YOUNG EUROPEAN FEDERALISTS

From COVID-19 towards a European Health Union: Proposals for Treaty reform on health

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About the paper

This paper is inspired by the Young European Federalists (JEF-Europe) policy resolution, "For a coordinated EU response to tackle the COVID-19 health emergency" (5 April 2020). In particular, the resolution "Calls for a revision of the Treaties (Art. 168 TFEU) to make public health a shared EU competence as the EU should be entrusted with real competences in the field of public health".

The paper itself is not an official JEF-Europe policy document. JEF-Europe's policy documents – the Political Platform, and thematic policy Resolutions – are adopted at JEF-Europe's statutory meetings through a formal voting procedure.

The paper serves to raise public and political debate around topics on which JEF-Europe exercises advocacy. Its publication on the JEF-Europe website has been approved by the JEF-Europe Executive Board.

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Executive summary

- Articles 4(2)(k) and 168 TFEU[1] give the EU the power to legislate on clearly delimited aspects of health, and the EU institutions have used these powers.
- The Conference on the Future of Europe (CoFoE) gave a clear recommendation for "health and healthcare" to be made a fully-fledged shared EU competence. Implementing the recommendation requires amendments to Articles 4 and 168.
- Though the mandate of the ECDC (European Centre for Disease Prevention and Control) is already expanding, reforming Article 168(7) would be necessary for an integrated health crisis response that goes beyond mere 'coordination'.
- The current Article 168 has proven to be an insufficient legal basis for joint procurement of medical supplies; an amendment would enable better European Parliament control over the matter, among other benefits.
- Changes to Article 168(7) would be necessary for the adoption of European minimum standards on the quality of national healthcare services.
- Mentioning a European Health Union in the new Article 3(3) TEU[2] would show that citizens' CoFoE proposals have been heard, and that Europe has emerged from COVID more united.

[1] Treaty on the Functioning of the European Union.
[2] Treaty on European Union.

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Introduction

The onset of the COVID-19 pandemic in 2020 represented an unprecedented health emergency for the European Union. The EU took action, for example through joint procurement of vaccines by the European Commission, and through promoting adequate supply of medical goods. However, the EU's seemingly limited possibilities to tackle the pandemic prompted discussion on the extent of the EU's competences on health policy.

In her 2020 State of the European Union speech, Commission President Ursula von der Leyen argued that the EU's competences on health were not "full", and explicitly called for debate on the question (European Commission, 16 September 2020). Indeed, in the Conference on the Future of Europe (CoFoE), the Citizens' Panel on climate change, the environment and health called for treaty reform to make "health and healthcare" a shared EU competence (CoFoE 2022, Recommendation 49). The

demand to amend Article 4 TFEU to include health and healthcare among shared competences is repeated in the final plenary recommendations of the Conference (Final report, p. 50).

This paper evaluates the need for treaty reform for strengthening the EU's competences on health. In the current TFEU, Articles 4 and 168 specifically refer to "public health", which can be defined as prevention of disease, promotion of longevity, and promotion of health at the level of the whole population (WHO). The concept of public health should therefore be considered distinct from "health and healthcare", which would refer to healthcare services (Greer et al 2019, p. 63). In line with the wording of the CoFoE recommendations, this paper's scope includes public health and health policy as a whole.

As the Conference on the Future of Europe has drawn to a close, the discussion on Treaty reform is relevant for ensuring adequate follow-up to the Conference. During the Conference, Commission Vice-President Dubravka Šuica stated that the Commission will support treaty reforms if citizens ask for it (Vasques, 21 January 2022). Moreover, using its rights under Article 48(2) TEU, the European Parliament is currently preparing to make its proposals for Treaty change (European Parliament, 4 May 2022). Accordingly, it is appropriate to elaborate on the need for Treaty reform.

This paper first summarises the current Treaty framework concerning health, offering an overview of EU competences and of legislation adopted pursuant to these competences. Secondly, the paper discusses EU structures for the management of public health crises, in particular the European Centre for Disease Prevention and Control (ECDC) and the Health Emergency Preparedness and Response Authority (HERA) which are the subjects of current policy initiatives. Thirdly, the paper considers opportunities for a more integrated European health policy in non-crisis times. As a whole, the paper offers an assessment of the limits of the current Treaty framework; the final section of the paper summarises the authors' recommendations for Treaty reform.

Current legal framework

In the Treaty on the Functioning of the European Union (TFEU), Title XIV is entitled "Public Health". The Union has enjoyed its own competence in the field of health since the Maastricht Treaty: health policy can therefore be the subject of own EU measures and cannot merely be considered as an annex to other areas. However, the competences granted to the Union in this area remain very limited. In principle, the Union cannot pursue an autonomous health policy, and the Member States remain the "masters of health policy". The Union's action is mainly limited to supporting, coordinating and complementary measures.

As per Article 6 of the Treaty on the Functioning of the European Union (TFEU), the "protection and improvement of human health" is a supporting competence. When

the EU has a supporting competence, it is able to support, coordinate or complement Member States' actions, but cannot pass legislation (European Commission).

Nonetheless, the current Treaty already provides certain avenues for EU legislation on public health matters. **Article 4(2)(k)** of the Treaty gives the EU and Member States a shared competence in "common safety concerns in public health matters, for the aspects defined in this Treaty". In the case of a shared competence, both the EU and Member States are allowed to pass legislation: however, when the EU legislates on a particular matter, Member States' legislative power is correspondingly limited, since EU law takes precedence over national law.

The EU's powers on public health are defined further in **Article 168** TFEU. Article 168(1) contains the so-called horizontal clause, which obliges the Union to ensure a high level of health protection in all its policies and activities. The fact that this clause is not included in the general provisions, as with other horizontal clauses such as Articles 9–11 TFEU, does not change its overarching binding nature and equal status with other objectives and horizontal clauses.

Article 168(4) outlines three public health matters in which EU legislation may be adopted, using the exception provided by Article 4(2)(k): safety standards for organs and substances of human origin, veterinary and phytosanitary measures aiming to protect public health, and safety standards for medicinal products and devices.

Article 168(4)(a) TFEU provides for measures to establish high standards of quality and safety for organs and substances of human origin, as well as for blood and blood derivatives. The special authorisation was created in order not to leave organs and substances of human origin to the economic logic of the internal market.[3] The measures taken under 168(4)(a) do not prevent the Member States from maintaining or introducing more stringent protective measures. The Union can therefore only set minimum standards.

Article 168(4)(b) authorises measures in the veterinary and phytosanitary fields which have the direct objective of protecting public health. The provision was introduced in the context of the Bovine Spongiform Encephalopathy (BSE) crisis, also known as "Mad Cow Disease", which faced Europe in the 1980s and 1990s.[4] The Article separates veterinary and phytosanitary measures from agricultural measures. Legally, Article 168(4)(b) thus represents a special provision to the agricultural policy provisions of Article 43 TFEU. The delimitation is based on the stipulation that Article 168(4)(b) can only be used for measures that "have as their direct objective the protection of public health", even if the delimitation is difficult in

[3] Johannes Christian Wichard, 'Art. 152 EGV', in Christian Calliess and Matthias Ruffert (eds.) *Das Verfassungsgericht der Europäischen Union mit Europäischer Grundrechtcharta*, Munich, Verlag C.H. Beck, 2007*;* Fischer, 'Art. 168 AEUV', in Carl-Otto Lenz and Klaus-Dieter Borchardt (eds.) *EU-Verträge Kommentar*, Munich, Verlag C.H. Beck, 2012.

[4] Gerald Sander, 'Europäischer Gesundheitsschutz als primärrechtliche Aufgabe und grundrechtliche Gewährleistung', *Zeitschrift für Europarechtliche Studien* 2/2005.

individual cases. Generally speaking, health protection must be the main objective of the foreseen measure in order to base any legislative act on Article 168(4)(b).

Article 168(4)(c) enables measures to set high quality and safety standards for medicinal products and medical devices. The competence was newly introduced by the Treaty of Lisbon, and acts as *lex specialis* to Article 114 TFEU.

Further, **Article 168(5)** lists additional matters on which the EU may legislate: incentive measures for improving human health and combatting "major cross-border health scourges"[5], measures for monitoring and combatting serious cross-border health threats, and public health measures regarding tobacco and alcohol abuse.

It is important to notice that measures under Article 168(5) must exclude any form of harmonisation of the laws or regulations of Member States. Hence, there cannot be any doubt that the authors of the treaties wanted to prevent any direct and normative interference into national health systems from European legislators. Although "measures" – that is, Regulations, Directives and Decisions – can be taken, any form of harmonisation is therefore explicitly excluded.

The listing of matters on which the EU may adopt legislation shows that the Treaty intends to clearly delimit the EU's powers on public health. **Article 168(7)** reiterates that the Member States are responsible for managing their health services and allocating resources to them, as well as defining their health policies. This can be explained against the background that health and social security systems are structured, organised and financed very differently in the Member States: for instance, some national systems are tax-financed, while other systems are contribution-financed.

Beyond the provisions specifically focused on health, Article 352 TFEU could in theory be used. The Article refers to a situation where the Treaties haven't provided the necessary powers for the EU to attain one of the objectives set out in the Treaties: in such a case, the Council would be able to adopt the necessary measures by unanimity. During the COVID-19 crisis, Article 352 was used as a legal basis to enable postponements to general meetings of certain types of companies (Council Regulation 2020/699). However, the Article has not served as a basis for action on health policy, and the exceptional nature of the Article means that the threshold for doing so would be high.

Finally, it is useful to draw a distinction between Articles 168 and 114 TFEU. Whereas Article 114(1) is widely used to harmonise legislation within the common market when its conditions are met, Article 168 gives much more narrow space for

[5] The term "incentive measures" is not clearly defined. Greer et al (2019, p. 64) write that the wording refers to financing tools but not binding legislation. Meanwhile, Purnhagen et al (2020, p. 301) also envisage the possibility of binding EU measures that would provide financial or other incentives, either positive or negative, for Member State actions. In any case, Article 168(5) foresees the ordinary legislative procedure for adopting these incentive measures, which suggests that the measures can take the form of secondary Union law, so long as they do not harmonise Member States' laws.

EU legislation. As noted above, Article 168(5) even excludes harmonisation in important fields of public health. Hence, it comes as no surprise that the choice of legal basis in matters touching simultaneously upon the single market and the health sector is controversial, and has given rise to numerous rulings by the European Court of Justice.[6] In any case, the legislator must always ask itself where the centre of gravity of the proposed legislative act lies, in order to determine the appropriate legal basis.

In sum, public health is in principle a supporting competence for the EU, which precludes legislative action by the EU. That said, through Articles 168(4) and 168(5), the Treaty provides six exceptions that enable legislation to be passed, using the ordinary legislative procedure. In this way, under the Lisbon Treaty, the EU competence on public health might be described as a supporting competence, with carefully defined elements of shared competence hidden in plain sight.

Use of Article 168(4) in practice

The EU institutions have used the opportunity to adopt legislation in the matters listed under Article 168(4). This section covers the matters listed in Article 168(4), paragraphs (a)–(c) in turn.

Regarding **safety standards for organs** (Article 168(4)(a)), the European Organs Directive (2010/45) sets requirements for example for the procurement of organs, for the traceability of organs from donor to recipient, and for the qualifications of healthcare personnel involved. Concerning **blood and substances of human origin**, also mentioned in Article 168(4)(a), revision of the EU legislative framework is ongoing (European Commission, 2022). The revision concerns Directive 2002/98 on the safety and quality of human blood and blood components, and Directive 2004/23 on the safety of human tissues and cells. The purpose of the legislation is to prevent the spread of communicable disease through transfusion or transplantation: the Commission justifies the revision, among other reasons, through increasing globalisation in the sector. The announced legal basis for the new legislative proposals, to be published in 2022, is Article 168 (see Annexes 1 - 4 to the Commission Work Programme 2021; EP Legislative Train Schedule): likewise, the existing legislation was adopted under the "public health" article 152 of the previous Treaty (Article 152 TFEU, Amsterdam version).

Similarly, updates of legislation using Article 168(4)(b) (**veterinary and phytosanitary measures**) are underway. Namely, the revision of the Feed Additives Regulation (1831/2003), for which a legislative proposal is upcoming (EP Legislative Train Schedule), uses Article 168 as a legal basis, alongside Article 43 which

[6] See for example *Philip Morris Brands SARL and others v The Secretary of State for Health* (C-547/14).

empowers the Commission to make proposals for implementing the Common Agricultural Policy.

Regarding **medical devices**, mentioned in Article 168(4)(c), new legislation is currently entering into force: Regulation 2017/745 on medical devices (in force since 26 May 2021), and Regulation 2017/746 on in-vitro diagnostic medical devices (entering into force on 26 May 2022). Both Regulations were adopted using Article 168 as the legal basis, complemented by the 'catch-all' legal basis of Article 114 that provides for the establishment of an internal market.

A proposal on **medicinal products** for human use (COM/99/0315) was first adopted in 2001 (Directive 2001/83) using the 'internal market' legal basis, as at that time, the Treaty did not yet include a specific provision for legislation on medicinal products. Following up on this, Regulation 726/2004 laid down rules for authorisation and supervision of medicinal products for human and veterinary use and defined the tasks of the European Medicines Agency (EMA). This regulation used the old "public health" article (Article 152 TFEU, Amsterdam version) as a legal basis, but only for parts concerning medicines of animal use (see Commission proposal, COM(2001)404). At the time, the Treaty provided for legislation on measures in the veterinary field, but not yet for measures for human use: therefore, for human medicinal products, the 'internal market' legal basis (Article 95) was used.

More recently, Article 168(4)(c) together with the Lisbon Treaty's 'internal market' article 114 served as legal basis for Regulation 2022/123, which reinforces the European Medicines Agency's role in crisis preparedness. The new legislation, adopted on 25 January 2022, focuses on monitoring and mitigating shortages of critical medical products: it codifies mechanisms that the EMA had established during the COVID-19 pandemic, while also giving new tasks to the agency (EMA, 2022). It for example establishes the Medicine Shortages Steering Group within the EMA, which is enabled to make recommendations to the Commission, Member States and other entities in order to mitigate shortages (Regulation 2022/123, Article 8). As another example, the Regulation provides for an Emergency Task Force within the EMA, which is tasked with providing scientific support for the development of remedies during public health emergencies, among other tasks (Article 15). The original Commission proposal (COM(2020)725, p. 4) suggests that the internal market legal basis justifies the measures taken to combat shortages of products within the internal market, whereas Article 168(4)(c) helps "ensure the quality and safety of medicinal products and medical devices developed during [crisis] periods". In short, the COVID-19 pandemic has inspired an enlargement of the EMA's competences for ensuring crisis response, with Article 114 providing the internal market rationale for the new actions for the availability of medicinal products; in the meantime, Article 168 remains the treaty basis for standard-setting for the new products.

As it is connected to Article 4 of the Treaty, Article 168(4) is the most explicit expression of existing EU legislative competence in public health. The above overview shows that legislation has been adopted pursuant to each of the sub-points of the Article, and that the potential of Article 168(4) has therefore been exploited productively. As an exception, the legislation on medicinal products precedes the specific EU competence to legislate in this field, which explains the historical use of the generic internal market legal basis, which is now used jointly with Article 168(4).

Use of Article 168(5) in practice

Though Article 168(5) gives the possibility for legislation to protect public health from tobacco, EU **tobacco legislation** has instead been adopted using the internal market legal basis. For example, the Tobacco Products Directive (2014/40) and the Tobacco Advertising Directive (2003/33) – adopted before the Lisbon Treaty, when the "public health" article of the Treaty did not yet mention tobacco specifically – do not use public health as a legal basis. Delhomme (2020) argues that the resort to the internal market legal basis is caused by the weakness of Article 168, which excludes any harmonisation of Member States' laws.[7] He continues that the use of the "wrong" legal basis undermines the legitimacy of EU action, exposes legislation to legal challenges insofar as it does not follow the internal market rationale of Article 114, and prevents the EU from adopting minimum standards, as the setting of minimum standards runs contrary to the logic of eliminating trade obstacles within the Single Market. As an example of the second issue, provisions of the 1998 Tobacco Advertising Directive that prohibited tobacco advertising in static places such as billboards could not be justified in terms of facilitating trade within the Single Market, and were therefore annulled by the European Court of Justice in the *Germany v European Parliament and Council* (C-376/98) case (Delhomme, 2020). A stronger treaty basis for EU legislative action on public health would therefore have been necessary for achieving the desired policy outcomes.

While Article 168(5) offers a possibility for legislation against **alcohol abuse**, EU action on the matter has been non-legislative, including support for Member State efforts. In the 2006 EU alcohol strategy (COM(2006)625), the Commission explicitly stated that it does not intend to substitute existing national legislation, citing the subsidiarity principle. The apparent lack of interest in alcohol legislation contrasts with the issue of **smoking in public places**, on which the Commission decided to act, but had to unwillingly resort to a non-binding Council recommendation (2009)

[7] The matters outlined in Article 168(4) appear to be an exception to this non-harmonisation rule, as the actions under Article 168(4) are taken "by way of derogation" from Article 2(5), which in turn excludes harmonisation in areas where the EU has supporting competence.

due to the lack of a strong enough treaty basis for binding legislation (Delhomme, 2020; Delhomme, 2018).

With the COVID-19 pandemic, the provisions of Article 168(5) on "**major cross-border health scourges**" and "**serious cross-border threats to health**" have become particularly topical. In 2013 the paragraph was already used as a legal basis for Decision 1082/2013, which for example foresaw the creation of the Early Warning and Response System by the European Centre for Disease Prevention and Control (ECDC) (Bacian, 2020). During the pandemic, the Member States have reported the numbers of COVID-19 cases on their territory by using the system (ECDC, 2022). All in all, the Decision provides the framework for constant communication between the ECDC, the Commission and national authorities within the Member States, as well as enabling joint advance procurement of medical countermeasures. In November 2020, the Commission made a proposal for a Regulation (COM(2020)727) that reinforces the framework for responding to serious cross-border health threats, and repeals Decision 1082/2013. Once adopted, the new framework will for example oblige Member States to report on their preparedness plans; though Article 8 of the proposal would empower the ECDC to 'audit' the preparedness plans, the recommendations the ECDC makes during the audits are not binding. Besides the audit of the preparedness plans, the Regulation would for example enable the Commission to organise training for public health professionals within the Member States.

More broadly, Regulation 851/2004, establishing the ECDC itself, was adopted using the public health treaty basis. Likewise, the ongoing legislative process for reinforcing the ECDC's powers (COM(2020)726, see below) is based on Article 168(5) – the following section discusses the ECDC in further detail.

On the international arena, Article 168(5) served as a legal basis for the Council's authorisation for the EU to negotiate on the WHO 'Pandemic Treaty' (Decision 2022/451). The agreement is to provide a global framework for pandemic preparedness and response, with the outcome of the negotiations due to be submitted to the WHO's World Health Assembly in 2024 (WHO, 1 December 2021).

Finally, one should note that annexes to the 2021 Commission Work Programme foresaw Article 168 as a legal basis for the upcoming legislative proposal on a European Health Data Space, without however specifying the intended paragraph within the Article (European Commission 2020, p. 5). However, the final Commission proposal (COM(2022)197/2, p. 6) no longer employs Article 168, but instead references Article 114 (the "internal market" article), as well as Article 16 which enables the Union to legislate on data protection matters. While the sharing of health data across national borders can promote public health, Articles 168(4) or 168(5) do not specifically provide for legislation on this matter; furthermore, Article 114(3) explicitly refers to the possibility of adopting legislation in the field of health, using the internal market legal basis where appropriate. Thus, while Article 168 appears

insufficient as a legal basis for the legislation on a health data space, Article 114 provides adequate cover.

In sum, the possibilities offered by Article 168(5) have not been used as comprehensively as those of Article 168(4). In particular, anti-tobacco legislation has avoided Article 168(5) in favour of the "internal market" legal basis: while legislation adopted under Article 168(5) cannot result in harmonisation, the internal market legal basis offers such an opportunity. Likewise, the European Health Data Space is being established on the basis of Article 114, despite the Commission's apparent interest in using Article 168 as a legal basis. That said, the establishment of the ECDC and the EU's work on the WHO Pandemic Treaty are examples of Article 168(5) being used in practice.

Public health crisis management post-COVID

The COVID-19 crisis has substantially expedited European integration in public health, with new frameworks for crisis management emerging during the pandemic.

Whereas the EU crisis response at the outset of the pandemic was at least initially perceived as lagging behind, it steadily picked up pace, and EU coordination has become a core asset in the management of the crisis. In particular, the European Centre for Disease Prevention and Control (ECDC) has provided for exchange of information about the spread of the pandemic, while the joint procurement procedure foreseen by Article 5 of Decision 1082/2013 has been used for common purchases of COVID countermeasures (European Commission).

Furthermore, the EU Health Security Committee (HSC) also played a pivotal role in COVID through directly interconnecting the Member State health ministries. Originally set up in 2001 at the request of national Health Ministers as an informal advisory group on health security at European level, hosted under DG SANTE of the Commission, its membership mostly consists of officials in national health ministries. In 2013, Decision 1082/2013 reinforced the HSC's role in coordination and sharing of best practice and information on national preparedness and response activities.

The growing importance of public health crisis management has given rise to new initiatives, such as the Commission proposal foreseeing the expansion of the mandate of the ECDC (COM(2020)726), or the creation of the Health Emergency Preparedness and Response Authority (HERA) which enables common investments in health preparedness through a dedicated budget. The following paragraphs elaborate on ECDC, HSC and HERA, and their role in health crisis management.

European Centre for Disease Prevention and Control (ECDC) and the Health Security Committee (HSC)

The ECDC was originally created through Regulation (EC) No 851/2004 after the 2002 SARS outbreak, as an add-on on top of existing networks for infectious diseases surveillance. By 2020, it oversaw a total staff of 286 and a budget of €60.4 million, with its main tasks including epidemic intelligence and surveillance, scientific advice, and training of Member State specialists for investigations (Scholz 2020). Furthermore, it takes action through thematic programmes, such as those on antimicrobial resistance, healthcare-associated infections, tuberculosis, and vaccine-preventable diseases (Scholz 2020, p. 7).

During the COVID pandemic, the ECDC expanded its remit of activities to respond to the crisis. While the ECDC's mandate has been limited to surveillance of health threats, as opposed to providing advice on risk management, during the COVID crisis the ECDC grew to provide advice to Member States and the Commission on crisis responses such as lockdowns and face masks (Deruelle & Engeli 2021). The Commission's proposal for the new expanded ECDC mandate (COM(2020)726) seeks to enshrine these developments legally, by enabling the ECDC to formulate recommendations on health threat management to the Health Security Committee (new Article 8b). Moreover, the ECDC would gain an operational capacity through the "Health Task Force", which it can mobilise to assist local response within Member States (Deruelle & Engeli 2021; COM(2020)726, new Article 11a). The European Parliament and EU Council have reached a provisional agreement on the text through trilogues, and the proposal is currently awaiting its first reading in the Parliament (EP Legislative Train Schedule, April 2022).

Early on during the pandemic, Deruelle had criticised the distinction between the ECDC's surveillance and the HSC's risk management role, which is not found in corresponding national-level institutions, and which hinders effective crisis response (Deruelle 2020). While the new enlarged mandate of the ECDC will increase coordination, it nonetheless poses the question of the precise relations between the HSC and the ECDC. Once the ECDC has a legal mandate to provide recommendations to the Health Security Committee, one may assume that the HSC's threshold for ignoring the recommendations becomes higher. Beyond legal text, only practical experience can reveal how the relationship between the entities evolves.

Further, one should note the difference between "recommending" and "prescribing" measures to prevent the spread of epidemics.[8] Even under the new legal regime, the ECDC's recommendations will remain non-mandatory: indeed, binding recommendations would risk raising legal concerns around Article 168(7) TFEU, which states that the "management of health services and medical care and the

[8] The word "prescribe" is mentioned in point 5 of the JEF-Europe resolution, "For a coordinated EU response to tackle the COVID-19 health emergency" (April 2020).

allocation of resources assigned to them" is a Member State responsibility (see Nolen & Stockebrandt 2021). In particular, binding recommendations could influence Member States' national control over resource allocation within their healthcare systems.

However, the COVID-19 pandemic has put the exclusive national prerogative in this field under question. Deruelle and Engeli (2021, p. 1393) suggest that future health crises might raise a need to go beyond the current 'coordination' arrangement for crisis management, towards 'regulation'. Further, during the Conference on the Future of Europe, the Citizens' Panel focusing on health noted that the EU "does not have enough competencies to legislate on healthcare", and called for the possibility to "issue binding regulations and decisions" (CoFoE 2022, Recommendation 49).

The context of crisis management provides the most obvious example for the need for such binding EU-level decisions. Binding rules could concern, for example, the methodologies on data collection and provision by national authorities, and the sizes of stockpiles in the Member States (Beaussier & Chabane 2020, p. 818). Robust democratic control at the European level for such measures would be essential for their legitimacy, especially if they come from an EU agency such as the ECDC. However, given the constraints imposed by Article 6 (public health as a "supporting competence") and by Article 168(7) (management of healthcare systems, including resource allocation, as a national responsibility), **the first necessary step towards achieving an appropriately integrated crisis response is Treaty change**.

Health Emergency Preparedness and Response Authority (HERA)

During the pandemic, the EU was criticised for the slow procurement of countermeasures, above all vaccines. Introduced by the Commission in September 2021, the Health Emergency Preparedness and Response Authority (HERA) is responsible for ensuring the rapid availability of medicines and other equipment such as PPE (personal protective equipment) during cross-border health emergencies. The Authority aims to strengthen the coordination between Member States, and also with industries, to ensure preparedness and crisis response. HERA is housed directly within the European Commission, and unlike ECDC, it is therefore not an EU Agency. (European Commission 2021)

HERA has access to a budget of €6 billion for the 2021/27 period, and is able to spend the budget on investments in health preparedness. The European Commission justifies the creation of HERA by reference to the limits of the ECDC's mandate, as the latter only extends to communicable diseases, and moreover does not include the procurement of medical countermeasures. Similarly, the European Medicines Agency (EMA), which certifies medicines to be used within the EU, does not have capacity to make procurements (European Commission 2021). Nonetheless, ECDC and HERA have some seemingly overlapping tasks. HERA is tasked with detecting health threats once they emerge and designing

countermeasures, whereas ECDC identifies and assesses emerging health threats in the field of infectious diseases, and will in the future make recommendations on national response measures.

In connection with the introduction of HERA, the EU is laying out emergency measures that may be taken when a cross-border health crisis emerges. An upcoming Council Regulation (see Commission proposal, COM(2021)577) foresees measures such as creation of a Health Crisis Board consisting of a representative from the Commission and each Member State, which coordinates action to ensure supply of medical countermeasures (Article 5). Moreover, the new Regulation includes a provision for the Commission to procure medical countermeasures on behalf of willing Member States (Article 7). In this way, the Council Regulation offers a basis for joint procurement efforts similar to those which the Commission headed after the onset of the COVID-19 pandemic.

The continuity also manifests in the choice of legal basis: Commission purchases of COVID-19 vaccines were made based on the Emergency Support Instrument (ESI), enabled by **Article 122(1) TFEU** (Lannoo & Sipiczki 2021), and the same Treaty Article is cited as the legal basis for the new Council Regulation. Located under the "Economic and monetary policy" chapter of the Treaty, Article 122(1) enables the Council to take measures "if severe difficulties arise in the supply of certain products". In other words, the proposed new measures are not taken under the Article 168(5) provision that mentions measures for "combating serious cross-border threats to health". The choice of Article 122 in joint procurement is reminiscent of the adoption of health-themed legislation under Article 114 instead of Article 168: EU action on health resorts to general internal market-based legal bases, instead of a specific competence on health. Indeed, the Commission's Q&A webpage (European Commission, 16 September 2021) about HERA mentions Article 168, which however is not mentioned in the relevant legislative documents.

As Article 122 foresees decisions by the Council without the European Parliament's involvement, providing new avenues for procurement under Article 168 – by means of an ordinary legislative procedure involving both the Council and the Parliament – would help bridge the EU's democratic deficit. Further, a specific competence under Article 168 would also facilitate joint procurement of medical supplies outside crisis periods, for example in preparation for ordinary flu epidemics within the confines of a predetermined budget (Naumann 2022, p. 259). In sum, a **stronger Treaty basis for procurement of medical supplies under Article 168** would ensure more flexibility for EU action, while also guaranteeing a stronger democratic control.

Opportunities for a health union beyond crisis management

Beyond crisis preparation and management, the COVID pandemic has precipitated discussion on European action for high-quality national healthcare systems. In a

2020 report for the Commission, an EU expert group found that multiple national health systems lacked the resilience required to respond to COVID adequately (European Commission, 2020). Bucher (2022, p. 10) argues for European minimum standards for health system resilience, and additionally highlights antimicrobial resistance (AMR) as one cross-border threat which would require binding commitments on the reduction of antibiotics use. Further, she argues for an extension of the ECDC's mandate to surveillance of non-communicable diseases, which would not only enable insights into disease prevalence, but also support a more effective crisis response, given that crises especially threaten demographics with pre-existing medical conditions (Bucher 2022, p. 11).

Though Article 4(2)(k) provides for a shared competence in "common safety concerns in public health matters", these are limited to "the aspects defined in this Treaty", namely in Article 168. Extension of EU legislative action to topics such as antimicrobial resistance would therefore entail either separately defining new matters on which legislation is allowed or, as the final recommendations of the Conference on the Future of Europe propose, a **fully-fledged, horizontal shared competence** on public health.

Furthermore, calls for European integration move beyond public health, extending to the organisation of national healthcare systems. While the organisation of healthcare can only remain national responsibility due to the financial costs involved, treaty reform could enable the EU to establish **minimum standards for healthcare systems**. Including such a possibility would align with the CoFoE recommendation of an EU competence on "health and healthcare".

The European Parliament has already made demands in a similar vein: in July 2020, a Parliament resolution called for the Commission to propose minimum standards for patient safety, healthcare workers' working conditions and resilience to pandemics (European Parliament, 10 July 2020). Though the Parliament noted the Member States' competence in the matter, such legislation could easily run into legal constraints under Article 168(7), unless the latter is amended. Further, Ujhelyi et al (2021, p. 10) report on Hungarian stakeholder consultations which revealed strong support for European standards on matters like waiting times for surgeries, and "the material and personal conditions of health services".

The last point is further elaborated in the manifesto for a European Health Union (europeanhealhunion.eu), which calls for common standards for the training of health professionals, and joint European and national action to address shortages of health workers in certain regions. Such actions would be an appropriate show of solidarity, especially as the cross-border mobility of healthcare personnel has been facilitated by free movement within the Single Market.

Besides amendments to Article 168(7) TFEU, an **amended Article 3(3) TEU** could enshrine the establishment of a European health union as an objective for the EU, as suggested by former Commissioner Vytenis Andriukaitis (2021, p. 5). Adding the mention of a Health Union to the Treaties would be a strong political signal of

commitment to European solidarity on health, consolidating the spirit of cooperation that Europe at its best managed to exhibit during the pandemic.

The EU already has **financial instruments for public health**: in the 2021/27 Multiannual Financial Framework, the EU4Health programme amounts to €5.75 billion, which includes investment in the strength of health systems, improving medical products, and protection against cross-border health threats (European Commission). The use of funding instruments can in the future continue to be a way for the EU to respond to popular demands for a stronger EU on health, whilst respecting Member States' prerogatives in managing their own health systems. For example, EU funding continues to provide added value for combatting rare diseases, among other topics (Andriukaitis 2021, p. 4).

The next section summarises the paper's recommendations for Treaty reform.

Recommendations

Articles 4, 6 and 168 TFEU: Giving the EU a horizontal shared competence on protection and improvement of human health

Firstly, the next Treaty reform should make good on the clear recommendation made by the Conference on the Future of Europe: Article 4 TFEU should be amended to turn health and healthcare into shared EU competences. Correspondingly, Article 6 TFEU should also be amended.

At present, Article 6 TFEU lists the "protection and improvement of human health" as a supporting competence for the EU (EUR-Lex). Meanwhile, Article 4(2)(k) adopts a more limited wording, giving the EU a shared competence in "common safety concerns in public health matters", "for the aspects defined in this Treaty" (EUR-Lex).

In the amended Article 4, the broader wording – currently found in Article 6 – would better align with the CoFoE recommendation, which extends to "health and healthcare", as opposed to mere "public health". Moreover, the broader wording would for example enable the EU to develop minimum standards related to health systems, as has been requested by the European Parliament and by various stakeholders during the COVID pandemic.

Moving away from an 'ad hoc shared competence' for matters specifically listed in the Treaty would enable EU legislation on emerging topics, such as antimicrobial resistance, which are not mentioned in the Treaty. It should be noted that public health, besides social policy, is the only policy area where the current Article 4 circumscribes the EU's shared competences *a priori*, by referring to "aspects defined in this Treaty". Therefore, a fully-fledged, horizontal shared competence would also simplify the Treaty, besides responding to citizens' demands voiced during CoFoE.

In short, the new Article 4(2) TFEU would read as follows:

"Shared competence between the Union and the Member States applies in the following principal areas:
[...]
(k) protection and improvement of human health"

Accordingly, the current Article 6(a) TFEU would be deleted.

After these changes, it would no longer be necessary to offer a specific list of matters on which the EU may adopt legislation. Thus, Articles 168(4) and 168(5) in their current form would be obsolete. The new Article 168 should specify that EU legislative power in health takes the form of minimum harmonisation, thereby allowing Member States to maintain and adopt higher standards (see Delhomme 2020). For this purpose, a wording borrowed from Article 193[9] would be an appropriate element to include in the new version of Article 168:

"The protective measures adopted pursuant to this Article shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. They shall be notified to the Commission."

Article 3 TEU: Making the creation of a European Health Union an objective of the EU

In TEU, Article 3 lists a number of objectives for the Union (EUR-Lex). Given the public discussion on a European Health Union, also raised by citizens during CoFoE, reference to a European Health Union in Article 3 would further indicate that the public's concerns are translated into the new Treaty. The round of Treaty reform happening after an unprecedented health crisis would seem a natural moment to add a mention of the Health Union to the Treaty.

A new line would be added to Article 3(3) TEU, in line with a proposal from Andriukaitis (2021, p. 5):

"It shall promote universal health coverage by establishing a health union."

Loosening the constraints of Article 168(7) TFEU

Article 168(7) TFEU includes a strong wording to protect Member States' discretion in defining their health policy, and the management of their health systems. The first

[9] Article 193 TFEU provides for the principle of 'minimum harmonisation' in the field of environmental protection.

two sentences of the paragraph currently read as follows: *"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."* (EUR-Lex)

By interpreting the Article narrowly, one might already argue that it is incompatible with current practice: for example, the Patients' Rights Directive (2011/24) influences the delivery of medical care within the Member State (see Delhomme 2020). However, admittedly, the Directive "respects the responsibilities of the Member States", and indeed Recital 19 of the Directive specifically mentions Article 168(7), in arguing that cross-border healthcare should be organised according to the laws of the country treating the patient (Directive 2011/24).

Nonetheless, as was argued previously, minimum standards on the quality of health services, and even binding rules on health crisis preparation, would raise challenges under the current Article 168(7), especially when it comes to the provision on the "allocation of resources". Specifying that EU measures take the form of minimum standards would already constitute an assurance that Member States retain independence in health policy. Additionally, a specific reference to the subsidiarity principle in the new version of Article 168(7) would offer a signal that Member States remain primarily responsible for defining health policy and how healthcare is organised, whilst enabling a European health policy to serve as a common backbone. After a Treaty reform, the new Article 168(7) could for example read as follows:

> *"The Union 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, in accordance with the principles of subsidiarity and proportionality."*

Article 168 TFEU: A robust Treaty basis for joint procurement of health supplies, involving the Parliament

This paper has noted that measures concerning joint EU purchases of medical goods to tackle crises have been taken based on Article 122(1) TFEU, which does not provide for involvement of the European Parliament (EUR-Lex, Article 122 TFEU). Article 122(1) specifically mentions that it should be used "without prejudice to any other procedures provided for in the Treaties", which invites the possibility of a specific procurement mechanism under Article 168. After Treaty reform, the new Article 168 can offer a specific legal basis for common procurement of health supplies, which can also affirm the Parliament's role in the process. A new paragraph, to be included in Article 168, would read as follows:

"The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and in accordance with the principles of subsidiarity and proportionality, shall establish a framework for ensuring the supply of medical goods and countermeasures in the Union."

Conclusion

After the Conference on the Future of Europe, it is the responsibility of the EU institutions to ensure follow-up on citizens' proposals. As the Conference took place during the COVID-19 pandemic, it is hardly surprising that the final recommendations of the Conference feature demands for more European integration on health. Both the randomly selected Citizens' Panels and the final plenary of the Conference endorsed proposals that specifically request health to become a shared competence. As the European Parliament is preparing its proposals for Treaty reform, it has the opportunity to make proposals that incorporate this public demand.

Through an evaluation of existing and upcoming EU measures on public health, this paper has offered arguments for the need for Treaty reform in order to achieve a more integrated European Health Union. Amending Article 4 TFEU, as the Conference has requested, is at the core of the necessary Treaty reform. Furthermore, amendments to Article 168(7) TFEU would enable a more integrated European health crisis response, and offer the opportunity for European minimum standards on good-quality healthcare. A reformed Article 168 can also safeguard the European Parliament's involvement in decisions on European-level procurement of medical goods. By mentioning a European health union in Article 3(3) TEU, the institutions can further offer a clear signal to citizens that their proposals have been heard, and that the EU has emerged from the COVID pandemic stronger and more united.

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