10

COVID-19: An Accelerating Force for EU Activity in Health?

Mary Guy

Introduction

Interest in the development of EU-level activity in health is not new, with attention arguably being focused on concerns relating to respective EU and Member State competence in this area and mapping expansion, inter alia in terms of both hard and soft law mechanisms (Greer et al. 2019; Guy and Sauter 2017).[1] Establishing a precise location for health within wider EU law and policy may appear elusive, insofar as health ". . . is either non-existent as an autonomous policy area, given that it is mainstreamed into all other policies, or that it is basically everything, in that all EU public policy is also health policy" (de Ruijter 2019, 52). However, successful attempts have been made by lawyers and political scientists to delineate—and develop—a field of EU health law and policy (Hervey and McHale 2004, 2015; Greer et al. 2014 and 2019; Brooks and Guy 2021). It is increasingly acknowledged that development of EU-level interest in health care is determined in terms of politics, both in terms of EU–Member State interaction, but also at EU level, in view of Commissioner Kyriakides' expanded mandate for health relative to the space afforded under the previous Juncker Commission (Brooks 2019; Brooks and Guy 2021). However, what is also starting to emerge is that the dynamism of EU law in the health context may have much to offer (Hervey and de Ruijter 2020).

EU-level responses to COVID-19 might be considered not only to highlight or amplify existing EU competence in this area, but also to galvanize

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or accelerate EU activities in the health field. What emerged in early 2020 was that EU competence in health was not well understood and was in need of elaboration (Purnhagen et al. 2020), and perceptions that health care system organization as a Member State competence inhibited wider EU-level responses (Greer 2020). The combining of both public health and health care in the "hard law" mechanism of Article 168 Treaty on the Functioning of the European Union (TFEU), and the delicate interplay between EU and Member State competence perhaps suggested a level of nuance unhelpful for a crisis response. Indeed, where a long-standing distinction between "public health" and "health care" exists, with EU competence being focused on the former and Member State competence on the latter, the multifaceted effects of, and responses to, COVID-19 perhaps suggest that this distinction is increasingly less clear. Or at least that EU-level policy interventions may no longer separate as easily along seemingly clear lines such as "public health," "internal market," and "fiscal policy" (Greer 2014).

It is therefore unsurprising that the initial EU-level responses led to calls for greater powers at EU level and for these to take a demonstrably concrete form, as evidenced by framings such as "a Europe for health" (Huffington Post 2020; Fortuna 2020) and calls for "Treaty change" (Nielsen 2020; Euractiv 2021). What has persisted since approximately May 2020 are calls for the development of a European Health Union. Initially proposed at EU level by the Socialists and Democrats in the European Parliament (Socialists and Democrats 2020a and 2020b), the concept gained traction by reference in Commission President von der Leyen's State of the Union address in September 2020 (von der Leyen 2020), with elaboration by the Commission following in November 2020 (European Commission 2020a). Further support for a European Health Union can be found with the elaboration of EU4Health, the latest EU health program, which incorporates (financial) commitment to "[m]ak[ing] the European Health Union a reality . . ." (European Commission, 2020b).

A concurrent movement outside of the EU institutions—the European Health Union (EHU) initiative—has gone further in elaborating a manifesto and proposals for Treaty change (European Health Union Initiative 2020/2021). Furthermore, consensus appeared to be building around the extent of a European Health Union, specifically that this should extend beyond the confines of the immediate pandemic response to other aspects of health (Luena 2021).

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So, it appears that defining the contours of a European Health Union in response to the COVID-19 pandemic may be difficult. Indeed, this echoes earlier conceptions of a "European Health Community" (Ribeyre 1952 cited in Parsons 2003); a "new compound European healthcare state" (Lamping 2005), and a "European healthcare union" (Vollaard, van de Bovenkamp and Sindbjerg Martinsen 2016). The complexity of defining the contours of these visions appears attributed primarily to the political sensitivities attaching to EU Member State competence interactions regarding national health care (Vollaard, van de Bovenkamp, and Sindbjerg Martinsen 2016), and the effects of this dynamic on global health visions (Steurs et al. 2018), although comparisons are inevitably drawn with "unions" in other sectors, notably banking (Bazzan 2020; Bartlett 2020).

The wide-ranging implications of the COVID-19 pandemic may suggest that there was sufficient impetus to operationalize implementation of a European Health Union by means of Treaty change, a higher threshold than introducing other legislation or soft law initiatives that characterize a notable part of EU health law and policy. This impetus can be tested by reference to wider questions of what enables policy change. The fluctuating budget granted initially in response to COVID-19 and latterly to the EU4Health program[2] might indicate that answers are by no means straightforward, insofar as the rarity of radical policy change may be linked with variations in public policy budgets (Jones and Baumgartner 2012). The role of crisis in shaping EU integration is well documented (Jones, Kelemen, and Meunier 2021; Nicoli 2019) and is also acknowledged in the development of EU health policy (Brooks and Geyer 2020). Furthermore, the conception of a European Health Union has been deemed a post-Westphalian health governance framework, in light of the unique window of opportunity presented by the failure of Westphalian governance responses to the COVID-19 pandemic (Fraundorfer and Winn 2021).

In September 2021, 18 months on from the initial EU responses to COVID-19, the European Health Union appeared to occupy a prominent place on the Commission's agenda, albeit with skepticism emerging (Deutsch 2021). This, and the restated commitment at national and EU levels both within and outside the EU institutions, would seem to indicate policy change (Kingdon 2014). However, just how far implementation of the European Health Union

[2] Initially €9.4 billion in May 2020, scaled back to €1.7 billion following the Council summit in July 2020, then agreed at €5.1 billion in December 2020.

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can go—to extend beyond the realms of crisis response or to prompt Treaty change to refocus EU and national competence in health—remained moot. These questions can be examined by reference to Kingdon's Multiple Streams Framework to analyze whether windows of opportunity were opened, have remained open, or may yet open. In broad terms, the problem stream represents COVID-19 responses but also encompasses wider issues, such as weaknesses in national health care systems and whether more or less EU-level activity is needed. The politics stream can comprise the European Commission and Member States. The policy stream is represented by the proposals for a European Health Union of both the Commission and the EHU initiative, but may also extend to the Conference on the Future of Europe, in view of the reservation of discussions of competence to this by Commission President von der Leyen in the State of the Union address in September 2020. Potential confluence of these streams (or of associated tributaries) can be identified at different points in the period May 2020 to September 2021.

This chapter therefore examines how COVID-19 can be said to accelerate EU-level activity in health by reference to the implementation of a European Health Union and proposals for Treaty change. This examination is framed by Kingdon's Multiple Streams Framework and "windows of opportunity" model to explore the chances for success for the European Health Union proposals. This can help highlight answers to questions of how change occurs with regard to EU health policy, and more specifically whether COVID-19 can be said to accelerate change in this area. The second section considers how the Treaty provision governing EU competence in health has developed and outlines how "Europeanization" can affect Member State competence (Sindbjerg Martinsen 2012; Vrangbaek and Sindbjerg Martinsen 2008). The third section sets out the calls for a European Health Union and how this has developed—to include proposals for Treaty change—between approximately May 2020 and September 2021 (European Health Union Initiative 2021). The fourth sectionoutlines Kingdon's model and explains how it can help answer the questions posed by the current discussion. The final section offers some concluding remarks.

The Development of EU Competence in Health and "Europeanization" of Health Care

The development (and expansion) of EU competence in health has been traced both in chronological terms (Hervey and McHale 2015, ch. 3; Guy

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and Sauter 2017; Greer et al. 2019, ch. 1), and as concepts such as the "three faces" of EU health policy, encompassing public health, the internal market, and fiscal policy (Greer 2014). A persistent theme has been the extent to which EU and Member State competence regarding health is delineated, and the extent to which the former may encroach on the latter. This section first considers briefly the inclusion of the public health Treaty provision as the prime example of health—and the delineation of respective national and EU-level competence—being incorporated into EU hard law. It then engages with the consideration that health represents a "least likely candidate" for integration but has nevertheless undergone "Europeanization" (Sindbjerg Martinsen 2012) by reference to the examples of the Patients' Rights Directive,[3] EU competition policy, and the inclusion of country-specific recommendations in the European Semester fiscal policy assessment framework.

Development of the Public Health/Health Care Treaty Provision

The interaction between the EU and Member State levels initially assumed a "complementary" character, but has evolved to balance this with a clear delineation between national and EU competence with regard to public health matters on the one hand (where overlap can have clear benefits), and health care system organization and policy on the other (which may be considered contained within individual Member States for a variety of reasons including historical and cultural).

A public health competence was outlined with Article 129 EEC, and subsequently Article 152 TEU (Hervey and McHale 2004, 72–84) which allowed for "Community action" to "complement" national policies directed toward improving public health (Article 152(1) TEU), "encourage cooperation between Member States (Article 152(2) TEU) and foster cooperation between Member States and with third countries (Article 152(3) TEU). A subsidiarity element was first incorporated in Article 152(5) TEU, and specified that:

[3] 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 health care.

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> Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care . . .

Subsequent to this, the current provision—Article 168 TFEU—includes the aforementioned focus for "Union action" on complementing and encouraging/fostering cooperation (Article 168(1),(2),(3) TFEU), but has also expanded in both implicit and explicit ways. Article 168(5) TFEU enables the European Parliament and the Council to adopt incentive measures designed to protect and improve human health, combat cross-border health scourges and threats, and protect human health regarding tobacco and alcohol abuse. However, Article 168(5) TFEU is clear that the adoption of incentive measures excludes harmonization of the laws and regulations of the Member States—a distinction illustrated by EU-level activity regarding tobacco advertising (now a formal power specified by Article 168(5) TFEU) and the Patients' Rights Directive (based on the harmonization provision of Article 114 TFEU) (Hancher and Sauter 2012, 15–16). Prior to considerations in connection with COVID-19 responses (discussed below), an illustration of incentive measures adopted in connection with Article 168(5) TFEU had been the example of the successive EU health programs in operation since 2003[4] (Hancher and Sauter 2012).

Article 168(7) TFEU was expanded relative to Article 152(5) TEU to offer a renewed framing of EU-level/Member State competence thus:

> Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

Article 168(7) TFEU underwent four subtle, but ultimately significant, amendments by reference to its predecessor: a decoupling of the subsidiarity focus on health care from "public health"; a change in Union focus from

[4] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008); Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13); Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020).

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"fully respecting" to merely "respecting" Member State responsibilities; explicit stipulation of "health policy" alongside these; and elaboration, in a new second sentence, of what the responsibilities include (Guy 2020). While Article 168(7) TFEU can be read as a clarification of the extent of Member State competence in the wider context of the TFEU (Piris 2010, 321), with the second sentence representing "statements of national autonomy" (Garben 2018), it has also been considered to introduce a "a delicate and sophisticated balance" in the context of EU competition policy and health care (van de Gronden and Szyszczak 2011, 486).

It is considered next how this "hard law" Treaty provision for health has been used to shape contours of "Europeanization" of health care, but the ambiguity of this should not be overlooked. On the one hand, "from the point of view of EU health lawyers, this Treaty recognition set health law on the road to becoming a recognised aspect of EU law" (Hervey and McHale 2015, 39). However, on the other hand, Article 168 TFEU has been depicted as a gate in a field around which sheep of EU policies as diverse as competition, the European Semester, the internal market, and agriculture are free to roam (Comic House/Floris Oudshoorn, cited in Greer et al. 2019, 176). This has led to suggestions that the separation of health from other policies, and consequently the interaction between EU and national levels, represents a porous barrier (Guy 2020).

How Far Does "Europeanization" in Health Care Go in Reframing the National/EU Competences in Health Care?

Despite seeming a "less likely" candidate, health care has undergone a process of integration and "Europeanization" as evidenced by the example of patient mobility and cross-border health care (Sindbjerg Martinsen 2012). In contrast to public health initiatives, the linking of patient mobility and the overarching objective of achieving the internal market can be seen as perhaps the strongest example of "Europeanization" in health care, given the involvement of the courts in case law underpinning the subsequent Patients' Rights Directive and harmonization providing the legal basis for this. If the Patients' Rights Directive can be described as "explicit harmonization," then it appears also possible to identify "implicit harmonization" in other policy areas absent recourse to the harmonization provision amid concerns about the pervasiveness of EU-level influence regarding competition and fiscal

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policy. This appears consistent with the view that "the degree of coerciveness and thus the imperative to Europeanize may vary considerably from one EU regulatory area to the other" (Sindbjerg Martinsen 2012).

The influence of EU competition policy on national health care systems, although acknowledged to be emerging, proves difficult to categorize (Morton 2021). The applicability of the EU antitrust and state aid rules (Articles 101; 102; 107–109 TFEU) would appear to circumvent national power regarding national policies to experiment with marketization reforms in health care (Prosser 2010; Andreangeli 2016). However, the ultimate influence on national competition reforms in health care may be evidenced more by the development of "EU-national competition rules for health care" with terminology reflecting the wider EU competition law framework (van de Gronden 2011; van de Gronden and Szyszczak 2014; Guy 2019). National health care policies may be considered strengthened by recourse to the Services of General Interest exemption or by designating specific activities as Services of General Economic Interest (another example of Member State competence—Protocol No. 26), but here too concerns emerge that the latter proves too cumbersome for engagement at a national level (Nikolić 2021).

The development of the European Semester fiscal policy annual assessment program has been considered a further expansion of EU-level influence over Member State responsibility for national health policy and health care system organization, particularly in view of the country-specific recommendations (CSRs) issued by the European Commission (Greer, Jarman and Baeten 2016). However, here too the parameters of the "incursion" of EU-level influence are less clear-cut than may first be thought. On the one hand, CSRs can be considered to represent a "particularly coercive form of soft law" (Garben 2018) and exercising clear influence over national health care systems (Azzopardi-Muscat et al. 2015). On the other hand, the process involved in elaborating the CSRs would seem to suggest a sense of "circularity" in the respective inputs of the national and EU levels, such that the focus shifts to the differing interactions between the EU and national levels as determined by the extent of fiscal restraints imposed (Guy 2020).

These broader considerations of the interactions regarding health care between the national and EU levels across diverse aspects of EU law and policy, and the wider expansion of EU health law and policy as a "patchwork" (Hervey and Vanhercke 2010), show that there has been clear expansion of EU-level influence over health care despite Treaty limits regarding national health care policy and system organization. Indeed, it has been considered

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that the expansion is such as to amount to a "European health care union," a system of cooperative federalism, albeit one of limited robustness due to the limited loyalty to the EU it generates (Vollaard et al. 2016).

The Development of a European Health Union in Response to COVID-19 (May 2020–September 2021)

What emerged in the first months of response to COVID-19 was that EU competence in health was not well understood, and that the salience of Article 168(7) TFEU as a constraining feature may be primarily political rather than legal (Purnhagen et al. 2020), given that it is considered to add little to the formal division of powers elsewhere in the Treaties (Greer et al. 2019, 63). It has also been considered that what was more notable than perceptions of a disappointing response at EU level was the support and solidarity which Member States showed one another (Brooks, de Ruijter and Greer 2020), although solidarity between Member States was also found wanting at various points.

The idea for a "European Health Union" can be traced back to calls by Emmanuel Macron for a *Europe de la santé* during a joint press conference with Angela Merkel in May 2020 outlining a health strategy for Europe (Huffington Post 2020; Fortuna 2020). This outlined a "health strategy" for a strategically positioned European health care industry which would upgrade the European dimension of health care and reduce EU dependency, while fully respecting Member State responsibility for health care systems.

At the same point, the Socialists and Democrats (S&D) party in the European Parliament outlined a vision for a European Health Union (Socialists and Democrats 2020a, 2020b). This call proved wide-ranging, encompassing aspects as diverse as access to pharmaceuticals, health research, and health and safety in the workplace, arguably consistent with the EU's diversity of powers which might be considered related to health. The S&D's call appeared premised on a fundamental need for more (or more explicit) EU-level cooperation because health care systems remain the responsibility of Member States (Guy 2020), and this respect for Member State competence has been prominent in setting the parameters for constructing a European Health Union.

A further development in May 2020 was the publication of the initial proposals for the fourth EU health program, EU4Health, to run between

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2021 and 2027. This provided for an ambitious health strategy encompassing not only more coordinated COVID-19 responses and key action areas for the improvement of the resilience of national health care systems, but also emphasizing strong embedding in the "One Health" approach, recognizing the interconnection between human health, animal health, and the environment. The ambition of this program may be considered recognized by the initial budget assigned to it in May 2020—€9.4 billion. However, this was dramatically cut to €1.7 billion following the EU summit in July 2020 under pressure from the so-called frugal countries —Austria, Denmark, Netherlands, and Sweden (Fortuna 2020b).

Calls for a European Health Union were given significant reinforcement in Commission President von der Leyen's inaugural State of the Union address in September 2020, with the words "For me, it is crystal clear—we need to build a stronger European Health Union" (von der Leyen 2020). This commitment was accompanied by recognition of the need to "future proof" the EU4Health program. The vision for a European Health Union outlined by von der Leyen in 2020 focused on strengthening crisis preparedness and managing cross-border health threats in a three-fold approach: reinforcing and empowering the European Medicines Agency (EMA) and the European Centre for Disease Control (ECDC); building a European Biomedical Advanced Research and Development Agency; and discussing the question of health competences. Indeed, the latter was confirmed by von der Leyen as a "noble and urgent task" for the Conference on the Future of Europe (von der Leyen 2020). Further impetus to calls for a European Health Union came from Angela Merkel in December 2020 (Stone 2020).

In November 2020, the Commission published a range of proposals to extend the mandate of the ECDC and the EMA and for a regulation on serious cross-border threats to health, as well as outlining a pharmaceutical strategy for Europe and a Communication on Building a European Health Union—preparedness and resilience. The Communication confirmed that it proposed the first building blocks for a European Health Union and that these were envisaged within the current Treaty provisions, particularly Article 168(5) TFEU:

> By upgrading the EU framework for cross-border health threats, these first building blocks of the European Health Union will bring greater overall impact while fully respecting the Member States' competence in the area of health (European Commission 2020a).

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This appears consistent with the initial calls for a European Health Union—as focused around an apparently immutable core of Member State competence in health care. However, the Communication is notable for its portrayal of EU–Member State interaction, in recognizing the need to work together and use the EU's potential to improve the health response and to support Member States to fulfill their responsibilities, and particularly with the concluding sentence: "The European Health Union will be as strong as its Member States' commitment to it."

The EU4Health program was subsequently elaborated as paving the way to a European Health Union[5] by investing in urgent health priorities, namely, responding to the COVID-19 crisis and improving EU-level resilience for cross-border threats, Europe's Beating Cancer Plan, and the Pharmaceutical Strategy for Europe. Just as the scope for the EU4Health program evolved, so too did the budget associated with it. In September 2020 von der Leyen had indicated support for the European Parliament's fight for more funding following the cutting of the budget to €1.7 billion in July 2020 by the European Council. In December 2020, the European Council and European Parliament agreed a budget of €5.1 billion for the EU4Health program, a move acknowledged by Commissioner Schinas as a vote of confidence in making a European Health Union a reality (Commission December 2020). The entry into force of EU4Health in March 2021 has been highlighted by Commissioner Kyriakides as meeting EU citizens' expectations of a European Health Union (Commission March 2021).

November 2020 also saw the launch of the aforementioned European Health Union Initiative, facilitated by the European Health Forum Gastein[6] and comprising a diverse group of academics and policymakers.[7] The initiative's independence means it has scope to outline a vision for a European Health Union which can be considered more ambitious than that proposed by the Commission, while stating its support for the Commission's action and Commission President von der Leyen's commitment to building a European Health Union. The European Health Union Manifesto is anchored around two aims: to call on the political leaders of Europe in the framework of the Conference on the Future of Europe to commit to creating a European Health Union, and to invite the people of Europe to engage in building a

[5] EU4Health 2021-2027—a vision for a healthier European Union | Public Health (europa.eu)
[6] European Health Forum Gastein (ehfg.org)
[7] Including Vytenis Andriukaitis former Commissioner for Health and Food Safety (2014–2019) and former president of the European Parliament, Klaus Hänsch.

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health policy that contributes to the EU's long-term sustainable development. Signatories of the Manifesto comprise an impressive array of health care practitioners, politicians at national and international levels, policymakers, civil society actors, and academics from across the EU and beyond.[8]

The connection of developing a European Health Union with treaty change has emerged in different ways and has received both cautious welcomes and more skeptical reception (Hervey and de Ruijter 2020; Guy 2020), amid recognition that expectations of EU citizens had changed (Alemanno 2020). Treaty change had already been hinted at by Commissioner Schinas in May 2020: "if the moment is right, it will happen" (Nielsen 2020). Although not referenced by Commission President von der Leyen in September 2020, the openness to reviewing EU and Member State competence was reiterated and linked again with the Conference on the Future of Europe. Angela Merkel outlined her support for Treaty change in connection with strengthening coordination of EU-level responses as recently as April 2021 (Euractiv 2021). While the Commission's proposals are clearly framed within the existing Treaty competences, the European Health Union Initiative was clear about its support for a Treaty change from the outset and have since published proposed amendments (European Health Union Initiative 2021). These amendments relate both to Article 168 TFEU and elsewhere in the Treaty, for example, by stipulating the European Health Union as an instance of a shared competence between the EU and the Member States under Article 4 TFEU.

The Initiative's vision for amending Article 168(7) TFEU sees the Member State–EU interaction regarding national health competence being linked explicitly with the principle of subsidiarity. As the Initiative notes, this may create a rebalancing of the EU–Member State dynamic such that a counterintuitive effect of stronger EU power in health might be that national health ministries and the attached health communities will have a more powerful role in determining whether or not EU legislation meets the test of subsidiarity.

However, the amendments to Article 168(7) TFEU are notable for two further reasons. First, they envisage the removal of "health policy" such that Member States would only be responsible for the organization and delivery of health services and medical care. Second, they elaborate the EU's role as "support[ing] the capabilities of Member States to promote health equality, reduce unmet medical needs, and strengthen the interoperability of their health systems." While the first amendment has echoes of a curious return to

[8] As of October 31, 2021, there were 1,265 signatures. https://europeanhealthunion.eu/#signatures

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the original formulation of Member State competence (Article 152(5) TEU), the second indicates a decisive change in focus which could provide a useful reframing of the interaction between the EU and Member States regarding national health care, insofar as "health policy" may be considered to be concerned with aspects such as health inequalities and responses to these.

In view of the foregoing, it is useful to focus the present discussion around the broad questions of whether the COVID-19 pandemic has opened a window to accelerate EU-level activity in health, but to amend the Treaty to reflect this and refocus EU-level and Member State–level interaction.

Kingdon's Multiple Streams Framework—"Window(s) of Opportunity" in the EU Health Context and COVID-19 Responses

Whether or not the COVID-19 pandemic provides a "window of opportunity" to accelerate EU-level activity in health care, and more specifically to put Treaty change on the agenda to extend the EU's competence in this area, can be examined using Kingdon's Multiple Streams Framework. While this has been widely used in the context of empirical research (Herweg, Zahariadis, and Zohlnhöfer 2018), its serviceability is widely acknowledged insofar as it has been considered ". . . not only [to] travel well to different policy areas and stages of the policy cycle, but also to different units of analysis" (Zohlnhöfer, Herweg, and Rüb 2015). While the use of this in a health care context may seem uncontroversial, given Kingdon's own focus on US health care (Kingdon 2014), the relevance of the Multiple Streams Framework to the present discussion, and indeed EU health law more generally, may be less immediately self-evident. However, the Multiple Streams Framework has increasingly been applied to policymaking at the European level since the late 2000s (for example, Zahariadis 2008; Ackrill et al. 2013). It has also been used to examine legislative changes, such as connections between negotiations prior to the Single European Act providing a "window of opportunity which the Commission required to launch a renewed offensive on the social dimension" (Cram 1997 cited in Zahariadis 2008), and the Dassonville[9] and Cassis de Dijon[10] cases, which proved decisive in shaping

[9] Case 8/74 *Procureur du Roi v. Dassonville and Others* [1974] ECR 837. ECLI:EU:C:1974:82.

[10] Case 120/78 *Rewe-Zentral AG v. Bundesmonopolverwaltung fuer Branntwein* [1979] ECR 649. ECLI:EU:C:1979:42

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the law governing freedom of movement to indicate interactions between EU institutions (Nowak 2010). The particular relevance of the Multiple Streams Framework to the calls for a European Health Union in response to COVID-19 can be linked to the view that it offers a good starting point for understanding what decisions are made and why by reference to who pays attention to what and when, and since it offers a lens of policymaking that assumes ambiguity and stresses a temporal order (Zahariadis 2008).

From the foregoing discussion, it might be considered that the politics stream comprises primarily the Commission and the European Parliament, but also national politicians who have called for Treaty change (notably Angela Merkel). The policy stream may appear to be populated primarily by the Commission and the European Health Union Initiative, given their focus on proposing solutions and alternatives, and the latter's entrepreneurial spirit. The importance accorded to the Conference on the Future of Europe for the discussion of competences would seem to suggest it may occupy a space both within the policy stream and the politics stream—such that it may make more sense to identify tributaries (and potential confluence of these) within the wider streams. While the outbreak of the COVID-19 pandemic appears clearly the main component of the problem stream, it provides a focusing event, as well as highlighting a problem–solution sequence, pointing out glaring deficiencies in health systems across the EU and prompting a search for specific solutions and policy coordination in a similar example to bird flu (Zahariadis 2008).

Before considering the potential coupling of these streams into windows of opportunity, it is useful to recall the sequence of events surrounding calls for a European Health Union:

What emerged over the course of successive events of the 18 months between March 2020 and September 2021 are two related but arguably ultimately diverging propositions: extending EU competence in health, and Treaty change. In keeping with the "streams" imagery, it may be possible to conceptualize the extension of EU powers in a health crisis response as a tributary flowing into a larger stream of extending EU powers, or reformulating EU and Member State interaction regarding health more generally. Similarly, Treaty change might be considered to represent a sea beyond the confluence of politics and policy streams. This can be explained by the complexities inherent in effecting Treaty change—including the requirement for approval from all Member States meeting in an intergovernmental conference and unanimous ratification at national level (Article 48 TEU)—and illustrated

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Table 10.1 Timeline overview of events May 2020—September 2021 connected with the development of a European Health Union

Month	Event
May 2020	Calls for a European Health Union by Macron and Merkel; S&D • Indication of Treaty change – link with Conference on Future of Europe by Commissioner Schinas Initial proposal for EU4Health (budget €9.4 billion)
July 2020	EU4Health budget cut to €1.7 billion
September 2020	Von der Leyen's inaugural State of the Union address
November 2020	Commission proposal for building EHU EHU Initiative manifesto launched
December 2020	Merkel call for EHU Agreement of EU4Health budget at €5.1 billion
March 2021	Entry into force of the EU4Health programme
April 2021	Merkel call for Treaty change EHU Initiative outline Treaty amendments
September 2021	Comments by Commissioner Kyriakides Von der Leyen's second State of the Union address

by the experience of implementing the Lisbon Treaty (Peers 2012). The convoluted inputs that combine to give effect to Treaty change should not be underestimated, with the implication that Treaty change is best understood as a process with different levels (Christiansen, Falkner and Jørgensen 2002). Demonstrations of the dynamism of EU law (Hervey and de Ruijter 2020) can also indicate that Treaty change represents a significant step, or a hurdle which is difficult to cross, leading to the suggestion that calls for Treaty change as a necessary mechanism for implementing a European Health Union should be treated with caution (Guy 2020).

With this in mind, how the problem/policy/politics streams couple, and at what point(s), becomes important in assessing whether (and where) windows of opportunity have opened, and the prospects for success of the different visions for constructing a European Health Union. There are also questions of the size of window that opens and the extent to which it opens (Natali 2004; Keeler 1993, cited in Nugent and Saurugger 2002). Thus, while the rapid spread of COVID-19 in the first part of 2020 may be seen as a severe crisis and an unpredictable "window," causal mechanisms are needed to link this to window-opening (Nugent and Saurugger 2002). One such mechanism may be the refocusing of health within the von der Leyen

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Commission relative to the Juncker Commission, and the mandate extended to Commissioner Kyriakides in December 2019. The evolution of the pandemic response, determined in part by the passage of time, may also prove instructive. Where "more Union" may be desirable in connection with an initial, short-term crisis response, it may be the case that "less Union" is called for over the longer term, even if activity can be linked ultimately with pandemic response (Guy 2020). In other words, windows may open only slightly, or for a short period of time.

EHU Vision 1: Extending the EU's Competence/Raising the EU's Profile in Health Crisis Responses

The first vision for a European Health Union—based primarily around facilitating EU-level response to health crises—provides the clearest instances of a coupling of the streams, as illustrated by Figure 10.1.

In this coupling, we saw the initial COVID-19 outbreak in the problem stream combining with the political will (at national and EU levels) to extend

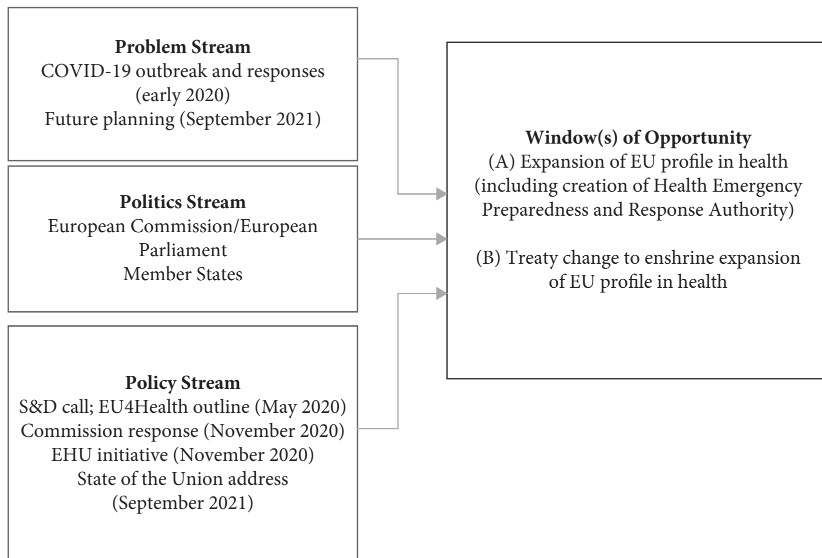

Figure 10.1 Coupling of the streams creating window(s) of opportunity for EHU Vision 1: strengthening EU competence/raising EU profile in health crisis responses.

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EU-level competence to respond. Thus, a window appeared to open in May 2020 with the confluence of the problem stream with the politics stream (EU institutions and Member States) and the policy stream (including the Socialists and Democrats' call). The initial proposal for EU4Health's conception as EU-level response to the pandemic, along with the initial commitment of a significant budget (€9.4 billion), can be understood as commitment within the political stream as well as a proposed solution in the policy stream. Although connections have been drawn between the implementation of policy and the funding available (Jones and Baumgartner 2012), the dramatic cut in the budget (to €1.7 billion) in July 2020, perhaps counterintuitively, appears not to have "undone" the coupling of the three streams. Rather, the window appears to have been kept open by the renewed commitment in September 2020 by Commission President von der Leyen to build a European Health Union, reinforced by Commission proposals in November 2020, and subsequent agreement by the Council and the Parliament to increase the budget (to €5.1 billion) and calls by Angela Merkel for a European Health Union, both in December 2020. Indeed, this window might be considered to still be open as at September 2021, albeit with a refocusing of the problem stream in view of Commission President von der Leyen's outline of proposals for "a new health preparedness and resilience mission for the whole of the EU . . . backed up by Team Europe investment of €50 billion by 2027" in her second State of the Union address (von der Leyen 2021).

A secondary window for Treaty change to enshrine this extension of EU-level competence in crisis responses has perhaps been less certain. As hinted at above, Treaty change would require any windows to be wide open, and for a relatively long period of time. Treaty change with regard to raising the EU profile in health crisis responses (as distinct from refocusing EU and Member State competence interaction) was indicated by Commissioner Schinas' comments in May 2020, and already at that stage was linked with debates in the Conference on the Future of Europe (Nielsen 2020). If this can be seen as a confluence of the three streams, then it may have generated a window of opportunity that received subsequent reinforcement by the outlining of the EHU initiative manifesto and Treaty amendment proposals (EHU Initiative 2020/2021), and by Angela Merkel's call in April 2021 for Treaty change, seemingly specifically with regard to the EU-level competence (such as extending the mandate of different agencies). However, as of September 2021, the extent to which this window could still be said to be open was moot.

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EHU Vision 2: Extending the EU's Competence by Reframing the EU–Member States Competence in Health (Beyond Crisis Responses)

It has been noted that it is much easier to tell when coupling and a window of opportunity have happened after the fact (Greer 2018). This can be illustrated well by the vision of a European Health Union which extends beyond crisis responses, insofar as the chance to refocus EU and Member State competence regarding health may be seen as a "missed opportunity" if no attempt was made to align this with the COVID-19 crisis response. In this sense, parallels and distinctions can be drawn between COVID-19 responses and responses to the economic downturn of 2008–2009, insofar as the latter prompted more EU-level interest (and influence) in health care via fiscal policy. However, an obvious impetus for Treaty change regarding health competence was lacking.

As noted above, the threshold for Treaty change affecting EU–Member State competence in health appears higher than for crisis response: a more unambiguous coupling of the streams would be needed for a window of opportunity to be open both to a larger extent and for a certain (longer) period of time. The three streams within this EHU vision are set out in Figure 10.2.

The problem stream within this vision would comprise both the crisis responses to COVID-19 and the inevitable continuity responses as Member States ensure delivery of non–COVID-19 related health services (and treatment of "long COVID" might be considered here, too). This can be seen to couple with the politics and policy streams not only in connection with the May 2020 Franco-German and S&D calls, but also the elaboration of EU4Health to incorporate policy aspects such as the Europe Beating Cancer Plan. While the entrepreneurship evident in the EHU Initiative's outlining of possible Treaty amendments lends notable definition to the policy stream, it may also be seen to contribute to the politics stream, in view of the range of supporters (including both national and EU-level politicians).

The reservation of discussion of competences to the Conference on the Future of Europe offers an interesting dimension to both the policy and politics streams, because this would seem to play a decisive role in determining the window for Treaty change, both in terms of the extent to which it is open and the length of time it remains open. While there is some skepticism about the Conference's ability to effect change (Nguyen 2021), the novelty of the Conference initiative—relying on a different logic, format,

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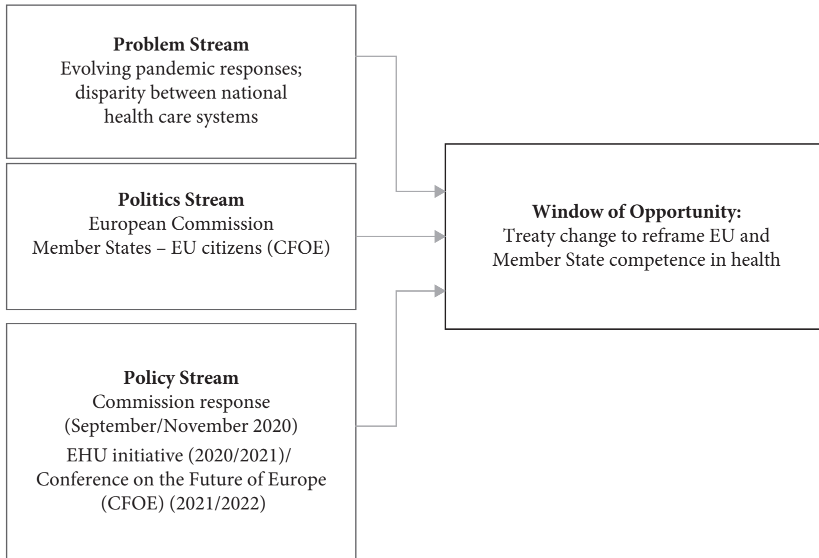

Figure 10.2 Coupling of the streams creating window of opportunity for EHU Vision 2: extending the EU's competence by reframing the EU–Member State competence in health (beyond crisis responses).

and legal basis (consultative, deliberative, and deliberative-constituent) (Alemanno 2021)—may give tentative grounds for optimism, or at least justify a more neutral stance. The effect of the Conference on the extent to which a window opens is difficult to assess, but if it is seen as a mechanism to engage actively with EU citizens, this may have notable implications for the constituency of the politics stream insofar as calls for a European Health Union have emanated not only from (national and EU-level) politicians but also medical professionals and civil society actors. The ability of medical professionals to influence national health policy can be significant, but is perhaps less evident at EU level. The ability of the Conference to affect the length of time any window remains open appears increasingly limited in view of the reduction in time allocated to it (from an original timeline of two years between May 2020 and May 2022, to approximately nine months to wind down in spring 2022 with approval of its conclusions—Alemanno 2021).

The extent to which there can be said to be a of the three streams might be considered undermined by the potential for the European Commission being present in both the politics and policy streams. The Commission's outline

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for a European Health Union in November 2020 was unequivocal that the legal basis for the initial proposals would be Article 168(5) TFEU, and that Member State competence in health would be fully respected (Commission November 2020). Indeed, scope for divergence—rather than confluence—may have been hinted at by the closing comment of the proposals: "The European Health Union will be as strong as Member States' commitment to it" (Commission November 2020). Further support for a lack of joining the three streams may be found in comments by Commissioner Kyriakides at the start of September 2021: "[a] strong European Health Union is not about redrawing the competences of Member States" would seem to underline this (Kyriakides cited in Deutsch 2021).

Concluding Remarks

September 2021 provided an important moment to reflect on the development of calls for a European Health Union in response to the COVID-19 pandemic. Approximately 18 months after the initial lockdowns across Europe, it became possible to start to identify further the parameters of a European Health Union—whether this as simply an extended EU-level crisis response device or a more robust mechanism to reconceptualize EU-level and Member State interaction regarding health (an issue of long-standing political sensitivity). The linking of the concept of a European Health Union with treaty change, perhaps with hindsight, appeared inevitable since the latter would represent a significant level of commitment, and a suitable rebuttal to the perceptions and misunderstandings of EU-level competence in health which accompanied the initial pandemic responses in spring 2020.

By juxtaposing some of the activities of the first 18 months of pandemic response with the expansion of EU-level interest in health across diverse policy areas, it is possible to contribute to the discussion of the need for a European Health Union. Making use of Kingdon's Multiple Streams Framework and identification of "windows of opportunity" enables us to start to identify what may be needed for (or missing from) ambitions for establishing a European Health Union. This has generated at least two main insights.

First, that the confluence of the problem, politics, and policy streams with regard to legislation intended merely to enshrine an extended EU-level

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mechanism for responding to health crises needs only to meet a certain threshold. Furthermore, the confluence is arguably unaffected by fluctuating factors that may prove more detrimental elsewhere (such as a notable reduction in budget).

Second, and conversely, that the confluence of the three streams needs to be more certain when attempting a more ambitious aim—such as Treaty change to reconceptualize respective EU and Member State competence in health. This confluence needs to support a window of opportunity which can open to a larger extent and for a longer period of time, given the complexity inherent in Treaty change.

Finally, the problem stream linked to the COVID-19 pandemic might be seen as comprising tributaries, both of crisis (hence unpredictable windows) and identifying underlying weaknesses in EU Member State health care systems—which are highlighted, but not caused, by a pandemic. This can have significant implications for the confluence of the problem stream with the politics and policy streams, and thus windows of opportunity and what can realistically be achieved with regard to "hard law" amendment.

Despite these different insights, if taken together, it might be considered that COVID-19 does represent an accelerating force for EU-level activity in health. This is clearly most evident in connection with EHU Vision 1, and it has yet to be seen how the more tentative confluence of the streams in connection with EHU Vision 2 may provide further opportunity to revisit EU and Member State competence interaction in the future. Certainly, it has been noted that in view of the political sensitivities that attach to health care, even a seemingly small change can actually prove significant (de Ruijter cited in Deutsch 2021).

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