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Stuck in the middle with you…wondering what it is I should do. Some considerations on EU's response to COVID-19

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1. Preliminary remarks

It is perhaps safe to say that with the spread of the virus Euroscepticism has reached its peak. The accusations formulated against the Union for its weaknesses, faults, shortcomings, however, need to be put into perspective. As will be seen, despite the existence of institutionalized fora and multilevel mechanisms to secure epidemiological surveillance and operational capacity, the effectiveness of the Union's response to major cross-border threats is still dependent on a rather bungled framework for emergency response, voluntary participation in joint initiatives and financial commitment on the part of the Member States.

At a time when the virus appears to have lost its initial thrust,[1] when most Member States have committed to opening borders and related travel restrictions and the Commission has proposed a gradual lifting of the external travel ban starting 1 July,[2] it is useful to reflect on the takeaways from COVID-19. One above all: the reaction of the Member States, at the national and regional level, must be corrected to preserve the internal market, protect the euro, and ultimately save lives.

The Lisbon Treaty has forged the applicable primary law provisions and shaped the existing legislation on cross border threats and civil protection in light of the experience developed in combating natural and man-made disasters. Still, public health matters largely fall within the

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[1] ECDC, Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK – tenth update, 11 June 2020, accessible at https://www.ecdc.europa.eu/.
[2] Communication from the Commission on the third assessment of the application of the temporary restriction on non-essential travel to the EU, COM(2020) 399 final.

supporting, coordinating or supplementing competences, and sincere cooperation and voluntary contribution are not sufficient to ensure an orderly, concerted response. *Rebus sic stantibus*, many improvements can be realized, but nothing structural, long-lasting; most importantly, nothing that would be able to discourage and prevent the same reaction on the part of the Member States in the case of future epidemics (Section 2).

The applicable legal framework has conditioned the overall response of the Union and the Member States to the sanitary crisis, highlighting the adaptability of the system and signaling the preference for informal decision-making and soft law instruments, even when regulating aspects relating to goods, professionals and patients. In coordinating their action, Member States have demonstrated the will to cooperate, but the solidarity effort posited by the limited EU competences in this field has not been up to expectations (Section 3).[3]

A number of conclusions can be drawn from the response to COVID-19 at the national and EU level. Firstly, the Union suffers from a structural weakness deriving from the absence of a complete set of standardized data functional to the adoption of sound political decisions in case of major cross-border health threats. Secondly, the mechanisms currently in place are not sufficiently efficient and compromise effective governance of health emergencies. Thirdly, the mantra of sustainability embraced during the last economic crisis has undermined the resilience of the Member States' healthcare systems. Fourthly, the rules governing the free movement of goods, professionals and patients should be improved with a view to facilitate accessibility to medical equipment and treatment. Finally, the EU budget is ill-equipped to tackle such appalling events and the introduction of new own resources can no longer be postponed (Section 4).

Many options are now open to discussion, some more effective than others – no surprise, their political feasibility is inversely proportional to their added value. With reference to the Recovery Plan recently presented by the Commission, four main areas have been identified that deserve particular attention: governance; risk and emergency regulation; reserves and resources; funding. The needed improvements in each of the mentioned areas cannot be realized without courageous decisions. The empowerment of the European Centre for Disease Control (ECDC), the endorsement of a (more) communitarian method in the decision-making process within the EU Integrated Political Crisis Response, a more channeled funding of investments in the healthcare sector, the federalization of minimum resources to contrast future sanitary crises, fiscal approximation and an increased budget firepower are all, however, highly controversial issues and the prospect of extensive revisions in the near future is very unlikely (Section 5).

And yet, voices in the institutions and civil society at large are advocating to take the Conference on the Future of Europe very seriously. A change in pace is reckoned essential to give new lifeblood to the European integration process. As improbable as they may appear, some reform proposals to advance the protection of public health in the event of major cross-border threats will be examined. In light of the package on the Recovery Plan and the Multi-annual Financial Framework presented by the Commission on 27 May 2020, and considering what is at stake, it is advisable to keep an open mind on possible, radical, adjustments (Section 6).

[3] Concrete Examples of solidarity between Member States can be found at https://www.ecfr.eu/solidaritytracker.

2. Public health, a stronghold of national sovereignty, but not so fast…

2.1. Constitutional limits to EU action in the event of major cross-border health threats

The protection of public health is by definition a matter of common concern, but the underlying responsibility is deeply rooted in State sovereignty. This state of affairs is well reflected in the treaty provisions concerning public health. Member States retain sole responsibility "for the definition of their health policy and for the organisation and delivery of health services and medical care"[4] and the incentive measures that the Council and the Parliament can adopt concerning monitoring, early warning of, and response to, major cross-border health scourges[5] cannot entail the harmonization of Member States' laws or regulations.[6]

On the other hand, "a high level of human health protection shall be ensured in the definition and implementation of all Union policies"[7] and "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".[8] Moreover, the Union "shall encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas". In addition, the Commission is assigned the task of favoring the coordination of national policies and programmes in this area via "the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation", keeping the EU Parliament duly informed.[9] Also, when it comes to combating major cross-border threats to health the Union can promote "research into their causes, their transmission and their prevention, as well as health information and education".[10]

Similarly, in relation to emergencies the Parliament and the Council can pass legislation with the specific objective of promoting "swift, effective operational cooperation within the Union between national civil-protection services", but without harmonizing national laws and regulations,[11] and the Council is granted the power to decide "in a spirit of solidarity […] upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products".[12] Moreover, once the solidarity clause has been activated at the request of the political authorities of the country targeted by a terrorist attack or the victim of a natural or man-made disaster, the EU and the Member States are expected –to act jointly "in a spirit of solidarity", and to assist each other in the event of [a terrorist attack or] a natural [or man-made] disaster.[13]

Despite its intrinsic limits, this fragmented primary law setting has fostered the creation of an elaborate and complex network of bodies, mechanisms and procedures designed to favor

[4] Art. 168(7) TFEU.
[5] Art. 168(5) TFEU.
[6] Arts. 2(5) and 6(a) TFEU.
[7] Art. 168(1) TFEU.
[8] Art. 35 of the EU Charter of Fundamental Rights.
[9] Art. 168(2) TFEU.
[10] Art. 168(1) TFEU.
[11] Art. 196 TFEU.
[12] Art. 122 TFEU.
[13] Art. 222 TFEU. Pursuant to Declaration No 37, annexed to the Lisbon Treaty, however, the provision, does not "affect the right of another Member State to choose the most appropriate means to comply with its own solidarity obligation towards that Member State"

coordination, cooperation and contribution. Over time it was possible to create, for surveillance, planning and response to cross border threats, the Health Security Committee (HSC) and the Early Warning and Response System (EWRS), as well as the ECDC, and, for prevention risk management, resource-pooling and preparedness in case of emergency, the Union Civil Protection Mechanism (UCPM), which can count on the Emergency Response Coordination Centre (ERCC), the European Emergency Response Capacity (EERC) and the Common Emergency Communication and Information System (CECIS). Furthermore, for overall coordination purposes, under the solidarity clause the EU integrated political crisis response (IPCR) arrangements offer the Presidency of the Council scalable, flexible, tools to manage emergencies; most notably, the possibility to convene meetings at the highest political and technical level (European Commission, European External Action Service, EU agencies, the Cabinet of the President of the European Council and national experts) for sharing, assessing, discussing and planning.

More concretely, when it comes to pandemics it is now possible to rely on Decision 1082/2013 concerning serious cross border health threats[14] and on Decision 1313/2013 establishing the UCPM.[15] Under both instruments the Commission has a strong steering role and can advance purchase of medical countermeasures through join procurement procedures. In both contexts the Member States are supported by Union services for risk management, surveillance and preparedness control (ERCC and EERC) and rapid alert (the EWRS and the CECIS). Dedicated technical and communication web-based platforms, such as the European Surveillance System (TESSy) and the Epidemic Intelligence Information System (EPIS) enable prompt communication and discussions among experts and national administrations at the supranational level. From an operational standpoint, moreover, the UCPM can rely on the European medical corps[16] and the rescEU programme has recently established a European reserve of resources made available by the Member States on a voluntary basis (firefighting planes and helicopters, medical evacuation planes, stockpile of medical equipment and field hospitals).[17] Despite the chairing and managerial role of the Commission – in the HSC, but also in the ERCC and EERC – both regimes have strong political connotation. Nonetheless, the technical component of the governance cannot be ignored. In this respect, the timely creation of a Commission expert panel on COVID-19 to reinforce the preparedness and response capacity of the Member States is particularly telling as to the central role progressively recognized to scientific evidence by the policy-maker.[18]

[14] OJ [2013] L 293, p. 1 (based on Art. 222 TFEU).
[15] OJ [2013] L 347, p. 924 (grounded on Art. 196 TFEU).
[16] Commission Implementing Decision (EU) 2018/142 of 15 January 2018 amending Implementing Decision 2014/762/EU laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism, OJ [2018] L 25, p. 40. On the reasons that led to the creation of a European Medical Corps and its operation added value, see J.M. HAUSSIG, E. SEVERI, J.H. BAUM, V. VANLERBERGHE, A. LAISECA, L. DEFRANCE, C. BRAILESCU, D. COULOMBIER, J. JANSA, *The European Medical Corps: first Public Health Team mission and future perspectives*, in *Euro Surveill*. 2017, pp. 1-6.
[17] Commission Implementing Decision (EU) 2019/1930 of 18 November 2019, OJ [2019] L 299, p. 55. The reasons for setting up the reserve and the resistances of the Member States in the legislative process leading to the adoption of the decision are analyzed in F. CASOLARI, Europe (2018), in *Yearbook of International Disaster Law Online*, 2019, pp. 346-354.
[18] Commission Decision of 16 March 2020 setting up the Commission's advisory panel on COVID-19, C(2020) 1799 final.

2.2. Beyond complementarity: the internal market acquis, economic coordination and cross-border cooperation in health matters

That being said, it is important to underline that while the protection of public health against major cross-border scourges (also in the context of civil protection cooperation instruments) is included among the supporting, coordinating and supplementing competences, the actual provision and receipt of healthcare services fall within the category of shared competences.[19] Indeed, important aspects related to health are already part of the internal market *acquis* and Member States are therefore pre-empted from exercising their competences. In this regard, suffice it here to recall that the free movement of medical devices,[20] medicines,[21] healthcare professionals[22] and patients[23] is ensured by means of coordinating and harmonizing measures at the EU level,[24] which also explains the remarkable increase in the migration flows of healthcare professionals[25] and the upward trend in patient mobility.[26]

In addition, the economic crisis has led to the inclusion of public health expenditure in the European Semester process, as a part of the necessary coordination of the economic policies of the Member States.[27] This allows the Commission and the Council to (try to) prevent and correct unsound, unsustainable expenses and to promote strategic investments. Since 2011, a growing number of country-specific Council and Commission recommendations have addressed health and long-term care expenditure focusing on cuts to public spending and efficiency driven reforms which favored privatization.[28] More recently, instead, Member States are invited to

[19] Art. 4 TFEU.

[20] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ [2017] L 117, p. 1.

[21] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ [2014] L 158, p. 1.

[22] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, OJ [2005] L 255, p. 22.

[23] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ [2011] L 88, p. 45.

[24] Arts. 114 and 168(4) TFEU.

[25] C. SCHULTZ and B. RIJKS, *Mobility of Health Professionals to, from and within the European Union*, International Organization for Migration, 2014; Single Market Scoreboard Professional Qualifications Reporting period: 2015 – 2017 available online; K. ADAMIS-CSÁSZÁR, L. DE KEYSER, E. FRIES-TERSCH (eds.), *Labour Mobility and Recognition in the Regulated Professions*, Study for the European Parliament, 2019:

[26] R. LEVAGGI, M. MONTEGIORI (eds.), *Health Care Provision and Patient Mobility. Health Integration in the European Union, Springer*, 2014, pp. 1-26; G. BERKI, *Free Movement of Patients in the EU. A Patient's Perspective*, Intersentia, Cambridge, 2018 and European Commission, *Member State Data on Cross-border Patient Healthcare*, available online.

[27] Arts. 3 TEU and 119(1) TFEU. See further, T. CLEMENS, K. MICHELSEN, H. BRAND, *Supporting Health Systems in Europe: Added Value of EU Actions?,* in *Health Economics, Policy and Law*, 2014, pp. 1-21; S.L. GREER, H. JARMAN, R. BAETEN, *The New Political Economy of Health Care in the European Union: The Impact of Fiscal Governance*, (2016) *International Journal of Health Services*, 2016, pp. 262-282; BAETEN, R. and VANHERCKE, B., *Inside the Black Box*: *The EU's Economic Surveillance of National Healthcare Systems*, (2017) 15 *Comparative European Politics* 3, p. 478-497. On the latest developments see also EuroHealthNet, *The European Semester 2019 from a health equity perspective*, available online.

[28] Cutbacks and "an overall declining share of health expenditure going to public health" in the post-financial crisis period has been amply reported. See G. QUAGLIO, T. KARAPIPERIS, L. VAN WOENSEL, E. ARNOLD, D. MCDAIDB, *Austerity and health in Europe*, (2013) 113 *Health Policy* 1–2, pp. 13-19; A. MARESSO, P. MLADOVSKY, S. THOMSON, A. SAGAN, M. KARANIKOLOS, E. RICHARDSON, J. CYLUS, T. EVETOVITS, M. JOWETT, J. FIGUERAS, H. KLUGE, *Economic crisis, health systems and health in Europe*, World Health Organization, 2015; B. RECHEL, *Funding for Public Health in Europe in Decline?*, (2019) 123 *Health Policy* 21); T. FORSTER, A.E. KENTIKELENIS,

prioritize investment-related economic policy on healthcare to ensure quality, effectiveness, accessibility and resilience; the key words being: digitalization, fiscal sustainability, affordability and trained health professionals.[29]

Finally, cross-border cooperation in the field of healthcare has progressively gained momentum to respond to specific geographical needs (mountain regions, rural and densely populated metropolitan areas, touristic destinations), shortages of healthcare personnel (doctors, nurses responsible for general care or specialists, managers), organizational matters (planning, procedures or standards, interoperability of national information and communication technology, mechanisms to secure continuity of care and facilitate free provision of healthcare services by professionals on a temporary basis).[30] Numerous cooperation projects have been financed by the European Union and are currently in place:[31] some initiatives have a broad scope of application[32], others only address certain categories of patients (*e.g.* children),[33] specific diseases (*e.g.* cardiopathy)[34] or medical services (*e.g.* telemedicine).[35] Besides these projects financed through the Interreg Programme, there are many specific bilateral/multilateral agreements in place concerning the supply of essential equipment, provision of healthcare services and mutual recognition of professional qualifications which also testifies to the acceptance that, for sustainability reasons, the management of healthcare cannot be contained within national boundaries.[36]

It follows from the above that if the protection of public health remains – formally – safely in the hands of the Member States, there is a growing awareness that serious cross-border threats to healthcare cannot be appropriately addressed and solved without sharing information and resources, coordinating economic policies – and most notably investments – in the field of health and long-term care.

3. Testing the response capacity of the Union in light of COVID-19

3.1. All for one and one for all?

Austerity and health in Europe: disentangling the causal links, (2019) 29 *European Journal of Public Health* 5, pp. 808 and 809; C. DI COSTANZO, *Healthcare Resource Allocation and Priority-setting. A European Challenge*, (2020) 27 *European Journal of Health Law* 2, 93-114.

[29] European Semester: Commission proposes health recommendations (2019). To capture the capacity of EU healthcare systems to respond to a crisis, the EU Commission and the OECD have developed a series of indicators reflecting on the long-term stability of resources and efficient and strong governance responses, including to plan and forecast healthcare infrastructure and workforce. European Commission, State of Health in the EU, Companion Report (2019) <https://ec.europa.eu/health/sites/health/files/state/docs/2019_companion_en.pdf>.

[30] Cf. Recital No 50 and Art. 10(2) and (3) of Directive 2011/24, cited *supra*.

[31] European Commission, *European Cross-Border Cooperation on Health: Theory and Practice*, 2017.

[32] TRISAN - A tool for structuring and coordinating cross-border health in the Upper Rhine; Putting Patients, Clients and Families First - A cross-border health partnership for the Republic of Ireland and United Kingdom; IZOM - Tailored healthcare in the Meuse-Rhine Euregio; The cross-border hospital in Cerdanya - One hospital, two States.

[33] INTERSYC - Treating and protecting children together for Greece and Bulgaria

[34] The Franco-German inter-hospital cardiology partnership project.

[35] Telemedicine Euroregion Pomerania - Move the data, not the patients.

[36] Bilateral or multilateral initiatives on healthcare in cross border regions are currently in place, for instance, between the UK and Belgium, Germany and Poland, Italy and Austria, France, Germany and Switzerland. For an overview of the international cooperation in the field of healthcare see further C. BEAUCILLON, *International and European Emergency Assistance to EU Member States in the COVID-19 Crisis: Why European Solidarity Is Not Dead and What We Need to Make It both Happen and Last*, (2020) *European Papers*, available online.

Taking stock of the experience sadly gained during dramatic events[37], the Union has for some time now been working on a common response framework in the event of natural and man-made disasters and the Lisbon Treaty introduced some important amendments which facilitated advancements in the management of cross-border threats to health.

With the rapid spread of the virus, however, the Member States did not fully exploit the elaborate apparatus for supranational healthcare governance and certainly did not make the most use of the available technical and communication platforms, national administrations being reluctant, not well equipped, or simply overburdened.[38] The reasons behind the "every man for himself" approach shown in the early stages of the crisis can be traced to the amply documented lack of preparedness on the part of the Member States,[39] adequate European resources to deploy where needed, and sufficient, readily available, funds to feed into the most affected national health systems. Be it as it may, the eclectic reactions at the national level had immediate negative effects on the Schengen borders code and the internal market, two cornerstones of European integration. Not only did they leave many citizens astray, they also endangered the supply of goods (including foodstuff) and the free movement of workers, fueled discrimination, and even accelerated rule of law back-sliding and social exclusion.

To prevent market disintegration and contrast the negative effects of the sanitary crisis a wide range of measures were issued: guidelines have been adopted to guarantee the availability of medicines, the mobility of healthcare professionals, the cross-border healthcare assistance to patients, the reliability and comparability of the methodologies used to assess the performance of testing devices and to define the requirements of apps to support contact tracing; State aid rules have been relaxed; contracts for medical equipment and supplies have been awarded through joint procurement procedures; export of personal protective equipment was subjected to prior authorization; European harmonized standards for protective equipment have been disclosed, and standards for medical devices clarified, for all interested companies; a common European reserve of medical equipment has been created; a European COVID-19 Data Platform to enable the rapid collection and sharing of available research data was activated; teams of doctors and nurses have been sent to most affected areas under rescEU; €48.25 million have been allocated within Horizon 2020; financial support of €80 million has been offered to CureVac, a German vaccine developer; the European Central Bank announced a Pandemic Emergency Purchase Programme (PEPP) with an overall envelope of €1.35 trillion; the European Bank of Investment has committed to a €25 billion European guarantee to support small and medium-sized companies; the Council approved a temporary scheme capable of providing up to €100 billion of loans under favorable terms to Member States to assist workers, including the self-employed (SURE); the European Stability Mechanism (ESM) credit line was made available to Member States for a total of €240 billion; and the European Council will now

[37] The pandemic influenza (H1N1) in 2009, the E. Coli outbreak in 2011, the Ebola virus in 2014 and the Zika in 2016.

[38] In the event of epidemics, however, underreporting is particularly dangerous in that it hinders the decision-making process. Most worrying is the reported lack of adequate cooperation by Member States within EPIS and TESSy. M. FLEAR, A. DE RUIJTER and M. MCKEE, *Coronavirus Shows How UK Must Act Quickly before Being Shut Out of Europe's Health Protection Systems*, (2020) 368 *Biomedical Journal*, m400.

[39] Report of the High-level Panel on the Global Response to Health Crises, *Protecting humanity from future health crises*, 2016, accessible at https://digitallibrary.un.org/record/822489?ln=en and Global Preparedness Monitoring Board, *A World at Risk*, WHO, 2019, available online.

decide on the ambitious €750 billion recovery plan presented by the Commission, which together with targeted reinforcements to the long-term budget (2021-2027), could unlock €1.85 trillion.

3.2. A tentative legal assessment of the legal flexibility manifested during the crisis

Although this normative and political effort is truly impressive, the actual impact of the measures adopted is (still) far from clear and difficult to ascertain. Many of the envisaged actions are contained in atypical, non-binding acts with various denominations (guidelines, roadmaps, etc.). Soft law has generally been preferred over binding legal acts, even in the presence of a clear legal basis and even when it would have been possible to recur to non-legislative and implementing acts.

To be sure, travel restrictions were not addressed under a Council recommendation pursuant to Art. 29 of the Schengen Borders code.[40] Rather the heads of State or Government of the Schengen Member States agreed to coordinate their action at the external borders and relied on the Commission for further guidance.[41] Likewise, the comparability of testing techniques was not pursued through an implementing decision under Art. 7(3) of Decision 1082/2013. In turn, the Commission issued guidelines on the different COVID-19 tests and their performance, specifying, however, that coordination of national strategies in a post-COVID-19 Europe "will be indispensable".[42] Also, independently of the support offered by the Commission and the – underfunded and under-staffed – ECDC, the gathering, processing and communication of data concerning the virus and its spread was largely managed by the Member States. An implementing decision, adopted pursuant to Art. 4(6) of Decision 1082/2013, defining a common form with the specifics to be communicated would probably have helped a more accurate assessment and reporting of the phenomenon, both at a national and Union level.[43] More generally, no formal invocation of the solidarity clause was addressed to the Presidency of the Council and the President of the Commission under Art. 4(2) of Decision 2014/415/EU on the arrangements for the implementation by the Union of Art. 222 TFEU and (thus) no decision was taken pursuant to Art. 5(3), according to which, upon a proposal by the Commission, the Council can adopt: "decisions on exceptional measures not foreseen by existing instruments" and "measures in support of a swift response by Member States".[44] Still,

[40] Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code), OJ [2016] L 77, p. 1 (as last amended in 2019).

[41] Cf. Communication form the Commission to the European Parliament and the Council COVID-19: *Temporary Restriction on Non-Essential Travel to the EU*, COM/2020/115 final and Communication from the Commission COVID-19 Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy, C/2020/2050. A full list of the communications and guidelines issued by the Commission during the crisis are available online.

[42] Cf. Communication from the Commission, *Guidelines on COVID-19 in vitro diagnostic tests and their performance*, C(2020) 2391 final, pt. 7. Testing strategies have also been closely considered by the panel of experts on COVID-19. Future initiatives in the field of testing are discussed in M. Morvillo, I Just Can't Get Enough (of Experts): The Numbers of COVID-19 and the Need for a European Approach to Testing, (2020) 11 *European Journal of Risk Regulation* 2, pp. 366-374, at p. 372.

[43] To the best of the author's knowledge, no specific guidelines on this matter were issued.

[44] Council Decision 2014/415/EU of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause, OJ [2014] L 192, p. 53. On the solidarity clause and the implications of the arrangements, cf. M. GESTRI, *EU Disaster Response Law: Principles and Instruments*, in A. DE GUTTRY, M. GESTRI, G. VENTURINI

planning and coordination did take place on the basis of those arrangements after the Croatian Presidency activated the ICPR mechanism on 28 January in information-sharing mode and subsequently increased the response to full-mode on the 2 March 2020.

Pivotal aspects relating to the functioning of the internal market – and therefore falling within the domain of shared competence – have been addressed by recurring to interpretative and decisional communications,[45] with potential long-lasting effects. Most notably, on more than one occasion the Commission has insisted on the adequate supply of essential goods (PPEs, medical devices, medicinal products) to the persons who are most in need.[46] As is well known, restrictions on exports can be justified by "the protection of health and life of humans"[47] provided they are appropriate, necessary and proportionate. As pointed out by Advocate General Trabucchi in *Dassonville*, reference is here made to the domestic context alone: Member States may rely on Article 36 "only for the purpose of the protection of their own interests and not for the protection of interests of other States"[48]; yet, according to the Communication on a coordinated economic response to the COVID-19, the objective deemed worthy of protection when considering the compatibility of national measures with internal market law is the protection of health of "people living in Europe".[49] This *de facto* alters the classic proportionality test, forcing national administration to 'think European'.

The rules on the mutual recognition of professional qualifications were also the object of important clarifications offered in non-binding communications which pressure the Member States to make full use of the current common framework to the benefit of patients and healthcare systems: it would be possible to remove administrative formalities (*e.g.* prior declaration, prior check for qualifications) and to speed up application procedures (*e.g.* shorter deadlines, fewer supporting documents, more relaxed stance towards compensation measures). In an effort to adapt the existing rules on free movement of healthcare professionals to the COVID-19 scenario, the Commission also suggests early graduation as a possible countermeasure to personnel shortage. As soon as the minimum requirements set out in Annex V of Directive 2005/36 are met (in cases where the training provided in the interested country goes beyond what is prescribed therein), it should be possible to award the diploma, which would consequently be subject to automatic recognition. By contrast, when such requirements are not satisfied, the relevant title could be obtained by virtue of an express, temporary derogation.[50] In this instance, Member States should allow individuals to compensate for the

(eds.), *International Disaster Response Law*, Springer, 2012, pp 105-128 and P. HILPOLD, *Filling a Buzzword with Life: The Implementation of the Solidarity Clause in Article 222 TFEU*, in *Legal Issues of Economic Integration*, 2015, pp. 209–232.

[45] On these categories of soft law instruments see, *inter alia*, U. DIEDRICHS, W. REINERS, W. WESSELS (eds.), *The Dynamics of Change in EU Governance*, Edward Elgar, 2011, pp. 25 ff and L. SENDEN, *Soft Law in European Community Law*, Hart Publishing, 2004, pp. 427 ff.

[46] Communication from the Commission, *Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak*, C(2020) 2272 final, pt. 5(a).

[47] Art. 36 TFEU.

[48] Case 8/74, ECLI:EU:C:1974:66, para 5.

[49] Cf. Communication from the Commission, *Coordinated economic response to the COVID-19 Outbreak*, COM(2020) 112 final and Guidelines for border management measures to protect health and ensure the availability of goods and essential services, C(2020) 1753 final, pt. 2.1.

[50] Art. 61 of Directive 2005/36, cited *supra*. It should also be noted that the possibility to provide for derogations from minimum harmonized training requirements under this provision needs to be assessed on the basis of clear and concrete information about the specific difficulties encountered in the specific Member States.

missed parts of the regular training and the Commission recommends to take into consideration – on a case-by-case basis – the "professional experience gained during the emergency or afterwards". And even when full qualification cannot be obtained, national authorities are not prevented from granting partial access to a given profession "via specific procedures put in place to respond to the crisis".[51] In legal terms, these suggestions represent little more than moral suasion, but illustrate the potential of existing legislation. Interestingly enough, however, none of these instruments insists on the IMI system as a powerful platform to ensure fast, safe and traceable communication between the competent national authorities.[52]

To manage the exchange of patients during the emergency, a vertical approach was preferred to a bilateral coordination between the national contact points set up under Directive 2011/24. The requests for assistance and signaled availabilities are to be recorded by the Commission on a summary table and processed through the HSC and the EWRS, but the Member States remain (of course) free to determine whether and when to ask for support, as well as to determine the details of transfers to hospitals and treatment. For expediency purposes, a general prior authorization should be considered and the reimbursement of all the expenses related to the treatment in the hosting public facility should be carried out directly by the Member State of affiliation. Again, these clarifications effectively create a new informal framework for handling the sanitary crisis outside the existing, fully functioning, 'ordinary' mechanisms.

Medical teams, PPEs and medical equipment were made available by a number of EU countries as a sign of solidarity and through rescEU, which, as noted above, ultimately relies on the voluntary contributions of the Member States.[53] Italy's difficulties in obtaining assistance and equipment through the UPCM during the initial stages of the outbreak are quite telling as to the shortcomings of a system based solely on spontaneous contributions in kind (helicopters, airplanes, medical teams), which can be withdrawn when least appropriate.[54]

The propensity towards a consensus logic in reacting and coordinating national countermeasures favors informal solutions over typical acts and flexible behavioral rules over strict legal obligations, thereby negatively affecting legal certainty and judicial protection.

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[51] Communication from the Commission, Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures – recommendations regarding Directive 2005/36/EC, C(2020) 3072 final.

[52] On the functioning, added value and shortcomings of the Internal Market Information System, see M. LOTTINI, *An Instrument of Intensified Informal Mutual Assistance: The Internal Market Information System (IMI) and the Protection of Personal Data*, 20 *European Public Law* (2014), pp. 107-125; G. HEIDBREDER, *Horizontal capacity pooling: direct, decentralized, joint policy execution*, in M. BAUER and J. TRONDAL (eds.), *The Palgrave Handbook of the European Administrative System*, Springer, 2015, pp. 369-382, at. 373 ff.; M. ELIANTONIO, *Information Exchange in European Administrative Law: A Threat to Effective Judicial Protection*?, in *Maastricht Journal of European and Comparative Law*, 2016, pp. 531-549 at 544 ff.

[53] Commission Implementing Decision (EU) 2020/414 of 19 March 2020 amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities, OJ [2020] L 82I, p. 1.

[54] It will, however, be conceded that the sanitary crisis generated by COVID 19 is unprecedented. On the general duty of assistance as a part of the right to health in international law see, in particular, Arts. 2 and 12 ICESCR, as complemented by General Common 3 (1990) and 14 (2000), respectively. See further, B. TOEBES, *International health law: an emerging field of public international law*, (2015) 55 *Indian Journal of International Law*, pp. 299–328. The decision to withdraw contributions and terminate assistance, indeed, could trigger the liability of the interested Member State. On the extent of the obligation during emergencies, see S. SIVAKUMARAN, *Arbitrary Witholding of Consent to Humanitarian Assistance in Situations of Disaster*, in *ICLQ*, 2015, pp. 501-531, at pp. 508 ff. and M. GATTI, IN A. SPAGNOLO, S. SALUZZO (a cura di), *La responsabilità degli stati e delle organizzazioni internazionali: nuove fattispecie e problemi di attribuzione e di accertamento*, Ledizioni, pp. 127-142, at pp. 133 ff.

However, it should not go unnoticed that the HSC has regularly met since 17 January 2020 and that national governments have by and large sought to coordinate their efforts within the UPCM. The activation of the IPCR mechanism by the Croatian Presidency on its own motion, and therefore independently of the activation of the solidarity clause, is also noteworthy in that it demonstrates the valuable contribution of the 2018 revision,[55] which injects more community method into the decision process and proceduralizes the management of emergencies. On the one hand, the Council and the COREPER are identified as crucial players in the implementation of the solidarity clause, as well as in securing consistency.[56] A leading role, especially in the activation, escalation and de-escalation of the IPCR, is attributed to the Presidency with the assistance of the Secretariat General of the Council, the Commission services and the EEAS, as well as the interested EU agencies and relevant stakeholders.[57] On the other side, the transparency of the decision-making process has been enhanced by detailing objectives, responsibilities, procedural steps and assessment criteria.[58] In particular, the Council has been entrusted with the task of developing a preparedness policy[59] and a communication strategy framework.[60] Normative improvements notwithstanding,[61] however, COVID-19 has made it abundantly clear that information concerning what is decided at the EU level does matter in terms of legitimation and its dissemination must be improved, together with the ability to tackle disinformation.[62]

4. Lessons learned

[55] Cf. Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response Arrangements, OJ [2018] L 320, p. 28.

[56] *Ibid*., Recitals Nos 2-5 and Art. 1(3). An important role is also recognized to the High Representative and the EEAS for crises with an external dimension (Recitals Nos 9 and Art. 4).

[57] The Presidency is competent to activate the ICPR in information sharing or full mode. The decision to activate the information sharing mode can be taken by the Presidency after hearing the affected Member States, the Commission and the HR or by agreement of the GSC, the Commission services and the EEAS, in consultation with the Presidency. Depending on the gravity, the Presidency could also opt for full mode, unless the solidarity clause has been invoked. In such case, in fact, the Presidency loses any margin of appreciation (cf. Arts. 2(1) and 4(1) and (6)). In addition, it is worth noting that with a view to guarantee timely consultations or decisions at European Council level, the Cabinet of the President of the European Council is invited to participate in the IPCR from the moment of its activation and for preparedness activities (Art. 13).

[58] *Ibid.*, Arts. 4, 6. To ensure an informed decision-making within the Council the implementing decision singles out four supporting instruments: a) informal roundtables (Art. 7); b) integrated situational awareness and analysis capability (Art. 8); c) dedicated and protected web platform for the exchange of information (Art. 9); d) central 24/7 contact point at Union level (art. 10). In relation to the first three instruments the implementing decision also specifies that they must be tailored, cover all the key sectors affected by the crisis, be integrated, detailed and delivered in a timely manner (Art. 4(3)).

[59] *Ibid.*, Art. 12. This policy includes the organization of tailored training on procedures and tools used in a crisis and cross-sectoral exercises, as well the definition of procedures and modalities for planning exercises.

[60] *Ibid*., Art. 14. *In concreto*, the Framework foresees the elaboration of common messages as part of the IPCR response measures.

[61] Cf. Art. 5 of Decision 2014/415/EU, cited *supra*.

[62] In its Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions *Tackling COVID-19 disinformation - Getting the facts right* (JOIN/2020/8 final), the Commission addresses the disinformation campaigns played out within and outside the Union involving actors such as Twitter, Facebook and Google. See also Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Tackling online disinformation: a European Approach* (COM/2018/236 final) and *EU Code of Practice on Disinformation* (available online).

COVID-19 taught us many lessons. For present purposes, only those which are believed to be most closely related to the overall preparedness and response strategy of the EU in the event of major cross-border health threats will be considered.

4.1. Lesson 1. A European strategy for health data

The absence of a complete EU toolset of shared, binding, adaptable indicators, benchmarks and protocols is responsible for the relatively low reliability and comparability of data collected, processed – by local authorities and by the ECDC – and then used to influence the political decision-making process.[63] This state of affairs is highly unsatisfactory and appears to be in striking contrast with the tenet, (re)affirmed in the Joint Roadmap towards lifting COVID-19 containment measures, according to which any normative intervention must be based on updated scientific knowledge.[64] As part of a wider network on global governance of health within the World Health Organization,[65] the Union and the Member States have long been gathering and sharing data, singling out and promoting best practices, and elaborating indicators and benchmarks to effectively anticipate and contrast epidemics.[66] In addition, technical standards and protocols are in the process of being developed in a vast array of fields related to healthcare protection (medical records, test kits, distancing apps, etc.). However, the fact remains that they are sectorial and voluntary. The leveling exercise on data facilitates the work of the ECDC and allows for greater accuracy and legitimacy in adopting lockdown and relief measures. A complete set of mandatory data to be acquired and notified must be developed. To be effective, however, these measures must be accompanied by a strengthened role of the ECDC, not only in surveillance and control activities, but also in providing assistance in orienting the policy maker. On the other side, the digitalization of public administrations, hospitals and other health facilities, and the implementation of eHealth solutions, enable the creation of a "federated European common health data space across all Member States for use in research, medical science and healthcare services, driving the development towards patient-centred and outcome-focused healthcare systems".[67]

4.2. Lesson 2. Streamlining the decision-making process

[63] As denounced in the Report by the OECD *Health in the 21st Century: putting data to work for stronger health systems* (available online), the health sector remains "data rich but information poor" (p. 21). On the real-world effects of poor preparedness and policies, see also S. Chakraborty, How Risk Perceptions, Not Evidence, Have Driven Harmful Policies on COVID-19 (2020) 11 *European Journal of Risk Regulation* 2, 236-239, at. 239. In particular, the author insists on the "negative psychological effects of severe social distancing measures, including posttraumatic stress symptoms, confusion and anger", which makes it even more important to follow comprehensive risk–benefit analysis and consistent risk communication to avoid decisions based on public fear (as opposed to reliable scientific evidence).

[64] The document was presented jointly by the President of the European Commission and the President of the European Council and is available online.

[65] M. BROBERG, *A Critical Appraisal of the World Health Organization's International Health Regulations* (2005) in *Times of Pandemic: It Is Time for Revision*, (2020) 11 *European Journal of Risk Regulation* 2, 202-209.

[66] The numerous initiatives in this area can be found at https://ec.europa.eu/health/indicators/echi/list_en.

[67] Report of the strategic forum for important projects of common European interest, *Strengthening Strategic Value Chains for a Future-ready EU Industry*, of November 2019, available online, p. 44. The Commission has already committed to propose sector-specific legislative or non-legislative measures on data governance to achieve this objective by 2030 (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A European strategy for data*, COM(2020) 66 final, p. 29).

Despite appreciable coordination efforts,[68] the co-existence of different mechanisms designed to address major cross-border threats to health – under Decision 1082/2013 or Decision 1313/2013 – is inefficient and makes it difficult to have an accurate overview of the multi-faced, multi-level, multi-disciplinary issues arising from events of such magnitude and complexity. The preference for intergovernmentalism over the community method is somewhat physiological when it comes to life-threatening situations, but potentially counterproductive: on the one side, it burdens the decision-making process; on the other side, it links operational capacity to the voluntary contribution of the Member States. In this regard, the Italian case reveals that – despite the creation of clearing houses – rescEU does not in itself secure the immediate, unhindered supply of PPE and medical equipment, nor the timely deployment of medical teams.[69] Moreover, it should not go unnoticed that the HSC is a "rather special animal, that is neither exactly under the Commission, nor under the Council's auspices"[70]. This is intended to safeguard national prerogatives in the field of health while ensuring technical assistance and support. However, risk management does require (a certain degree of) transparency and political accountability. With this in mind, it is believed that, in the event of cross-border health threats, a one-stop-shop mechanism would be more suited to ensure effective coordination between the various institutions, bodies, agencies involved in the process of assessing risk, and taking decisions during an emergency. The mechanism should ensure that measures are adopted in a timely fashion, duly motivated, grounded on reliable scientific evidence, proportionate and subject to judicial review. As suggested above, the (renewed) ICPR mechanism can prove to be an effective framework to ensure flexibility without endangering effectiveness, legal certainty and transparency.

4.3. Lesson 3. Resilience and centralization

The efficiency driven approach which followed the last economic crisis has weakened the resilience of the healthcare systems of the Member States. The instructions formulated by the Commission between 2011 and 2014 to reduce healthcare spending and/or privatize health services have left many Member States – in particular those based on the Beveridge model and with a high public debt – struggling to maintain adequate stockpiles of PPE, medical equipment and medicines, sufficient and rationally distributed hospital beds and ICUs, as well as trained staff. Thus, the blocks, delays and export bans. In this respect, the joint procurement procedures that have been organized with the support of the Commission and the adjustments which can be made to the export authorization scheme are appreciable ex post remedies, but insufficient to prevent systemic violations of Art. 35 TFEU – and, possibly, of Art. 35 of the Charter. In order to avoid the inefficiencies of the voluntary process a centralized EU capacity must be developed for the procurement of protective devices, medical equipment and medicines, including vaccines. On the other hand, the Member States must continue to invest in digitalization, sustainability and resilience, which as suggested in legal literature might also

[68] Cf. Art. 1(6) Decision 1313/2013, cited *supra*.
[69] See further H. DE POOTER, *The Civil Protection Mechanism of the European Union: A Solidarity Tool at Test by the COVID-19 Pandemic*, (2020) 24 *ASIL Insights* 7.
[70] A. DE RUIJTER, *EU Health Law & Policy. The Expansion of EU Power in Public Health and Health Care*, Oxford University Press, 2019, p. 128.

imply greater "centralisation in healthcare governance, especially to address health emergencies".[71]

4.4. Lesson 4. Regulatory challenges: essential equipment, professionals and patients

Certain aspects pertaining to the free movement of goods and professionals are crucial in health emergency situations and need to be further regulated. The uncertainty surrounding standards and marketing authorizations for PPEs and medical equipment not covered by specific EU law acts significantly delays the process of reconverting production and distribution to match the sharp rise in demand. On the other hand, as currently regulated, professional and patient mobility are inapt to respond to the urgent need for healthcare personnel and services. As to the former aspect, the automatic recognition procedure reserved to nurses, midwives, doctors, dentists and pharmacists, although expedited, can still prove burdensome in times of crisis. As to the latter aspect, instead, the rules on authorization and reimbursement procedures laid down in Directive 2011/24 are insufficient to remedy all the complications stemming from the reduced complementarity between the healthcare systems of the Member States. The Commission concerted with standardization bodies to facilitate production and marketing of personal and medical equipment,[72] adjusted the proportionality test applied under Art. 36 TFEU and subjected the exportation of PPEs to an authorization to cope with national restrictions,[73] promoted an extensive reading of the rules on the mutual recognition of professional qualifications to enable the free movement of health workers and recurred to the HSC to manage the exchange of patients between Member States through the EWRS. The soft law instruments adopted to avoid market disintegration and assist the healthcare systems – despite their non-binding legal nature – have to a certain degree imposed mutual trust, accelerated convergence, promoted administrative simplification and furthered complementarity. The advancements in the areas mentioned above, however, should be confirmed once the emergency is over by means of legislative acts adopted under Art. 114 TFEU, possibly in combination with Art. 168(5) TFEU.

4.5. Lesson 5. More own resources to sustain adequate healthcare expenditure

The EU budget is not sufficiently equipped and flexible to face a major sanitary crisis. Hence, heavy reliance on voluntary solidarity, which fuels the ill-founded dichotomy between the EU and Member States that feeds the sovereignist narrative purporting the idea that essential assets are subtracted from national resources. And yet, this is not the case. The contributions of the Member States to the EU budget are relatively low (not in the excess of 1.20% of the sum of all their GNI for payments and of 1.26% for appropriations for commitments) and the VAT

[71] A. RENDA, R. CASTRO, *Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic*, (2020) 11 *European Journal of Risk Regulation* 2, pp. 273-282, at p. 280.

[72] Commission implementing decisions 2020/437 (C/2020/1901), 2020/438 (C/2020/1902) and 2020/439 (C/2020/1903), of 24 March 2020 on the harmonised standards for medical devices, active implantable medical devices and in vitro diagnostic medical devices, respectively. In light of the pandemic, the EU legislator also adopted Regulation 2020/561 amending Regulation (EU) 2017/745 on medical devices regarding application dates of certain of its provisions, OJ [2020] L 130, p. 18. Allowing more time to comply with the standards laid down therein is intended to alleviate the pressure on the national healthcare systems and manufacturers facilitating the achievement of short-term priorities dictated by the spread of the virus.

[73] Commission Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorization, C/2020/1751, as amended by Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 (C/2020/1864).

call rate is contained (0.30% for all Member States except Germany, the Netherlands and Sweden that benefit from a reduced call rate of 0.15%). In addition, the EU budget follows the principle of equilibrium – whereby revenue and expenditure must always be in balance – and there is little room for financial creativity. The need to remain strictly within the boundaries of the Treaties in the monetary/economic realm has been made abundantly clear by the *Bundesverfassungsgericht* in its latest judgment on PPSP, which – above and beyond the disregard for the principle of primacy – casts serious doubts on the future of the PPEP.[74] A viable alternative to finance the necessary investments is to issue bonds on the financial markets on behalf of the EU using the difference between an increased own resources ceiling of the long-term budget, plus other (old and) new revenues to be foreseen in a revised version of the budget decision, and the actual spending as a guarantee. This is precisely what the Commission has proposed in its recovery plan - Next Generation EU.[75]

5. And now what?

5.1. Setting the coordinates for future action

The progressive inclusion of public health into primary law betrays a rather timid approach to life threatening problems. The important modifications and additions introduced by the Lisbon Treaty certainly contributed to further integration, but stop short of enabling a true European response to major health scourges like the present epidemic. To be sure, capitals have already started to challenge the EU's response to COVID-19 and have brought to the attention of the European Council "the need for stronger European cooperation in order to ensure better preparedness in Europe for future health pandemics".[76]

Many factors have influenced the decision to close borders, to stop the entry of goods and workers, and to ban exports of PPE and medical equipment: the resilience of the healthcare system, surveillance, monitoring and control capacity, (adequately trained) workforce and funding. What can be done to prevent this from happening again? As noted by the Commission back in 2009, "[C]oncerted action on health security and responses to health threats requires a strategic framework allowing both long-term policy planning and short-term emergency responses".[77] These concerns are singled out and confronted in the Roadmap for recovery, which is declaredly based on the assumption that "[A] functioning system of governance is a

[74] This judgment has triggered a heated debate in legal literature. See, amongst the many EU scholars who have harshly criticized the reasoning of the Karlruhe judges, G. Davies, The German Constitutional Court Decides Price Stability May Not Be Worth Its Price, (2020) *European Law Blog*, 21 May, G. TESAURO, P. DE PASQUALE, *La BCE e la Corte di giustizia sul banco degli accusati del Tribunale costituzionale Tedesco*, (2020) Il *diritto dell'Unione europea online*, F. MARTUCCI, *La BCE et la Cour constitutionnelle allemande: souligner les paradoxes de l'arrêt du 5 mai de la Cour constitutionnelle allemande*, (2020) *Le club des jurists* and J. ZILLER, *L'insoutenable pesanteur du juge constitutionnel allemand. A propos de l'arrêt de la deuxième chambre de la Cour constitutionnelle fédérale allemande du 5 mai 2020 concernant le programme PSPP de la Banque Centrale Européenne*, (2020) *Eurojus*, available online.

[75] The additional funding will be channeled through EU programmes and repaid over a long period of time throughout future EU budgets – not before 2028 and not after 2058.

[76] How to ensure EU's preparedness for pandemics of 9 June 2020, letter sent to the Commission by Denmark and signed by France, Germany, Spain, Belgium and Poland, accessible at https://www.politico.eu/wp-content/uploads/2020/06/Clean-How-to-ensure-EU-preparedness-for-future-pandemics.pdf.

[77] Commission Staff Working Document Health Security in the European Union and Internationally, SEC(2009) 1622 final, p. 9.

key requisite for overcoming the crisis and ensuring recovery".[78] The document advocates more resilience, efficiency and effectiveness, but also respect for the principle of subsidiarity, as well as the rule of law and fundamental rights.[79] As a matter of fact, the threat to the health and safety of citizens has *hélas* triggered illiberal reactions in some Member States, and even when not blatantly in breach of the values enshrined in Art. 2 TEU, the containment measures have provoked a heated debate in various EU countries. Moreover, as recently highlighted by the European Agency on Fundamental Rights, the lockdown strategies implemented at the central and local level have exacerbated discrimination, with evident prejudice to the principle of equality and human dignity.[80]

If these are the broad coordinates for exiting the crisis making the best of the experience developed in the past few months, the funds available under Next Generation EU should be invested across three pillars: namely, support to Member States with investments and reforms, kick-starting the economy, and addressing the lessons of the crisis. Against this background, it is suggested that with a view to implement the Recovery Plan EU action should in the future revolve around four main axes: governance, emergency regulation, reserves and resources, budget.

5.2. Governance of cross-border health threats

Governance of cross-border health threats must be institutionally solid, politically inclusive, and operationally flexible. The plethora of bodies involved in the management of public health in emergency situations is cause for concern, as is the voluntary participation/contribution of the Member States in the creation of a true common health area. Proper coordination and streaming will only work if Member States are genuinely willing to engage in the supranational management of sanitary crises, which also means that strategical fora like the e-Health Network[81] and the Network on Health Technology Assessment[82] must be exploited, and

[78] Roadmap for Recovery - *Towards a more resilient, sustainable and fair Europe*, of 15 April 2020, available online, p. 5.
[79] *Ibid*., p. 2.
[80] Cf. Arts 2 and 6 TEU and Arts. 1 and 21 of the Charter. Specific Reports can be found at https://fra.europa.eu/en/themes/covid-19. With specific reference to the ECHR context, see also A. SPADARO, *Select COVID-19: Testing the Limits of Human Rights COVID-19: Testing the Limits of Human Rights*, (2020) 11 *European Journal of Risk Regulation* 2, 317-325.
[81] The e-Health Network, was set up pursuant to Art. 14 of Directive 2011/24/EU (cited *supra*) and operates in conformity with Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU, OJ [2019] L 270, p. 83. This voluntary network connects national authorities responsible for eHealth to support and facilitate cooperation and the exchange of information. During the pandemic the Network has been involved in the development of distancing apps. Cf. Commission Recommendation of 8 April 2020, on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data, C(2020) 2296 final and eHealth Network Mobile applications to support contact tracing in the EU's fight against COVID-19, *Common EU Toolbox for Member States* of 15 April 2020, available online.
[82] The Network, set up under Art. 16 of Directive 2011/24 (cited *supra*), connects national authorities or bodies responsible for health technology assessment (HTA) with a view to provide strategic guidance and policy orientation for scientific and technical cooperation. More precisely, the Network carries out two kind of assessments: on the one side, the medical/therapeutic added value of technologies (so called Rapid Relative Effectiveness Assessment or REA); on the other side, the national and regional dimension of healthcare, such as, for instance, cost-effectiveness, budget impact, applicable legal framework (Full HTA). See also Commission Implementing Decision of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment, OJ

cooperation therein should no longer be considered optional. The system of parallel routes which can be pursued by Member States when reacting to cross-border health threats reflects the textual and conceptual stratification resulting from the current version of the Treaties but is far from efficient and effective. Surveillance, control and notification duties should be taken very seriously and enforced by having recourse – if necessary – to Art. 258 TFEU, tantamount to what happens when Member States breach internal market rules.[83] To be sure, adoption of public health related measures in response to the crisis were certainly not all notified; yet to the best of the author's knowledge no infringement action has been brought for violation of Decision 1082/2013.[84]

The prevailing consensus logic – typical of the intergovernmental method – burdens the decision-making process and tends to discourage resort to the EU level when time is of the essence but, as indicated above, the 2018 IPCR Decision does – at least to a certain extent – communitarize the process and suggests that the mechanism is a viable forum for planning and coordination purposes. Assuming that this trend will be confirmed and developed, what is missing is a greater involvement of the Parliament to ensure democratic control. However, regardless of the legal and technical arrangements, sound political decisions require a thorough understanding of the relevant systems and their specificities, which posits the need to access accurate, complete and uniform data and involve the relevant stakeholders. Hence, the viability of what could be called – borrowing the expression from the information management world – a "federated approach", which posits the ability to access information and communicate between disparate content silos (*i.e.* the national healthcare systems) and govern them under one umbrella, that of the EU. As advocated in the proposal to amend decision 1313/2013, of 2 June 2020, Member States should "improve disaster loss data collection at the national or appropriate sub-national level to ensure evidence-based scenario building" and the Commission should be able to "define Union disaster resilience goals to support prevention and preparedness actions".[85]

Especially in the coordination of medical responses during sanitary crises, a more prominent role should be recognized to the ERCC. Most notably, the enhancement of the Centre's operational, analytical, monitoring, information management and communication capacities would improve the ability to respond to pandemics like COVID 19 in a timely and effective

[2013] L 175, p. 71. In order to achieve more market access, guarantee a high level of health protection, avoid duplication and enhance sustainability, in January 2018 the Commission has presented a Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU COM(2018) 51 final, based on Art. 114 TFEU.

[83] With specific reference to goods considered as essential (*e.g.* personal protective equipment, medical devices and medicinal products), the Commission made it clear that: "[I]n case Member States do not sufficiently adapt their rules, the Commission will take legal action" (Communication on the economic response the pt. 3.1.). See also P. OLIVER, *COVID-19 and the Free Movement of Goods: Which Prevails?,* (2020) *EU Law Live,* 19 March, available online.

[84] National competent authorities are under an obligation to notify via the EWRS the emergence or development of a serious cross-border threats (Art. 9 of Decision 1082/2013), and to inform and consult the other Member States and the Commission on the envisaged public health measures to combat them (Art. 11(2)(3) of Decision 1082/2013).

[85] Proposal for a Decision of the European Parliament and of the Council amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism of 2 June 2020, COM(2020) 220 final, Art. 1 (amending Art. 6 of the Decision).

manner.[86] In addition, more powers should be carved out for agencies such as the European Medicines Agency (EMA) and the ECDC. Based on the experience acquired during the crisis, the former should be more involved in monitoring pharmaceuticals at risk of deficiency, as well as securing adequate communication with healthcare professionals, whilst the latter could be decisive in assessing when to activate and de-activate the emergency response mechanism, but also in monitoring national progress in terms of preparedness and resilience. Endowing these agencies with a stronger role begs the question of what standards should be applied in recruitment and what procedures should govern the selection process. The same applies to other bodies involved in the process of providing authoritative strength to the policy-maker, like the newly created panel of experts on COVID-19, a group of seven experts in epidemiology and virology, public health and crisis management from different Member States appointed in a personal capacity and entrusted with the task of formulating "science-based EU response guidelines and coordinate risk management measures".[87] Here, the credibility and independence of the policy-influencers is of the utmost importance and special attention must be paid to the background, qualifications, experience and motivation of the candidates.

5.3. Emergency regulation

A credible response capacity must also be able to count on an organic set of rules for emergency response planning and crisis management; it cannot rest on the adoption of atypical non-binding acts, some of which are not even published in the Official Journal.[88] The multi-layered normative framework resulting therefrom is difficult to reconcile with the principles of legal certainty, transparency and judicial protection. As suggested by some authors, many of the guidelines could and should be translated into legislative acts adopted on the basis of Art. 168(5) TFEU.[89] Attacks on the rule of law during the lockdown are widely reported and openly condemned.[90] The idea to link the enjoyment of the benefits deriving from the increased EU financial firepower to the absence of generalized deficiencies as regards the protection of the values enshrined in Art. 2 TEU law is undoubtedly welcome,[91] but transfers on the Union the burden of being unassailable in this respect. This calls for heavier reliance on typical binding measures and a conversion of some of the most far-reaching soft law instruments adopted

[86] *Ibid*., art. 1 (amending Art. 7 of the Decision).
[87] The panel, set up by virtue of a mandate by EU Member States, is chaired by the Commission President, Ursula von der Leyen, and co-chaired by Stella Kyriakides, Commissioner for Health and Food Safety.
[88] In this regard, public health is no exception: the tendency to rely on informal instruments during emergencies also characterized the EU's response to the migration crisis. See F. CASOLARI, *The unbearable 'lightness' of soft law: on the European Union's recourse to informal instruments in the fight against illegal immigration and the economic crisis*, in E. BRIBOSIA, N. JONCHERAY, A. NAVASARTIAN (sous la direction de), *L'Europe au Kaléidoscope. Liber Amicorum Marianne Dony*: Etudes européennes, Editions de l'Université de Bruxelles, 2019, pp. 457-468.
[89] A. ALEMANNO, *The European Response to COVID19: From Regulatory Emulation to Regulatory Coordination?*, (2020) 11 *European Journal of Risk Regulation* 2, pp. 307-316, at p. 316.
[90] Diplomatic statement of 1 April 2020 by Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Spain, Sweden (available online). On the progressive centrality that the rule of law has acquired in the EU legal order in the post-Lisbon era, see P. VAN ELSUWEGE and F. GREMMELPREZ, *Protecting the Rule of Law in the EU Legal Order: A Constitutional Role for the Court of Justice*, (2020) 16 *European Constitutional Law Review* 1, 8-32.
[91] Cf. Proposal for a Regulation of the European Parliament and of the Council on the protection of the Union's budget in case of generalised deficiencies as regards the rule of law in the Member States, COM/2018/324 final - 2018/0136 (COD).

during the emergency,[92] and maybe also revives the argument in favor of the Union's accession to the European Convention on Human Rights.[93]

Moreover, during the recovery process the EU institutions and the Member States should pursue further harmonization, standardization and coordination in the field of PPEs, medical equipment, healthcare professionals and patients. Particular attention should be paid to advancing convergence in the field of training of medical professions, including their numerous specializations. This could be done, for instance, by updating the conditions laid down in, and expanding the scope of, Annex V of Directive 2005/36. But nothing seems to prevent the EU legislator from dictating a specific regime applicable during a sanitary crisis, be it through the adoption of a dedicated act or an amendment to the directive. Securing inter-operability and portability of health data (*e.g.* for medical records and e-prescriptions), thus favoring the implementation of new health technologies such as m-health apps and telemedicine, should also be promoted through normative approximation in accordance with Directive 2011/24. Their tremendous added value when mobility restrictions are in place, especially for those affected by chronic diseases, has now become apparent, not only during a sanitary crisis.

Finally, the meaning of the new proportionality test put forward by the Commission in its Communication on a coordinated economic response to the COVID-19 should be clarified, if only in relation to pandemics and other serious cross-border threats to health. This could be done, *inter alia*, by spelling out in greater detail the assessment criteria indicated therein – namely, the concepts of clearly identified scope, actual needs and solid rationale[94] – and by introducing a system of prior notification of restrictive measures, along the lines of the Directive on regulated professions.[95] This could also be a good occasion to clarify the applicability of the case law of the Court of Justice on the public health derogation during sanitary emergencies, most notably in relation to the requirements of legal certainty, transparency, science-based justifications and coherent and systematic enforcement of the exception.[96] According to the Commission, restrictions must be duly motivated, supported by World Health Organization

[92] The extended use of soft law instruments in the field of State aid and antitrust law has attracted some criticism in relation to the legitimacy credentials of the authors, inefficient duplications, the lack of coherence and the unclear legal effects, with possible negative repercussions on effective judicial protection, accountability and effectiveness (O. STEFAN, *COVID-19 Soft Law: Voluminous, Effective, Legitimate? A Research Agenda*, (2020) *European Papers*, available online). To some extent, these shortcomings also affect the soft law instruments relating to goods, healthcare professionals and patients.

[93] P. CRAIG, *EU Accession to the ECHR: Competence, Procedure and Substance*, (2013) 36 *Fordham International Law Journal* 5, p. 1114-1150; B. DE WITTE, Š. IMANOVIĆ, *Opinion 2/13 on Accession to the ECHR: Defending the EU Legal Order against a Foreign Human Rights Court*, (2015) 40 *European Law Review*, p. 683-705 and P. EECKHOUT, *Opinion 2/13 on EU Accession to the ECHR and Judicial Dialogue: Autonomy or Autarky*, (2015) 38 *Fordham International Law Journal*, pp. 955-992. On 7 October 2019, the Council reaffirmed its commitment to accede to the ECHR (3717th Council meeting, 12837/19).

[94] *Coordinated economic response to the COVID-19 Outbreak*, cited *supra*, pts. 2.1. and 2.2.

[95] Directive (EU) 2018/958 of the European Parliament and of the Council of 28 June 2018 on a proportionality test before adoption of new regulation of professions, OJ L 173 [2018], p. 25. Further indications can be found in the Guidelines for border management measures to protect health and ensure the availability of goods and essential services (cited *supra*) according to which restrictions must be enshrined in public statements/documents, duly motivated in relation to the COVID-19, science-based and supported by WHO and the ECDC recommendations, relevant and mode-specific and non-discriminatory (p. 2).

[96] Cf. Case C-539/11, *Ottica New Line*, ECLI:EU:C:2013:591, para 47; Case C-169/07, *Hartlauer*, ECLI:EU:C:2009:141, para 55. However, it is important to underline that – partly as a result of the harmonization/standardization process in the field of goods – this case law manly concerns the freedoms protected under Arts. 49 (establishment) and 56 (services) TFEU, and not Arts. 34 and 35 TFEU.

(WHO) and ECDC recommendations and enshrined in public statements/documents.[97] At the same time, Member States are reminded of the need to "guarantee the supply chain of essential products such as medicines, medical equipment, essential and perishable food products and livestock". As mentioned above, this is intended to protect the lives of EU citizens and effectively federalizes the public health derogation, at least during emergencies. Yet the actual test to be applied is far from clear. For instance, with regard to the coherence and systematic enforcement requirement, could the presence of similar intra-state restrictions to guarantee a minimum supply of PPEs, relevant medical equipment and medicines justify a ban on exports under Art. 36 TFEU?

5.4. Reserves and resources

Resilience, sustainability and fairness can only be guaranteed if adequate reserves and resources are available. Preparedness requires, firstly, the leveling up of the current standards in terms of digitalization hospital capacity, workforce, stockpile of PPEs, medical equipment and medicines.[98] The investments recommended by the Commission and the Council in the context of the European Semester, and by the former institution in its Recovery Plan, are precisely intended to reduce the current notable gap between the Member States. The Recovery and Resilience Facility is designed to facilitate structural reforms, whilst InvestEU targets strategic private investments. On the other hand, a new ambitious Health Programme with a budget of €9.4 billion is expected to strengthen health security and prepare for future health crises. In this sense, EU4Health should constitute the cornerstone of a European health Union; and not only because of its consistence. A centrally managed programme can in fact highly contribute to the improvement of surveillance, accessibility, diagnosis, prevention and care, crisis-management, efficiency and resilience of health systems, cooperation and increase protection against serious cross-border health threats, both at the national and supranational level. Also, a €2 billion reinforcement of rescEU is envisaged and a total of €3.1 billion should be made available via grants or joint procurement managed by the Commission for emergencies response infrastructure (storage capacity, systems to transport medicines, doctors and patients). Secondly, preparedness cannot be guaranteed without a minimum intra-EU production of essential equipment. The crisis has highlighted the dependence on third countries like China and India for the supply of PPEs, active ingredients of medicines and medical equipment. Without having to sacrifice the benefits of globalization *tout court*, as well as those linked to free competition, the Commission is proposing a highly selective public contracting for the vaccine.[99] Thirdly, what is needed to prevent blocks, delays, export bans and speculations is a

[97] Cf. pts. 2 and 4 of the cited Guidelines on the availability of goods and essential services.

[98] The lack of accurate information on the situation in national healthcare systems is effectively represented by E.M. SPEAKMAN, S. BURRIS, R. COKER, *Pandemic legislation in the European Union: Fit for purpose? The need for a systematic comparison of national laws*, (2017) 121 *Health* Policy, 1021-1024. On the state of advancement of digitalization in the healthcare sector the reader is referred to the OECD Report Health in the 21st Century - *Putting Data to Work for Stronger Health Systems*, 2019, accessible at http://www.oecd.org/health/health-in-the-21st-century-e3b23f8e-en.htm and the Commission report on *Digital Economy and Society Index* (DESI) 2020, available online.

[99] Communication from the Commission, *EU Strategy for COVID-19 vaccines*, COM(2020) 245 final. Interestingly, the priority given to public health seems to outweigh the centrality of environmental protection in public discourse. To hasten the process, the Commission also proposes to temporarily lift the duty to obtain a risk assessment on possible GMOs used in the development of the vaccine (pt. 3.4.).

supranational, autonomously disposable stockpile of personal and medical equipment and material managed through clearing houses located at EU premises (and, possibly, independent emergency health facilities and trained healthcare personnel of EU officials).[100] This should also entail the power to take decisions as to where and when to allocate the pertinent resources (*e.g.* ventilators, protective gear, chemical supplies for tests, production and distribution of medication, medical teams) at the supranational level. The solution seems to be endorsed by France, Germany, Spain, Belgium and Poland: in a document entitled "How to ensure EU's preparedness for pandemics" – sent to the Commission on 9 June 2020 – they propose to "create a stockpile of critical medicines, protective gear, medical devices and vaccines that could supply the entire EU for three months in an emergency".[101] Although it is questionable whether a truly centralized command and control power can be envisaged without a revision of the Treaties, the Commission believes it should be able to define via implementing acts the rescEU capacities[102] and to "directly procure an adequate safety net of rescEU capacities in overwhelming situations such as a large-scale emergency".[103] Moreover, to guarantee the most effective territorial coverage during an emergency these strategic capacities should be pre-positioned and should be accompanied by "the necessary logistical, warehousing and transport capacity".[104] Nothing, however, is said in relation to the premises and the personnel involved in the management and allocation of the available resources, which would continue to be handled domestically.

5.5. Financial support

COVID-19 is a 'wicked problem' and it calls for a change in mindset and pace. Adequate funding is needed to recover from the crisis and face future threats. This can only be done by making sure that the Union is financially equipped the next time around. Resilience and preparedness require awesome investments in primary care and digital infrastructures, connectivity, cybersecurity and research. More own resources for the Multi-annual Financial Framework 2021-2027 mean more contribution of Member States but also other additional sources of revenue generated from the Emissions Trading System, a Common Consolidated Corporate Tax Base and a national contribution calculated on the amount of non-recycled plastic packaging waste in each Member State.[105] On the other hand, more flexible budgetary

[100] As noted by Renda and Castro, "[O]verstocking medicines at the national level is less efficient than doing so at the pan-European level" (cited *supra*, at p. 282).
[101] Cited *supra*, pt. 2.
[102] Proposal for a Decision amending Decision 1313/2013, cited *supra*, art. 1. According to the proposed new version of Art. 10(2) said capacities would be defined on the basis of identified risks, resilience goals, scenario-building and overall capacities and gaps. See also Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism, OJ [2019] L 77I, p. 1, art. 1 (amending Art. 11 of Decision 1313/2013, cited *supra*).
[103] *Ibid*., p. 6. See also, Recital No 10 of the Proposal. It should also be noted that in its vaccine strategy presented on 17 June, the Commission foresees the conclusion of contracts with pharmaceutical companies working on behalf of the Member States with advanced payments that can allow the upgrade of production facilities and the acquisition of raw material. *EU Strategy for COVID-19 vaccines*, cited *supra*, pts. 1 and 2.2. The risk acceptance by the Commission would be counterbalanced by the commitment to supply the vaccine to the Union when ready.
[104] *Ibid*., art. 1 (replacing Art. 23 of Decision 1313/2013, cited *supra*).
[105] According to the Commission these new Own Resources represent about 12% of the total EU budget. The proposed basket of new Own Resources includes: 20% of the revenues from the Emissions Trading System; a 3% call rate applied to the new Common Consolidated Corporate Tax Base; a national contribution calculated on the amount of non-recycled plastic packaging waste in each Member State (€0.80 per kilo).

rules should be introduced to allow for swift reinforcements when necessary.[106] The ongoing negotiations on the next MFF make it difficult to predict whether radical changes to the budget will actually be introduced. Indeed, although the need for more resources is broadly acknowledged, it should not be forgotten that pursuant to Art. 311 TFEU, the revision of the Own Resources Decision is subject to a unanimous decision by the Council, consent of the European Parliament and ratification in all Member States according to their constitutional requirements. For the time being, the decision on how to proceed is in the hands of the European Council, but the common debt argument no longer appears to be a taboo.

6. *De iure somniando*: some possible reforms ahead

6.1. Expanding the scope of EU action on the basis of the current Treaties

As recently argued "legal impediments to Union action are less restrictive than is commonly understood": the "web" of EU health competences supports a broader reading of the scope of EU action in this field.[107] Adhering to this line of thought – valuing a systemic interpretation of the Treaties – it is believed that many of the reforms and adjustments suggested above could be realized without a treaty modification. More coordination and complementarity in preparedness, risk management and research could be achieved through legislative and implementing acts, assisted, or not, by (mainly) interpretative soft law instruments, aimed at further aligning and strengthening the surveillance and response capacity of the national healthcare systems. However, no autonomous, freely disposable own-owned stockpile could be created, no binding centralized decision as to what resources to acquire and mobilize, as well as when and where to deploy them, could be fully in the hands of the EU institutions, nor could Member States be forced to gather certain minimum sets of data for response and communication strategy purposes. None of these measures could at present be reasonably expected to receive the sufficient political endorsement nor to stand judicial scrutiny.

Failure to reach an agreement within the Parliament and/or the Council could in principle trigger an enhanced cooperation pursuant to Art. 20 TEU. A group of Member States could, for example, decide to further cooperate in general and/or during emergencies, to follow common protocols, to improve standardization of data collection and sharing, to simplify administrative procedures relating to professional and patient mobility and to increase technical inter-operability. Given that the objective pursued is the enhancement of public health, the flexibility clause could in principle be activated to partly compensate for the lack of an explicit legal basis. Nonetheless, however cohesive the participating Member States may be in pursuing the complementarity of their healthcare systems, they would still have to be based on the treaties,

[106] However, it should be recalled that the European Parliament and the Council have set aside €2.7 billion from the budget for advanced payments under the Emergency Support Instrument. The latter also supports the Union Civil Protection Mechanism and rescEU, the Joint Procurement Procedures, the Coronavirus Response Investment Initiative and the European Structural and Investment Funds. In particular, €220 million are available to support the transport of medical equipment where most needed, the cross-border transfer of patients to guarantee treatment for as many people as possible and the transport of medical personnel and mobile medical teams to ensure access to medical assistance. The need to ensure flexibility for budget implementation during emergencies is also acknowledged in the Proposal for a decision amending decision 1313/2013, cited *supra* (cf. Recitals Nos 17, 18 and 25).

[107] See also, K.P. PURNHAGEN, A. DE RUIJTER, M.L. FLEAR, T.K. HERVEY AND A. HERWIG, *More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak*, (2020) *European Journal of Risk Regulation*, pp. 297-306, at p. 303.

be open and internal-market neutral.[108] As to the first requirement, the harmonization of domestic laws and regulations outside the areas mentioned in Art. 168(4) TFEU is not permitted, not even relying on the doctrine of implied powers.[109] In this sense, the judgement of the *Bundesverfassungsgericht* on the PPSP is a harsh reminder of the need to strictly comply with the principle of conferral and it is doubted that these legal solutions (*i.e.* the flexibility clause and the doctrine of implied powers) are actually capable of compensating for all the existing constitutional limits to health integration. Additional concerns are linked to the openness and market-neutrality of enhanced cooperation in the field of healthcare, which are more likely to bring together countries following similar models of healthcare.[110]

In the alternative, the Member States could pursue sustainability and complementarity[111] – which also discourages the adoption of self-inflicting restrictive measures – opting for bilateral and multilateral international treaties *inter-se*, outside the framework of the treaties. Since cross-border agreements, particularly between neighboring countries, are expressly encouraged under Art. 168(2) TFEU and Art. 10(3) of Directive 2011/24, the concern and distaste of the Court of Justice for this solution should not stand in the way of differentiated integration in the complementarity of healthcare systems,[112] which makes this a valuable, perhaps preferable and certainly welcome solution for the time being, but again not suitable to effectively react to pandemics at the EU level.

6.2. The Conference on the future of Europe and the elusive revision of the Treaties

Against the drawback of nationalistic argumentation channeled through the media and social networks, there are voices being raised in the academic, political, entrepreneurial and working communities, and in civil society circles, calling for more Europe. Even Angela Merkel hinted at the possibility, or the perspective, of treaty changes, albeit only after the pandemic. As is well known, the possible alternatives ahead should have been addressed within the Conference on the Future of Europe, initially scheduled for May 2020.[113] Despite the initially low

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[108] Arts. 326-334 TFEU.

[109] See *contra* G. TESAURO, *Senza Europa nessun Paese andrà lontano*, (2020) *Aisdue*, availabe online, p. 16. On the possibility (or need) to recur to Art. 352 TFEU, see also F. MUNARI, L. CALZOLARI, *Le regole del mercato interno alla prova del COVID-19: modeste proposte per provare a guarire dall'ennesimo travaglio di un'Unione incompiuta*, in *L'emergenza sanitaria Covid-19 e il diritto dell'Unione europea. La crisi, la cura, le prospettive*, (2020) *Eurojus – Special Issue*, available online, pp. 15-37, at pp. 34 ff.

[110] As pointed out by C. GERARDS and W. WESSELS: "Northern as well as Central and Eastern European MS are less likely to participate in [enhanced cooperations] than Western and Southern European MS" (*Enhancing 'Enhanced Cooperation': constraints and opportunities of an inflexible flexibility clause*, *College of Europe Policy Brief*, March 2019, p. 3). As a consequence, recourse to this instrument may increase the divide between richer and poorer countries.

[111] For instance, through consortia with universities. In this regard, the Franco-Belgian cooperation on the border - Organized zones for cross-border access to healthcare (ZOAST) - is particularly noteworthy as it testifies to the possibility to share sources and resources in the field of healthcare and to conclude framework agreements capable of replicating, *mutatis mutandis*, the successful experiences with neighboring countries, and generating potential economies of scale.

[112] As is well known, the Court of Justice admits that Member States entrust tasks to the EU institutions outside the framework of the treaties provided that, on the one side, the areas concerned do not fall under the EU exclusive competence, and, on the other, those very tasks do not alter the essential character of the powers conferred on those institutions under primary law. This has recently been confirmed by the Grand Chamber of the Court of Justice in the *Pringle* judgment (Case C-370/12, ECLI:EU:C:2012:756, para 158).

[113] See further F. FABBRINI, *The Conference on the Future of Europe A New Model to Reform the EU?*, (2019) *Brexit Institute Working Paper Series* 12, available online.

expectations, this may very well turn out to be an important turning point for the development of a more responsive and accepted European emergency public health policy. The Conference was planned to last for two years (with Germany starting first semester 2020 and France concluding first semester 2022 with EU Council presidency), and because of the pandemic has been postponed. And it is precisely by reason of the weaknesses in the Union highlighted by the pandemic that the European Parliament has expressed its determination "to start the Conference as soon as possible in autumn 2020".[114]

Although the trust in the EU has dropped significantly, health remains a key concern for citizens.[115] Should the Member States actually venture out in a treaty revision process, a radically different emergency response scenario could be envisaged: one where a minimum stockpile necessary to rapidly contrast major cross-border health threats is managed at the supranational level and where topical binding decisions can be taken by the Commission and/or EU agencies, and by the Council with a qualified majority vote (as opposed to the European Council by consensus), under the control of the European Parliament. Just like in the Member States COVID-19 has determined an overall centralization of power in the hands of the executive branch, so the federalization of emergency response presupposes the ability to make swift and life-saving choices in the interest of public health. The degree of acceptable delegation of power and agencification is a matter for speculation and will not be addressed here.[116] It will be agreed, nonetheless, that it is capable of defining the effectiveness of any future EU governance of cross-border health threats. At the same time, the surrender of national sovereignty in the management of pandemics postulates wider institutional modifications in terms of democratic representation and control.

A number of possible constitutional changes can be contemplated to prepare the Union for the next sanitary crisis. Legal technicalities aside, however, any serious reform rests on the premise that the protection of public health is recognized as a founding value of the Union. Solidarity is certainly at the heart of the healthcare systems of the Member States but it is also "closely linked to the[ir] financial arrangement".[117] The capacity to prepare adequately for, and react promptly, efficiently and effectively to major cross-border threats to health is about sharing resources, burdens and responsibilities; it is about vesting solidarity with a supranational vocation.

Although it will be conceded that, given the notable disparities at the national and sub-national level, "one-size-fits-all solutions are neither politically feasible nor normatively desirable"[118] and that compliance depends on flexibility, it is believed that further convergence, more transparency in the decision-making process, improved information and dissemination

[114] Resolution of the European Parliament of 18 June 2020 on the Conference on the Future of Europe (2020/2657(RSP)), pt. 8.
[115] Standard Eurobarometer 90 Autumn 2018, available online.
[116] H.C.H. Hofmann and A. MORINI, *Constitutional Aspects of the Pluralisation of the EU Executive Through 'Agencification',* (2012) *European Law Review*, pp. 419-443 and M. SIMONCINI, *Paradigms for EU Law and the Limits of Delegation. The Case of EU Agencies*, (2017) 9 *Perspectives on Federalism* 2, pp. 47-71.
[117] Council Conclusions on Common values and principles in European Union Health Systems of June 2006, available online. The document of the Health Ministers of the (then) 25 Member States is actually a 'kind response' to the expansive case law of the Court of Justice in the field of cross border healthcare management and assistance, from an internal market and competitional law perspective.
[118] G. FALKNER, O. TREIB, M. HARTLAPP and S. LEIBER, *Complying with Europe: EU Harmonisation and Soft Law in the Member States*, Cambridge University Press, 2005, 1.

strategy and clear, enforceable (and enforced) legal obligations are indispensable. To that effect, a first, relatively minor, change could be to expand the list of areas falling within the category of shared competences to grant the EU legislator more harmonizing power. In truth, this would not be a novelty as the draft Spinelli Treaty on European Union already foresaw the possibility to approximate "the rules governing research into and the manufacture, active properties and marketing of pharmaceutical products, the prevention of addiction, the co-ordination of mutual aid in the event of epidemics or disasters".[119] More recently, in its Resolution of 17 April 2020 on the EU's response to the COVID-19 pandemic, the European Parliament also advocated "greater powers for the Union to act in the case of cross-border health threats, with new and strengthened instruments to ensure that in future the Union can act without delay to coordinate the response at European level, and direct the necessary resources to where they are most needed, be they material (*e.g.* face masks, respirators and medicines) or financial, and enable the collection of quality, standardised data".[120]

The inclusion of aspects such as data standardization, training, protocols and administrative procedures, (as well as those mentioned in the Spinelli draft Treaty) among shared competences would of course also require an (extensive) amendment of Art. 168(5) and (7) TFEU. This provision is firmly chained with Arts. 2(5) and 6 TEU and thus cannot be modified pursuant to the expedited procedure of Art. 48(6) TEU. Should this epic change actually occur, Member States in any case must resist the temptation to tie the upgrading with unanimity. Rather, to facilitate the timely adoption of vital measures for EU citizens and the internal market it would be perhaps advisable to opt for a reverse qualified majority voting rule, at least in times of emergency.

If assisted by substantial, soundly allocated, well managed investments in resilience, digitalization, and accessibility of healthcare services, enhanced fiscal approximation and extended standardization, the harmonization of national laws and regulations in accordance with the modified internal market rules (*i.e.* including certain strategic aspects of public healthcare protection now included amid complementary competences) is capable of raising the level playing field, but far-reaching proposals might not stand the test of subsidiarity or proportionality. That is why it could even be argued – *somniando* can be translated with "daydreaming" – that in the case of major cross-border threats to health, the Union should have an exclusive competence. Similarly to what happens in relation to competition,[121] the institutions could be assumed to be competent to take the measures necessary to prevent the disintegration of the internal market. This, of course, would entail integrating Art. 3 TFEU (*e.g.* "the protection of public health in the event of major cross-border health scourges and natural or man-made disasters") and amending Art. 168(7) TFEU so as to allow the Union, for instance, to create adequate stockpiles of blood and organs reserved as supply for public threats. Naturally, this would also recommend the adoption of legislation clarifying competences and assessment criteria applicable to emergency situations. However, it follows from the above that, besides from being politically impossible, this option should be discarded. Indeed, especially during sanitary crises, the management of healthcare cannot prescind from the local

[119] Arts. 55 and 56 of the draft Treaty, available online.
[120] European Parliament Resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences (2020/2616(RSP)).
[121] Art. 3(1)b TFEU.

national/regional specificities and centralization of power can be ineffective, and even counterproductive, by virtue of the socio- economic, cultural and legal differences between the Member States.