

Chapter 2

Covid-19 and European Union health policy: from crisis to collective action

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Introduction: crisis and collective action

The European Union (EU) did not look particularly good or effective in February and early March 2020 during the first weeks of the Covid-19 crisis. For many, the EU scarcely merited mention. It appeared to be side-lined – not just incapable, but ignored by Member States as core tenets of EU integration such as open borders and the prohibition of export bans were flouted. Amidst panic, national interests dominated.

Looking back, from the perspective of the summer of 2020, the initial confusion is not what stands out. What stands out is how quickly European Member States began to work together in the midst of one of the largest public health crises they have ever had to face. For almost its entire history, the two salient characteristics of EU public health policy have been its weak legal basis and the minimal enthusiasm from Member States for creating significant health policy at EU level. Covid-19 is changing that. The scope and salience of the EU's action in health is poised to increase significantly in the coming period.

The immediate response of the EU through March and early April 2020 included coordinating the repatriation of stranded citizens, sharing and jointly building up relevant epidemiological knowledge, stockpiling key supplies, reopening borders for medical and critical goods, initiating joint procurement processes for medical and protective equipment, deploying health personnel, and releasing new funds for urgent health care spending. As the first wave of Covid-19 passed, proposals for longer-term measures began to emerge. In addition to a vaccine development strategy and acceleration of the upcoming pharmaceutical strategy, the European Commission rolled out an ambitious new health strategy – 'EU4Health' – which is poised to receive a budget of €1.7 billion (compared to the last budget of around €450 million) for the period 2021 to 2027 (European Commission 2020a).¹ Some commentators and Member States have criticised the response as insufficient, while others have called for the EU to play a greater role in responding to health emergencies and supporting the strengthening of national health systems. Whilst there are no formal proposals to expand the EU's formal health competences, the political space for reconfiguring EU health governance is wider and more salient than ever before. The question, therefore, is whether that space – as a window of opportunity presented by a pressing health crisis – might lead to greater health integration.

1. In May 2020, the Commission proposed a public health budget of €9.4 billion. At the European Council summit in July, this figure was reduced to €1.7 billion. The final budget is currently being negotiated by the European Council and the European Parliament and is due to be formally adopted before the end of the year.

Reviewing the weak legal basis that Member States have provided for the EU's health action, this chapter argues that the EU has responded to Covid-19 in precisely the way that Member States intended – as little more than a tool of national governments. We go on to show, however, that the formal delimitation that circumscribes the EU in crisis response has been relatively ineffective at preventing the growth of EU influence in public health in the past (de Ruijter 2019) and that crisis events and the critical junctures that they produce have often resulted in an expansion of the EU's role over the longer term (Greer 2009). Outlining the EU's public health response to Covid-19, this chapter assesses the current window of opportunity and reflects upon the future role of the EU in health. *Does an increased policy space, a larger budget and an ode to solidarity suggest the beginning of a more impressive and redistributive European health care union* (Vollaard et al. 2016), or *will the EU continue to practice an unstable form of health federalism, operating primarily as a regulatory state* (Greer 2020a)? Adopting a past-present-future framework, the remainder of this chapter is organised as follows: Section 1 reviews the historical development of the EU's health policy and the tools consequently available to it when Covid-19 hit. Section 2 describes how these tools have been utilised in response to the crisis and the proposed changes to EU health policy currently on the table. Finally, Section 3 looks to the future, discussing the prospects for change in light of the EU's response to Covid-19.

1. The past: the development of an EU health policy

The inclusion of health within EU structures dates back to the European Coal and Steel Community (ECSC) Treaty of 1951, which created a public health exception to the free movement of coal and steel workers, in the absence of appropriate social security arrangements. Health would continue to feature in this way, as a justifiable exception to free movement rules, for decades to come. Paradoxically, this framing would prove key to Brussels' expanded involvement in health (de Ruijter 2019: 63). In the context of an EU built through the construction and regulation of markets, this has given health policy three distinctive faces (Greer 2014): a) actions targeting public health; b) legislation affecting health but rooted in the internal market; and c) measures addressing health within the context of the fiscal governance framework. The three-faces framework makes clear the limitations put upon EU health action by the Treaties and the different tools of governance available to it when responding to a health emergency.

1.1 EU public health policies: establishing a limited crisis response capacity

Article 168(4) of the Treaty on the Functioning of the European Union (TFEU) gives the EU the competences to harmonise Member State health laws in the areas of organs and substances of human origin, blood and blood derivatives, pharmaceuticals, and measures in the veterinary and phytosanitary fields. However, with regard to taking incentive measures for combating cross-border health threats, ordinary legislation is required. Outside of Article 168 TFEU, the EU has a mandate to protect health via action on consumer protection, the environment, and occupational health and safety (OSH). The latter field, covered by Article 153 TFEU, has been particularly relevant

during the Covid-19 crisis, as workplaces quickly became key sites of transmission, offering another avenue for EU action. In other areas of health, the EU is restricted to ‘complementing’, ‘encouraging’ and ‘coordinating’ Member State initiatives which can be enacted through guidelines, indicators and monitoring. Here, it makes use of soft(er) powers, such as creating networking forums and platforms – the Platform on Diet, Nutrition and Physical Activity and the Alcohol and Health Forum being two key, if ill-fated, examples – to bring together stakeholders and seek consensus on necessary actions. The EU establishes hubs of expertise – the Expert Group on Cancer Prevention, the Expert Group in Health System Performance Assessment and the Expert Panel on Effective Ways of Investing in Health are all good examples – to feed into common guidance, best practice and recommendations. It also directly funds research and projects implementing its health objectives, usually via the EU Health Programme, a funding instrument to support common and cooperative health projects (see Section 2.3 below). It has ample regulatory powers to affect health, through Treaty articles on social policy, health, consumer protection, and environment as well as the internal market and its global profile, but it has not always been easy to utilise these in pursuit of health objectives (Bartlett and Naumann 2020).

Most pertinent to its crisis response and management capacities are (a) the EU’s tools for communicable disease control through monitoring and data collection; and (b) its mechanism for civil protection. Communicable disease control is a classic area of international cooperation where European countries have been working across borders with one another for over a century (de Ruijter 2019). As a special case, the EU has funded the surveillance of communicable diseases since the 1980s. The Bovine Spongiform Encephalopathy (BSE) crisis had a profound constitutional impact on the EU, leading to the Treaty of Amsterdam amendment giving the EU the power to harmonise Member State policies in the specific areas of organs, substances of human origin, blood and blood derivatives, and specific measures in the veterinary and phytosanitary fields. This was followed by an uncoordinated and inefficient response to the SARS outbreak in 2003, which led to the establishment in 2005 of the European Centre for Disease Prevention and Control (ECDC), a hub to coordinate monitoring and data collection, and the creation of Unit 3C within the European Commission’s Directorate-General of Health and Food Safety (DG SANTE) for responding to cross-border health threats. The ECDC’s task is risk assessment, supported by surveillance and monitoring, and the development of some public communication strategies, though it has also begun to develop some operational capacities and to deploy specialists to affected regions (Greer 2012). It is, effectively, a network of scientists, public health experts and national communicable disease bodies, loosely coordinated by a team of 300 staff at its headquarters in Sweden. Unit 3C coordinates joint procurement for medical countermeasures and its head chairs the Health Security Committee. The latter is part of the EU Health Security regime that developed after the swine flu outbreak but had already been in place, in an informal and intergovernmental manner, since 2001 in response to the 9/11 and anthrax attacks. Only after the adoption by the European Parliament and Council of the EU Decision on Cross-Border Health Threats (2013) did this regime become formalised. Depending on the severity of the threat under discussion, Member States are represented on the Committee by ministerial officials with relatively high clearance and the political mandate to decide on mutual coordination (de Ruijter

2019). The Committee relies directly on the work of the ECDC, which also has a seat at the table, as does the European Medicines Agency (EMA). The 2013 Health Threats Decision also provided for the establishment of the Joint Procurement Agreement (JPA). It facilitates the collective purchasing of medicines, medical devices and other goods or services, such as laboratory equipment or personal protective equipment, with sufficient financing to support high-volume purchases.

The ECDC has had a number of successes since its creation, but its role is constrained on two fronts. Firstly, risk regulation in the EU is split across levels, with the ECDC and the EU responsible for risk assessment and Member States responsible for risk management (Pacces and Weimer 2020). As such, whilst the ECDC can inform, guide and recommend, the EU generally lacks the power to intervene or implement public health responses. The swine flu pandemic of 2009 (H1N1) illustrated the implications of this stark division of responsibilities, as many Member States reverted to protectionist approaches despite European Commission attempts at coordination. A second constraint, following from the first, is that crisis response depends upon communicable disease control capacities, infrastructure and resources at national level. These vary significantly, with several studies highlighting the dangerously patchy infrastructures that exist across Europe (Elliot *et al.* 2012; Reintjes 2012; Speakman *et al.* 2017; Flear and de Ruijter 2019). Moreover, as demonstrated during Covid-19, coordination between national communicable disease actors is minimal, and the EU is hampered in supporting such coordination by the absence of a clear map of national public health laws, competent bodies and emergency preparedness plans (Alemanno 2020; Greer and Matzke 2012).

Whereas, despite its challenges, the ECDC's role in emergency response works relatively well, the Civil Protection Mechanism (CPM) – the EU's disaster risk management tool – is trickier to operate. The EU civil protection framework is based on the solidarity clause in the TFEU which posits, in Article 222, that in the case of a large-scale crisis, natural or man-made disaster, Member States (and European Economic Area (EEA) states, which are also CPM members) are to help each other and stand together in solidarity. Within the CPM, response capacity is pooled by Member States to ensure quick deployment in the event of a crisis. An Emergency Response Coordination Centre (ERCC) monitors global events and maintains direct links with relevant national authorities; should a crisis arise, any Member State can request assistance and draw on the European Civil Protection Pool, a reserve of resources committed by national governments. However, despite the creation of an EU medical corps, the alignment of these tools with the Health Security Committee is far from evident. In 2019, the CPM was upgraded and supplemented by RescEU, a financial instrument that provides a legal basis for the EU to purchase emergency supplies in case of a large-scale event. In this model, the EU co-finances Member States' acquisition and maintenance of the resources belonging to the Civil Protection Pool.

1.2 Health via the internal market

The second face of EU health policy is where its promulgation – despite the carefully circumscribed language of Article 168(5,7) TFEU that limits EU power to harmonise Member State law for public health and health care – is propelled by internal market activities and law. Though Member States tried to use the Lisbon Treaty to make clear that the organisation, financing and delivery of health services is a national prerogative, the Court of Justice of the EU (CJEU) has consistently ruled that health services do not enjoy a default exemption from the laws of the internal market.² The result is that the EU has had a sustained and significant impact upon health via the enforcement of the ‘four freedoms’ – free movement of goods, services, people and capital – that form the cornerstones of the internal market and over which the EU enjoys considerable legislative power. The process works by targeting Member State provisions that favour national businesses or citizens, forcing their removal and re-regulating from above. Examples of this dimension of EU health policy abound, including the regulation of professional qualifications for health workers, the provision of health services in other Member States, the authorisation of pharmaceutical products and patient mobility. The latter is a particularly good example of an issue in which concern for the internal market can drive a complex, far-reaching and politically sensitive piece of health care legislation that either ignores health altogether or addresses the wrong element of it (Glinos 2012).

The development of health policy as a by-product of internal market growth is thus a mixed bag. In some cases, tobacco control being a notable example, health actors have been successful in harnessing the EU’s extensive market powers for the betterment of health (Jarman 2018). The more common occurrence, however, is the development of policies that affect health without holding health as an objective. Moreover, regardless of which of these routes to EU health influence is followed, Member State attempts to ‘keep Brussels out of health’ have been repeatedly thwarted. The Working Time Directive and its role in determining shift patterns for health professionals, and the Patients’ Rights Directive and its requirement that patients be allowed to seek treatment abroad, are two prominent cases in point.

1.3 Fiscal governance of health

Rooted in the EU’s fiscal governance framework, a final face of EU health policy has been more recently institutionalised. Though its origins stretch back to the mid-1990s (Baeten and Thomson 2012), this third face was born of the crisis in 2010, initially as a series of bailout packages for countries struggling to recover from the sovereign debt crisis in Europe, and later as a long-term framework to prevent a recurrence and ensure economic stability. Representing a large proportion of national expenditure, health soon became a target of the European Semester – the EU’s annual fiscal planning framework – and the EU began to make Country-specific Recommendations (CSRs) to Member States, calling on them to, for example, increase ‘cost-effectiveness’ and

2. Case C-158/96, *Raymond Kohll v Union des caisses de maladie* (1998), ECR I-1931; Case C-466/04, *Yvonne Watts v Bedford Primary Care Trust, Secretary of State for Health* (2006), ECR I-4325.

ensure ‘health system sustainability’. Whilst these are, formally, recommendations, the Semester is a form of ‘harder soft governance’, meaning that it is formally non-binding but supplemented by a number of more binding elements which increase pressure for compliance and introduce the possibility of sanctions or penalties (Bocquillon *et al.* 2020). This explains how situations have arisen whereby, for example, in spite of the limitations imposed by Article 168 (7) TFEU – the EU instructed France to review its policy on medical school admissions, and Austria to set and achieve targets for moving treatment outside of hospitals (Greer *et al.* 2016). It is another example of how a carefully delimited mandate and minimal enthusiasm from Member States have failed to exclude the EU from the health sector (Baeten and Vanhercke 2017).

However, here again the side-effect of this non-health policy in the field of health has been to cause disruptions and exacerbate existing divergences between Member States. Consequently, the process has faced opposition, particularly in the context of the Semester and the austerity measures that its earlier cycles imposed. Health actors – including in civil society and forums of national and EU officials – have worked effectively to undermine it by increasing its consideration of health objectives, interests and progress indicators (Greer and Brooks 2020). Though more recent cycles of the Semester have achieved a better balance between controlling national expenditure and encouraging social investment, the system continues to exacerbate internal divergence between the wealthy ‘creditor’ states in the north and the poorer ‘receiver’ states in southern and central Europe, forcing the latter into a permanent periphery (Greer 2020a; see also Clancy 2020).

The legacies of austerity and market primacy have been laid bare by the onset of Covid-19. Historic underinvestment has resulted in huge variance in the capacity of national health systems to respond, as well as in the reach and resilience of the public health infrastructure and the underlying health status of populations. Moreover, the free movement of people has facilitated a brain drain in the health professions, with (predominantly eastern and southern European) doctors and nurses migrating to better-paid positions in other (predominantly western and northern) Member States, prompting concern that under-staffed health systems would struggle to cope.

1.4 A constrained health policy and crisis response competence

The three faces of EU health policy, the way in which they have developed historically, and their potential trajectories in the aftermath of the current crisis are underpinned by the EU’s status as a regulatory state (Majone 1996). Rather than making use of the full range of taxing, spending and distribution tools available to governments, the EU relies heavily on regulation. Moreover, it is a special kind of regulatory state, in that its treaties instil a bias for regulation which is market-promoting, as opposed to that which compensates losers or cushions the impact of imposed rules (Scharpf 2002). This has its advantages. It enables the EU to function on minimal resources, since implementation of its regulations – the bit that costs money – is done by national governments (Page 2001), whilst enforcement is provided by national courts (Obermaier 2009; Kelemen 2011; Martinsen 2015). But it also removes from the EU’s toolbox some crucial components

of health policy, such as the financing of welfare programs or the redistribution of income via social policies and organising interstate solidarity. The three faces of health policy described above are a direct result of this constitutional asymmetry and are consequently driven by a neofunctional logic (Greer 2006; Kumm 2006a, 2006b). The steady expansion of the internal market requires continual regulation – be it to facilitate the provision of health services across borders, the movement of health professionals, or the sale of pharmaceuticals in different markets – which the EU provides. The inherent demand for further measures is met and pushed along by committed and strategic ‘entrepreneurs’ within the EU institutions (Haas 2004), who employ a strategy of creative opportunism and shape the health agenda (Cram 1994), as seen when the Court began to engage in health care law in the late-1990s (Brooks 2012).

The EU does however engage in some forms of redistribution, most notably through its various structural funds and its extensive research programmes (de Ruijter 2019). This applies to health too – structural funds can be used to finance health infrastructure, for instance modernising hospitals or procuring new medical equipment, while the Health Programme redistributes funds for health projects and initiatives, such as the development of common registries for rare diseases or networks of organisations working on similar issues. However, a stark imbalance persists, limiting what the EU can hope to achieve in health. Relying on regulation means that it can forcefully create a competitive market for health goods and services, but it cannot affect the distribution of an individual’s entitlement to said goods and services in their given Member State. This means that it can support, for instance, the development of a new vaccine, but cannot ensure that such an innovation will be evenly enjoyed across the EU (Hervey *et al.* 2017: 8-9).

2. The present: the EU health policy response to Covid-19

As outlined above, the imbalance in the EU’s regulatory and welfare roles, as established by Treaties at the behest of the Member States, limits its capacity in situations of immediate emergency. But as we have seen in Section 1, such crises can open windows of opportunity for longer-term institutional and legal change.

2.1 Initial crisis response

The EU’s role in the event of a crisis, under the existing legislative framework, is to support Member States in their response, acting as a hub for expertise, information and, theoretically, coordination (Hervey and McHale 2015; Flear and de Ruijter 2019). It has two resources at its disposal – its health security regime, including the ECDC and the EMA, and its regime for civil protection under the European Commission’s DG for Humanitarian Aid and Civil Protection (ECHO).

When we observe the initial response of the EU from a longitudinal perspective, comparing it with, say, the BSE and the swine flu outbreaks (de Ruijter 2019), the regimes now in place have brought some notable improvements. Whereas the swine

flu response at the level of the health ministries in the capitals was fully informal and intergovernmental, after the 2013 adoption of the Health Threats Decision (European Parliament and Council of the EU 2013), Member States had some established working methods and decision-making tools at their disposal. Clearly there is still some work to be done in situations where the emergency threatens all Member States; Italy's plea for help was ignored despite the presence of formal coordination mechanisms, as governments sought to protect their own supplies in the face of imminent threat. Indeed, a review of the minutes of the Health Security Committee³ shows in a staccato manner how information and decisions made at national level are shared and coordinated between Member States. Furthermore, the ECDC and the EMA were at the table in this context at all times.

In this regard the ECDC seems to have performed well within the confines of its purview. Pertinent data was collected and circulated and, though Member States generally did not rely solely on the EU (or the World Health Organization (WHO), for that matter) for guidance and information, the ECDC utilised its network of national contact points and fed into state-level committees and structures. The Commission, meanwhile, created a Clinical Management Support System – a variant of its successful European Reference Networks, which connect experts on specific rare diseases – and used this to facilitate communication between clinical professionals. Moreover, the Health Security Committee played its role and, once the initial series of knee-jerk, protectionist reactions had become untenable, was able to coordinate Member State responses and initiatives, for instance on joint procurement.

Slower to mobilise, it seems like the Civil Protection Mechanism worked in parallel rather than in deep coordination with the Health Security Committee process. Nonetheless, medical teams from Norway and Romania, and disinfectant from Austria, were dispatched to Italy in early April. Pre-existing weaknesses in civil protection were becoming apparent, however. The CPM primarily functions as a match-making service, coordinating the donation of pre-committed resources from countries with surpluses to countries in need, with the addition of some European reserves via RescEU. Since it depends on the willingness and ability of countries to contribute, however, the CPM does not work so well when all countries are experiencing shortages of the same things and are increasingly fearful for themselves (Greer *et al.* 2020). At the same time, there was the parallel process within the Health Threats Unit in the then DG Health (now SANTE) where there was already some experience in joint procurement of influenza vaccines. In this context, while funds and stocks remain at the participating Member States' disposal, there are many potential advantages in terms of purchasing power, negotiating positions and even solidarity exchanges. The current regime was built up to counter the inefficiencies resulting from a lack of solidarity in the response to swine flu. And although there are still many bridges to cross in this respect, the experience gained through previous purchases seems to have helped in the joint procurement of medical equipment for Covid-19. By contrast, the purchasing done in the context of the CPM through RescEU is fully centralised through DG ECHO and needs only

3. The minutes of the Health Security Committee can be accessed here: https://ec.europa.eu/health/hsc_covid19_en

one participating Member State. While increasing its potential for centrally deciding on solidarity exchanges, however, this diminishes the funding available for creating stockpiles of medical supplies and pits the EU against the Member States as all states and the EU are attempting to purchase in the same markets (European Commission 2020b). Nevertheless, various supplies have been purchased in the EU context for Covid-19, including ventilators, personal protective equipment, pharmaceutical products and laboratory equipment, with resources dispatched to Spain, Italy and Croatia by early May 2020.

Beyond the public health policy framework, the EU has also made use of its OSH mandate. SARS CoV2 was added to the list of agents in the Biological Agents Directive in June, though not in the highest risk category, and without the adaptation and amendment of other key aspects of the directive that trade unions argue are vital to protect workers, including health care professionals (European Trade Union Confederation 2020a). This is an avenue with potential to affect health care professionals, particularly as the EU prepares its new Strategic Framework on Health and Safety at Work, as requested by the Council of the EU (2019).

2.2 Defending the market and supporting national economies

As seen in the migration crisis and Brexit, for instance, the four freedoms, usually held to be foundational to the existence of the EU, come under pressure in times of crisis. As Covid-19 hit, state after state imposed restrictions on the free movement of goods and people, closing borders and issuing export bans. In addition to resting on a weak public health evidence base, in the case of closing borders to people, these actions directly contravened the norms of the internal market and solidarity. The Commission reacted quickly by threatening infringement proceedings against Germany and France for their export bans. At the same time, the internal market was protected by initiating an EU-wide export ban to third countries. With regard to this course of action, there was an initial indication that the internal export bans and lack of solidarity would reveal weakness – *surely national governments would be more concerned about maintaining control of national stockpiles than legal action by the Commission?* – but a taskforce of reviewing Member States was created to establish a stronger peer-pressure mechanism (de Ruijter *et al.* 2020a). In practice, bans were quickly lifted. Removing restrictions on individual mobility has proven harder, but coordinated European decision-making has emerged under the leadership of the Justice and Home Affairs (JHA) Council, which leads Council actions on border management and migration, among other issues. Interestingly, health care workers were among those exempted from travel bans, and EU measures have continued to focus on the free movement of critical workers. Guidance adopted in April urged Member States to facilitate ‘smooth border crossing for health professionals’, without mention of staffing capacities in these professionals’ domestic health systems (European Commission 2020e).

Temporary flexibilities have also been adopted in other areas of the internal market; for instance, the EU's stringent competition and state aid regimes have been relaxed to permit government subsidies for small- and medium-sized enterprises (SMEs) and wages, as well as the channelling of government funds to strategic industries and sectors, including health. In March 2020, for example, the Temporary State Aid Framework was used to approve an Italian scheme to support the production of medical devices and personal protective equipment (European Commission 2020f). Perhaps the most interesting – and potentially most significant – development in the market-health conundrum that has underpinned EU health law and policy in the last decades is the EU's reinterpretation of a key facet of internal market law. In its 13 March 2020 Communication outlining its planned action and responding to the growing number of national export restrictions on essential supplies, the European Commission re-interpreted the legal framework for public health exceptions to national market barriers. It acknowledges Member States' long-established right to adopt trade restrictions where necessary to protect public health, as set forth in Article 36 TFEU and in 'rule of reason' case law, which requires that both the positive and negative effects of a measure be used to determine whether it violates free movement law.⁴ In its depiction of this key derogation, however, the Commission introduced a remarkable new interpretation. Whereas the restriction of free movement had historically been justified with regard to the protection of *national* public health, the March 2020 Communication states that the legality of restrictions will be judged according to their impact upon 'the objective of protecting the health of people living in Europe' (European Commission 2020c: annex II, note 2). Hence, the Commission importantly floated the idea of a re-interpretation of the public health derogation that is based on a notion of European public health and solidarity, rather than that confined to the nation state (de Ruijter *et al.* 2020a).

A similarly remarkable step towards solidarity has been seen in the third face of health policy, within the fiscal governance framework. Whilst the European Central Bank freed up cash for businesses and went about ensuring stability in the Eurozone (see Myant, this volume), the EU moved quickly to enact the 'general escape clause', which relaxes the stringent rules on budget deficits and national expenditure. But it then went further, making an unprecedented decision to issue common European debt to finance responses to the Covid-19 crisis. Far from the conditionality-laden bailout packages provided at the height of the economic crisis in the early 2010s, and thus embodying something of the solidarity that was refused during this period, this would also include a role for the EU in allocating the funds. Though the Council diluted, altered and cut several aspects of the Commission's original proposal, re-balancing control of the funds in favour of Member States, it would be inaccurate to characterise the deal as anything less than a significant intensification of European integration. Moreover, on 20 May 2020, the European Commission issued its CSRs as part of the Semester cycle.⁵ In contrast to previous years, in which around half of Member States received recommendations related to health, these were issued to every Member State. The recommendations call for measures to enhance the resilience of national health systems, marking not only the

4. Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* (1979) ECR 649.

5. The 2020 CSRs can be accessed here: <https://bit.ly/2G6mize>

first instance of universal health-related recommendations but also a clear recognition of the importance of health systems within the fiscal governance framework.

2.3 Post-Covid recovery measures: a new EU Health Programme

As the first wave of Covid-19 passed, space to consider appropriate next steps opened up. Quick to capitalise on this, the European Commission proposed a new EU Health Programme. EU health programmes fund collaborative projects contributing to the EU's wider health strategy. Since 2003 they have been integrated into a series of multi-year instruments; the first covered the 2003 to 2007 period, the second ran from 2008 to 2013, and the third from 2014 to 2020. The programmes identify a set of objectives and issue calls for grants and tenders, often jointly financing activities with public authorities, civil society organisations and research institutions (European Commission 2014). Their budgets are small: the €413 million budget originally proposed for the latest programme, comparable to the budgets of previous programmes, was described as 'pocket-money' by Commission Vice-President Margaritis Schinas (European Commission 2020d). The proposed budget for the revised 2021–2027 EU4Health programme, agreed as part of the Covid-19 response, stands in stark contrast and offers €1.7 billion. Though far short of the €9.4 billion proposed by the Commission in May, this four-fold increase gives health unprecedented salience within the EU budget. Moreover, the proposal reverses an original plan to roll the Health Programme into the much bigger European Social Fund Plus, instead reinstating a standalone health policy instrument.

The 2021–2027 EU4Health programme has three priorities: protecting people from cross-border threats, improving the availability of medicines and strengthening health systems. These priorities are to be pursued via ten specific objectives (see Box 1). The programme retains the objectives of the original proposal and is not dissimilar to the objectives of previous health programmes, which generally identify cross-border health threats and health security as areas of particular focus. The text also states that the 2021–2027 programme will give priority to Covid-19 response measures and to preparedness measures to mitigate the threat of future crises, and the Commission has noted that action points on crisis resilience will be frontloaded into the first years of the programme (European Commission 2020d). However, the programme takes a holistic approach, recognising that the ability of health systems to respond to a crisis is determined by their overall resilience and sustainability, in turn shaped by the health of the populations they serve. As such, it would seem that an effort is being made to ensure that other elements of health also benefit from the prevailing salience of EU health action and interest in its strengthening.

Box 1 The proposed EU4Health programme

The EU's fourth health programme (2021–2027) has ten specific objectives.

1. Strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;
2. Ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of medical, health care and support staff to be mobilised in case of a crisis;
3. Support actions to ensure appropriate availability, accessibility and affordability of crisis relevant products and other necessary health supplies;
4. Strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, the uptake of digital tools and services, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health;
5. Support actions aimed at strengthening health systems' ability to foster disease prevention and health promotion, patient rights and cross-border health care, and promote the excellence of medical and health care professionals;
6. Support action for the surveillance, prevention, diagnosis, treatment and care of non-communicable diseases, and notably of cancer;
7. Foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, and more environmentally friendly production and disposal of medicines and medical devices;
8. Support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;
9. Support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the European Reference Networks and other transnational networks;
10. Support the Union's contribution to international and global health initiatives.

Source: European Commission (2020a).

The EU4Health Programme is accompanied by an EU Vaccines Strategy, published on 17 June 2020, and will soon be supplemented by a Pharmaceutical Strategy, due for release at the end of 2020. The latter will address longer-term issues, such as access to medicines, pharmaceutical supply chains and innovation in the sector. Meanwhile, the Vaccines Strategy seeks to develop, manufacture and distribute a vaccine for Covid-19 – a process which might normally take ten years – within 18 months. It is a centralised mechanism, adopted by the Commission and implemented jointly with Member States. Within it, the EU signs advance purchase agreements with pharmaceutical companies on behalf of Member States and coordinates the supply and distribution of the eventual vaccine. Marking a significant change, this can be seen as a response to the revealed weaknesses of the existing JPA and mechanisms under RescEU. Though giving the Commission a bigger role in allocating procured goods, RescEU has access to less funding. Since Covid-19 struck, four calls for supplies have been launched, but protectionist national measures thwarted the mechanism in the early phases of the crisis and the framework remains intergovernmental, voluntary and too slow to respond to urgent needs (de Ruijter *et al.* 2020a: 18). The Vaccines Strategy seeks to address this by giving the EU – including the EMA as the centralised body responsible for the rules around product trials, authorisation and marketing – a greater role.

3. The future: a window of opportunity?

An overview of the EU's health competences and its public health response to Covid-19 to date reveals two important things. First, the pandemic has shown that the EU's capacity to act as a first responder, or even as a coordinator of first responses, is weak. The health security and pandemic preparedness mechanisms that exist have worked as designed, but they constitute a small and unambitious system whose capacity is limited by Article 168 TFEU (Greer *et al.* 2020). Second, it has shown that health solidarity can buckle under the pressure of a crisis, even if, in contrast to the swine flu experience, solidarity has to some extent been regained. This is a remarkable development, given the much higher stakes in the Covid-19 pandemic. In challenging the egotistic behaviour of Member States, the European Commission has now found space to advance a significant reinterpretation of the rules, with the potential to underpin an expansion of EU health policy. Health policy through the market has always been the most important face of EU health policy, so it is fitting, if ironic, that a potential re-interpretation of the EU's public health exception may now come about because of efforts to safeguard the internal market.

In sum, a window of opportunity has opened to reform the EU's role in health (see the discussion on the 'crisisification' of health care policies in Vanhercke *et al.*, this volume). The question, then, is to what extent the changes proposed to date would represent a significant integrative step, and what the prospects of such integration in the health sector are, given the reluctance of Member States to cede competences in this area.

3.1 A shift towards solidarity-based European health governance?

It should first be noted that full-scale Treaty change, formally transferring power to the EU and perhaps affording it a greater redistributive role in health, does not seem likely. Despite some early calls for this,⁶ such a reform is not currently on the table. Given the degree of consensus needed – unanimity, plus a series of high-stakes national referenda and ratifications – formal integration and expansion of competence are unlikely in the immediate future, with consensus reigning among EU health scholars that constitutional change is anyway unnecessary. Although there are limitations, and for constitutional reasons a Treaty change would be preferable, in principle the EU already has many legal tools for health law and policy making; these simply need to be interpreted more holistically and supported politically (de Ruijter 2019; Purnhagen *et al.* 2020).

The initiatives proposed in the EU4Health Programme and the ideas advocated by various commentators and observers focus on weaknesses in current systems and mechanisms, broadly identifying three areas where the EU's role should be strengthened

6. The European Trade Union Confederation (ETUC 2020b) was among those calling for an increase in EU health competences. Moreover, the weakness of the existing competence was commonly cited in response to criticisms of the EU's role during the pandemic – see, for instance, Health Commissioner Kyriakides in response to MEPs' questions on 21 April 2020. <https://bit.ly/35WYayX>

and extended: (a) the surveillance of epidemiological data, including the monitoring of threats to health and the capacities of the ECDC in this regard; (b) the funding of research into vaccines and treatment for Covid-19 and future viruses; and (c) a collective health security and emergency response (Forman *et al.* 2020; de Ruijter *et al.* 2020b; Greer 2020b; Paccès and Weimer 2020). These ideas fit in with a conception of public health and health security as public goods and of the EU as the appropriate level at which these might be provided (Pisani-Ferry 2020). They also represent, for the most part, an extension or intensification of existing areas of activity, rather than new EU roles. The ECDC was set up precisely to provide epidemiological surveillance, while the abovementioned Health Threats Decision reiterated and formalised the potential high-level involvement of Member States in emergency response. Increasing the resources and capacity of the ECDC or the Health Security Committee, for instance, would be an uncontroversial decision. Similarly, the EU has a well-established research funding architecture (specifically including health) and investing more – potentially earmarking funds for developing specific vaccines or treatments – would be another step we can expect.

Health security, particularly where it involves the creation of stockpiles and the centralised distribution of the stockpiled supplies, might prove more contentious. The EU Vaccines Strategy discussed in Section 2.3 provides for the EU to take responsibility not only for coordinating development and production of a Covid-19 vaccine, but also for the allocation and distribution of available stocks among Member States. Similarly, the RescEU emergency stockpile and the EU4Health long-term stockpile initiatives put the EU, specifically the Commission, in a central, distributing role. Marking a considerable step forward, these initiatives plug an important gap in the current regimes, which are voluntary and intergovernmental. Another interesting element to watch unfold will be how much emphasis is put upon the health system strengthening aspect of health security and preparedness planning. Similarly, this role might be extended to renewed EU action on non-communicable diseases as core contributors to morbidity and mortality associated with Covid-19, whilst the European Semester's narrow concern with financial sustainability seems to have given way to calls for greater health system resilience. Though health systems' organisation and financing are a national responsibility, diverging public health capacities present a clear threat to collective health security; though the wording in the EU4Health proposal is soft (emphasising 'support', 'coordination' and 'promotion'; see Box 1), a renewed commitment here may see EU involvement in health systems and health promotion increase.

Considered alongside a reinterpretation of the public health exception for internal market barriers and the proposal for the first-ever shared European debt, the changes afoot in EU health governance are significant. Little is guaranteed – the timeframe in which attention and enthusiasm is focused upon health will be short – and, once the crisis has passed and memory of it has faded, financial and political support may again dwindle. But in the context of historical EU health policy development, they are major steps forward.

3.2 Prospects for long-term change

What will determine the extent and success of the post-Covid-19 EU health policy framework? The short answer is: Member States. Intergovernmentalism, one of the two core theories explaining why and how integration of the EU has developed, tells us that integration only happens when Member States perceive it to be in their interest. The history of EU health policy shows us that this is not true, at least not exclusively. Rather, and as neofunctionalism, intergovernmentalism's sparring partner, suggests, integration can gain a momentum of its own, proceeding in the absence of Member State support, or even in the presence of explicit opposition. Predictably both theories have merit; Member State support is crucial to integration in some instances, and less important in others. The establishment of a patient's right to claim from their national health system for the cost of treatment obtained in another Member State did not require the support of national governments. In fact, it was secured over quite significant opposition via the courts. Approving a €1.7 billion standalone health programme, thereby reversing a previous trend of side-lining EU health policy, was also relatively straightforward. The presence of a crisis and its political salience were enough to facilitate this significant decision. Granting the EU extensive new health powers, however – whether via formal Treaty change or an expansion of existing activities – will require a degree of political will.

Historically, when comparing the position of Member States on EU health action, there has been a broad and crude division between large and small states. Large states, which generally (though not exclusively) have strong health systems and money to invest in them, are not in favour of EU involvement in health. Smaller states, often with weaker health systems that are losing health professionals to richer systems and have more to gain from pooled expertise and resources, support a greater EU role. Within this rather crude grouping there are further divisions – Germany, Poland and historically the UK have opposed almost all health cooperation, whilst France, Italy and Spain have engaged in voluntary action. Similarly, the enthusiasm of Malta, Ireland, Belgium and others has been counterbalanced by the scepticism of Bulgaria, the Czech Republic and Denmark, which favour Europeanisation only where it affords full respect to national sovereignty (Kirch and Braun 2018). Sovereignty was a key theme of the proposal for increased action put forward by Emmanuel Macron and Angela Merkel at a joint press conference in mid-May 2020. The French and German leaders called for change that 'takes the European dimension of health care to a new level' and establishes 'strategic sovereignty' in the health sector. By this they refer to collective research and development capacities, the stockpiling of strategic goods, increased capacities to produce such goods within the EU, coordinated procurement, uniform health data standards and the creation of an 'EU Health Task Force' within the ECDC to lead the development of prevention and response plans (Federal Government Press and Information Office 2020). Reflected in the EU4Health Programme, most of these proposals build on calls for cooperation from the leaders of Belgium, Denmark, France, Germany, Poland and Spain (Momtaz *et al.* 2020), and on proposals tabled by the European People's Party (EPP 2020) as well as the Socialists and Democrats (S&D 2020).

As to the constitutional and political procedure that might be involved in changing the role of the EU in health law and policy, the continued interest and involvement of actors like the ECDC and the Health Security Committee, and the extent to which this is invited by the European Commission, will also have a bearing on the longer-term prospects of the EU4Health Programme and a strengthened EU health policy. The Commission faces a choice: *should it capitalise on the issue salience provided by Covid-19 to openly proclaim its stake and role in health, to politicise its proposals by involving the European Parliament in budget allocation and priority-setting, and to flesh out an ambitious agenda on health system strengthening, inequalities and health determinants, for instance? Or should it opt for a softer, more technocratic model of implementation, resting more heavily on the ECDC and EMA and channelling its health systems role via the EU4Health and the European Semester?* The text of the EU4Health proposal indicates that the dramatically increased funding envelope will continue to be allocated by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), which supports DG SANTE, suggesting the latter as the preferred option for the moment.

Conclusion

The EU's existing health competence, that with which it entered the Covid-19 crisis, is patchy. Much of it has come about as a side issue to internal market law, and most of it was created in the absence of demand or support from Member States. The Commission and the CJEU, often supporting one another, have steadily extended the mechanisms used elsewhere in the internal market and fiscal governance framework, often considering health only as a secondary objective. More directed, purposeful expansion has been achieved in the aftermath of crises – BSE, thalidomide, blood infection, SARS – predominantly via regulation. However, the EU system is built with Member States at its core, and they remain the key players. Particularly where softer 'policy programmes' are concerned, the success of attempts to extend the EU's role depends upon the willingness of national governments to make space.

The EU4Health Programme and its various components centre on areas where the functional logic of cooperation is relatively easy to sell. As such, it is possible that Member States will be convinced of the value of a more integrated EU health policy, but this is an analysis conducted in the very early stages. Covid-19 looks set to stay with us for far longer than SARS or swine flu, both of which resulted in symbolically and potentially important innovations in EU health governance – the creation of a separate DG for Health and Consumers (SANCO) in 1999, the ECDC in 2005, adoption of the Health Threats Decision in 2013, introduction of joint procurement in 2014 – but could not sustain reform sufficiently to effectively mitigate a further crisis. Covid-19 may give time for more holistic action, but if a vaccine is quickly found and the issue quickly dissolves, further surface-level commitments may be the best that can be achieved. Moreover, several Member States are heading into elections in the coming months and, particularly for those leaders facing opposition from populist parties, this may put pressure on any commitment to a European health policy. Thus, whilst cooperation would seem necessary

to coordinate the lifting of lockdowns and the recovery of economies, there are plenty of exogenous factors which may yet shift Member States' perception of their interests.

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