emerging health threats to the EU and Member States, through data gathering and analysis in collaboration with the Member States.[29] The budget to achieve all of this work is small, especially when compared to the funding allocated by Member State governments to their national agencies.[30]

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24 Article 4, Regulation (EC) 851/2004.
25 Article 5, Regulation (EC) 851/2004.
26 Article 6, Regulation (EC) 851/2004.
27 Article 7, Regulation (EC) 851/2004.
28 Article 9, Regulation (EC) 851/2004.
29 Articles 10 and 11, Regulation (EC) 851/2004.
30 Official Journal of the European Union C529/32 29.3.2019.

In terms of the Coronavirus pandemic, the ECDC work has been through the EWRS and in publishing, since early January 2020, technical guidance and technical reports, on risk and response strategies, in relation to the virus and disease.[31] It also includes surveillance and aggregating information, at EU level, and addressing strategies for dealing with the virus and disease, in relation to hospital facility preparedness, the needs for personal protection equipment, social distancing and, most recently, contact tracing.[32] It has contributed to the understanding of the pandemic and to the development of health education for the general population and for policy-makers and regional and local healthcare managers. It is providing coordination for information for testing laboratories (on the nature of tests and also on where such laboratories are situated in institutions across the EU/EEA). Whereas there is some provision for emergency in-the-field response through the ECDC, this is for small-scale deployment outside the EU (in developing economy countries); in-the-field response within the EU is by Member States. Where there has been sharing of resources, between Member States, it has been largely on a bi-lateral level, between individual Member States. Perhaps one question that will be raised, particularly by the less economically developed EU countries, is how far the ECDC should develop a resource-sharing response facility, to coordinate shared public health delivery across EU Member States.

Conclusions that might be drawn about the ECDC are that it needs strengthening. With indications from the WHO that the Coronavirus and Covid-19 problems will take years to control[33] and that a vaccine or drug therapy is some way off, the measures that ECDC provide for the EU and beyond are crucial. One might see an argument for both greater funding, and a strengthened legal status for this agency. There is no strong argument to support the centralisation of laboratory (lab) resources or to create other similar infrastructures. Decentralised lab capacities, for testing, and different research groups working on vaccines, seem to have greater potential. The ECDC must have clear authority in harmonising case definitions and harmonising case reporting, authority to define the minimum requirements for a comprehensive European surveillance infrastructure and network including the real-time and unfiltered access to the surveillance data from all Member States and the authority to recommend

31 https://www.ecdc.europa.eu/en/covid-19/all-reports-covid-19 (last visited 13 June 2020).

32 https://www.ecdc.europa.eu/en/publications-data/download-todays-data-geographic-distribution-covid-19-cases-worldwide (last visited 13 June 2020).

33 Reported comments by Dr. Soumya Swaminathan, WHO chief scientist, at Financial Times, Global Boardroom 13.5.2020.https://www.cnbc.com/2020/05/14/coronavirus-who-warns-it-could-take-up-to-5-years-to-control-pandemic.html (last visited 13 June 2020).

and coordinate containment strategies once more than one Member State is affected by an outbreak, including the authority to recommend and assess regional strategies, independent of national borders.

EU Legislation to Support Privacy and Access to Health Care

Responses to the Coronavirus pandemic must include a vaccine and other pharmaceuticals that seek to alleviate the symptoms or cure the disease. Politically, the EU has contributed enormously to the international effort, particularly through the Global Pledging Summit, and pushing for a major WHO resolution, to respond to the pharmaceutical challenge.[34] Surveillance and monitoring of the rate of the infection will require "*track and trace*" technologies to identify those who are at risk of infection.

For both these areas of scientific and technological response, there are health law aspects. These relate to fundamental human rights: the protection of participants in trials; access to medicines; protection in relation to medical devices; and privacy in relation to personal data. EU legislation is in place that already relates to these aspects, including the Charter of Fundamental Rights of the European Union (CFREU), the Clinical Trials Directive, the Medical Devices Directive and the General Data Protection Regulation.[35]

The Governance of Track and Trace-Technologies

Privacy is a concern in relation to "*track and trace*", as it requires individuals to divulge their locations to the State or to the commercial provider of the software used for the tracing. Each Member State is required to observe the European Convention on Human Rights, and the CFREU. Both these instruments create the right to private life, as a right in balance with the public interest, not as an absolute right.[36] The General Data Protection Regulation reflects this. To process personal data fairly, lawfully and transparently, the Data Controller must have a legal basis for processing under Article 6 (general

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34 See, for example, https://global-response.europa.eu/index_en; https://healthpolicy-watch.org/who-european-commission-announce-plan-to-raise-7-5-billion-euros-to-ensure-equitable-access-to-covid-19-diagnostics-drugs-vaccines/; and, https://healthpolicy-watch.org/74317-2/ (each last visited 13 June 2020).

35 Respectively Directives 2001/20/EC and 93/42/EEC, and Regulation (EU) 2016/679.

36 As stated above, rights under the Charter of Fundamental Rights of the European, in line with the Universal Declaration of Human Rights Article 12 and the European Convention on Human Rights Article 8, are not absolute: Article 52 allows the rights to be restricted to meet "the need to protect the rights and freedoms of others".

personal data) and Article 9 (sensitive personal data - including health data). The legal bases for the processing are Article 6(1)(e) "*processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller*" and Article 9(2)(i) "*processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy*".[37]

What is equally clear is that when there is an appeal to the public interest, the Data Controllers and Data Processors must still comply with the other elements of the GDPR, that the Data Subject should be informed of: the name and contact details of the Data Controller and the purpose of the processing;[38] that the data must be kept securely, only for the stated purposes and not further processed for purposes incompatible with those purposes; and only data required for the processing must be gathered.[39] The Data Controller, in devising the processing, must ensure compliance with the principle of "data protection by design and default" (that compliance with data protection is not an afterthought).[40] Given the risks to individual privacy from "*track and trace*", it must be in the range of processing subject to an impact assessment and be of a sufficiently high risk to warrant prior consultation with the national Supervisory Authority.[41] The GDPR brought significantly increased fines for data breaches (over those available under Directive 95/46/EC).[42] Where the processing of the personal data involves a transfer of the data, outside the EU, the processing institutions must comply with the GDPR.[43]

The European Data Protection Supervisor and European Data Protection Board must be at the forefront in setting standards that maintain public trust and confidence in the "*track and trace*" systems. The GDPR contains opportunities to

37 For a detailed discussion of the relationship between public health and security concerns, and the link to the EWRS, see H. van Kolfschooten & A. de Ruijter (2020) "COVID-19 and privacy in the European Union: A legal perspective on contact tracing" Contemporary Security Policy DOI: 10.1080/13523260.2020.1771509

38 Articles 13 and 14, GDPR.

39 Article 5, GDPR.

40 Article 25, GDPR.

41 Articles 35 and 36, GDPR.

42 Article 83, GDPR.

43 Articles 44 to 50, GDPR.

process personal data in a way that both realises the necessity of "track and trace", and is privacy-protecting. Writing at a time where a number of EU countries are moving towards whole population "track and trace" with global data science companies providing the software, and public concern about who will have access to sensitive data that reveals more than the Coronavirus status of the data subject, this will be a test for the GDPR, to see whether it is robust enough to provide both the confidentiality and the efficacy that the public demands.

Clinical Trials and Medical Devices

In terms of the development of the software application, clinical trials and the licensing of any new pharmaceutical products, the practical demand is for a regulatory system that protects citizens generally, and patients and research participants specifically. The EU has created key legislation (with procedures), as part of creating a single, harmonised research area, in relation to medical research, and single processes for licensing new pharmaceutical and medical devices, for sale in the EU. Each element has some problems. The European Medicines Agency overseas the licensing process for new pharmaceuticals to the EU. This is a well-established process but, like all regulators in this regard, it is faced with the challenge of what level of safety risk is acceptable for a product to respond to a pandemic that presents such devastating and immediate risks to the health of the population. This translates into the amount and quality of scientific data required to convince independent assessors of the safety and efficacy of the applicant drug. This is a challenge that has been addressed recently in relation to Ebola; the ethical issue continues in the current pandemic: who is a representative of the stakeholders in the debate and how are they heard in the debate?

In relation to medical devices, there is a question that has been emerging in recent years, not fully resolved at the practical or conceptual level: how far is a computer programme, or a wearable (or other) device, a medical device? As "track and trace" employs mobile phones and the GPS functions of smart watches, does this medical, public health function bring the whole device into the scope of EU medical devices law? This is compounded because the Medical Devices Regulation 2017/745 (MDR) was due to come into force in May 2020 but the European Parliament adopted the proposal, presented by the European Commission, postponing the entry into application of the MDR until May 26th 2021.[44] Therefore the Directive 93/42/EEC remains in force.

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44 https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices (last visited 13 June 2020).

A similar situation has occurred in relation to the EU legislation on Clinical Trials. The Clinical Trials Regulation 536/2014 should, by 2020, have been fully implemented. The process requires the development and implementation of the Clinical Trials Information System (CTIS) which includes a portal to facilitate the digital operation of the new trials approval system and a directory of trials. The creation of the CTIS has been extremely problematic and has delayed the implementation of the Regulation.[45] The current legislation, for clinical trials approval, in the EU is the Directive 2001/20/EC. One of the main complaints about the Directive, and a motivation for the revision and development of the Regulation, is the time that it can take for the review of a protocol. Under the Directive, this could be a maximum of 60 days[46], with the possibility of extensions on the basis of inadequate information. A review could be expedited (and the European Network of Research Ethics Committees (EUREC) advocates that Research Ethics Committees (RECs) should prioritise Coronavirus and COVID-19 research applications, whilst observing all ethical standards). With the different infrastructures and arrangements for RECs across Europe, substantially reducing the time needed for a review could be difficult. The process created in the Directive, for multi-centre, multi-jurisdiction trials, does not have a mechanism for the coordination of REC assessments. Where a trial seeks to operate in multiple different jurisdictions, the applicants make multiple separate applications to the local RECss, and receive multiple separate evaluations that the applicant must reconcile. Expediting the process for emergency drugs is not clear. The ordinary process requires three phases for a clinical trial and usually a company will apply for a separate ethics review for each phase of the trial. How this process is expedited for emergency medicine situations is unclear.

Economic Recovery

One of the areas where there has been a lot of EU activity is in relation to maintaining the economies of the EU and its Member States.[47] It is relevant

45 Regulation (EU) 536/2014 indicated that implementation would not be sooner than May 2016 (Article 99). Once the CTIS is in place, it requires an independent audit of the system, and the implementation of the Regulation will be six months after the completion of that audit. The current estimation by the EMA is that the audit will start in December 2020.

46 Article 6(5), Directive 2001/20/EC. For "trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms" the period can be extended to 90 days - Article 6(7).

47 For a broader discussion of the economic issues, see Remco van de Pas, (2020) Globalization Paradox and the Coronavirus Pandemic. Clingendael Report: Clingendael

because a strong economy is essential to realise the Charter Article 35 Right to Health Care and there are Treaty obligations on the EU to consider Health in All Policies.

The economic crisis, relating to COVID-19, follows countries' strategies of "lockdown" - to require or advise individuals to isolate themselves, not to leave their homes unless it is essential, and to close many non-essential businesses and education institutions. In the EU, the responses of the Member States have been social lockdown to a greater or lesser extent, with consequent unemployment, collapse of many businesses, lost tax revenue and increased social-welfare spending demands.

The proposed EU response is to create a €750 billion fund of loans and grants.[48] This money will be raised on the international markets, using the EU's high credit rating to secure lower borrowing costs than might be available to some of its Member States individually.[49] The draft budget proposals, for the next cycle of EU spending, had already reversed the previous policy regarding health and proposes a standalone health programme, with a view to raising health standards across the EU.

The experience of the response to the banking crisis of 2008 (the European Semester) was an embracing, by the EU, of austerity measures. This produced disproportionate impacts on the poorest members of society. If the response to the economic problems, caused by the COVID-19 pandemic, are met with the same policies (resisting and reducing public spending), then once again, this could have a longer-term impact on the health of the poorer European citizens. This is where the commitment to "*Health in all Policies*" and to the Charter's Article 35 Right to Health Care will be tested.

Conclusions

This paper, has limitations. It is written only a few months into the COVID-19 pandemic in Europe, and more detailed evidence will emerge to make deeper judgements about the long-term contribution of the EU to the public and

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Netherlands Institute of International Relations. https://www.clingendael.org/publication/globalization-paradox-and-coronavirus-pandemic (last visited 13 June 2020).

48 https://www.politico.eu/article/ursula-von-der-leyens-big-gamble-with-borrowed-money/ (last visited 13 June 2020).

49 "The common EU response to COVID-19 | European Union." 13 May. 2020, https://europa.eu/european-union/coronavirus-response_en (last visited 13 June 2020).

economic health of its Member States and on the international stage. The purpose of the paper is: to explain the nature of the responses that have been seen in the EU health law context; to highlight where there are already issues in the current law or its operation; and to indicate where future effort is needed, both at the technical and conceptual level in relation to EU health law.

Whereas the EWRS worked in providing alerts about the nature of the threat, the EU does not have sufficient authority to coordinate the delivery of healthcare, at the point of use, between Member States. Practical healthcare support, between countries, has been largely bi-lateral.[50] Whether this is the sort of response that realises the aims of the EU, or its commitment to fundamental human rights, should be debated (especially given the potential continuing duration of the pandemic). How far do the Member States (and their citizens) wish to move towards a federal EU? It is appropriate to link this debate to the response seen to the last crisis, faced by the EU, - the economic crisis of 2008 - where, as now, the instinct of the individual Member States was to sideline the EU and to assert their authority over the EU institutions. Will there be an economic response, based on austerity, and will any economic response be measured against its impact on individual citizens' fundamental human rights, to access to health care and to share in the scientific and cultural (i.e. medical) advances of their community?[51]

There are practical ways that the existing EU health law could be strengthened: the (spirit of the reforms in the) Clinical Trials Regulation and Medical Devices Regulation need to be implemented as soon as possible; the safeguards of the General Data Protection Regulation, particularly in relation to risk assessment and data protection, by design and default, must be ensured by robust scrutiny and enforcement by national and European supervisory authorities.

Beyond its own boundaries, the EU has taken a strong stance in contributing to the international effort in responding to the pandemic. The problem is one that is likely to remain for a number of years. One of the crucial elements, in responding to the continued crisis, is likely to be international co-operation,

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50 This tension can also be observed with the procurement of prospective Covid-19 vaccines, whereby a coalition of four EU member states have concluded a joint EU vaccine strategy and budget coordinated by the European Commission. The concern raised is that four Member States have acted to bind all the Member States. https:/ /www.euractiv.com/section/all/short_news/belgium-criticises-vaccine-buying-solo-run/ (last visited 16 June 2020).

51 See, Universal Declaration of Human Rights, Articles 25 and 27(1) (The United Nations, 1948, art. 21.3)

especially in the face of the United States of America's withdrawal from the WHO. The EU's continued voice, in international collaboration, is extremely important. The EU has a commitment to ensuring fundamental human rights. There is a temptation to see a pandemic as requiring a "*state of exception"* – an extraordinary response compared with the normal expectations, particularly in relation to human rights. Perhaps the greatest contribution that the EU could make is to: ensure that responses to the COVID-19 pandemic respect fundamental human rights to dignity and autonomy in the imperative context of solidarity; and that all jurisdictions recognise that one of the fundamentals of effective public health is maintaining human rights and the rule of law.

Appendix - A Brief Introduction to the EU and Health.

The European Union (EU) is a supranational organisation that has evolved into its current iteration as part of the twin projects to create a new Europe after its long history of wars culminating in World War II. The Council of Europe was created as an international, intergovernmental body to ensure European justice and culture;[52] the EU is the current expression of the project to ensure peace through free trade,[53] and to strengthen the combined position of its Member States in the context of the shifting geopolitical gravity.

After World War II, Belgium, France, West Germany, Italy, Luxembourg and The Netherlands first formed an alliance, around the production of coal and steel - the means of war.[54] The broader project was to create a greater alliance. Churchill spoke of the need for a "*United States of Europe*"; Schumann created a plan to move to a united Europe.[55] The twin growth trajectories of the degree of federation of the Member States, and the number of Member States have followed. From the 1950s, the number of Member States has moved from six, to nine, to 12, to 15, to 25, to 28, and, with Brexit, to 27. In terms of a geographical coverage, most of the countries in Western Europe are Member States of the EU and share public health risks through EU free movement policy.

52 For more information, see e.g. R. O'Connell and S. Gevers, 'Fixed Points in a Changing Age? The Council of Europe, Human Rights, and the Regulation of New Health Technologies', in: M.L. Flear, A.M. Farrell, T.K. Hervey and T. Murphy (Eds.), European Law and New Health Technologies, Oxford: Oxford University Press 2013, p. 46-69.

53 See Article 3(1) TEU

54 European Coal and Steel Community, Treaty of Paris, 1951.

55 Churchill, W. S. "Speech to the Academic Youth", University of Zurich, 1946; Schumann, R. Declaration of 9th May 1950.

The move from shared control over coal and steel to a European Economic Community was about creating a free trade area.[56] The Maastricht Treaty, of 1992, took that trade community further towards a federal union - a "*European Union*" with the internal market, single currency and the social chapter. This proved a movement too far for many, with negotiated opt-outs from the social chapter and single currency from the outset. The derailment of the next phase of the trajectory followed with the rejection by Member States of the proposed "*Constitution" of the EU*.[57] The purpose of the Lisbon Treaty (entering into force in 2009), in relation to the degree of federalisation, require two perspectives: it is merely a consolidation of the administrative changes necessary to run institutions with 27 Member States; it is the next step to federalism. From the early 1970s, this EU project has had, at its heart, the idea that Europe is one market where free movement of people to participate in that market is crucial. Where there is movement of people, animals, goods and services, across national (and internal) borders, there is a public health issue.

The TEU and TFEU create an explicit balance between the power of the EU and the power of the Member States.[58] The EU has no exclusive power relating to health.[59] The EU has shared power with the Member States to act in relation to "*common safety concerns in public health matters, for the aspects defined in [the TFEU]*".[60] Under specific conditions,[61] the EU has a supplementary competence to: create legislation in order to meet common safety concerns in relation to health matters within specified, narrow areas relating to human blood and organs; to pharmaceutical and medical devices regulation; to phytosanitary issues in relation to health;[62] it also has power to support Member States in relation to the promotion of health. It has a stated policy of "*Health in All Policies and Activities*" - that in everything it does, the institutions of

56 Treaty Establishing the European Economic Community, Treaty of Rome, 1957.
57 Treaty Establishing a Constitution for Europe, 2004. Rejection by Dutch and French voters, 2005 led to the abandoning of the Treaty.
58 See generally, A.P. van der Mei and E. Vos, 'EU health law and policy', in: P.J. Kuijper et al. (Eds.), The Law of the European Union, Fifth Edition, Alphen aan den Rijn: Wolters Kluwer 2018; D. Sindbjerg Martinsen, 'Governing EU health law and policy - on governance and legislative politics', in: T.K. Hervey, C.A. Young and L.E. Bishop (Eds.), Research Handbook on EU Health Law and Policy, First Edition, Cheltenham, UK: Edward Elgar Publishing 2017, p. 36-60.
59 Compare Article 3 TFEU.
60 Article 4(2)(k), TFEU.
61 See Articles 6 and 168 of the TFEU.
62 Article 168(4), TFEU.

the EU must consider the impacts on human health.[63] The EU can also create legislation, binding on all its Member States, to "*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*" but excluding any harmonisation of the laws and regulations of the individual Member States.[64]

63 Article 168(1), TFEU.

64 Article 168(5) TFEU, which goes on to include specific power to create "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."