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Expanding EU Competence in Health?

The Need for and Feasibility of Treaty Change

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Following the COVID-19 pandemic, various voices proposed to change the EU Treaties to expand EU competence in the field of health. But is such treaty change needed? Is it even feasible?

Current EU competence in health

At the moment, EU legal competence in health is quite limited, at least on paper. Under Article 4(k) of the Treaty on the Functioning of the European Union (TFEU), 'common safety concerns in public health matters' is a shared competence between the EU and the Member States; and under Article 6(a) TFEU and the 'protection and improvement of human health' is a supporting competence of the EU. The main article that allows the EU to adopt health legislation is Article 168 TFEU on the protection of public health, and various articles foresee that a high level of human health protection must be ensured in the definition and implementation of all EU policies and activities (Articles 9 and 168(1) TFEU, and Article 35 of the EU Charter of Fundamental Rights). However, the primary responsibility for the definition of health policy, the organisation of the health services and medical care, and the allocation of the resources assigned to them lies with the Member States (Article 168(7) TFEU). Finally, it is worth noting that health norms are also adopted within the frameworks of other fields, such as Article 114 (internal market) and Article 153 TFEU (social policy).

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EU health law

As maintained by Hervey and McHale, the EU thus has a 'limited formal competence in the field of health'.[2] Nonetheless, despite these narrow legal bases, EU action and the normative framework on health-related issues are quite wide.[3] Among others, the EU has adopted binding legislation on pharmaceuticals,[4] medical devices,[5] clinical trials,[6] standards of quality and the safety of organs and substances of human origin, blood and blood derivatives,[7] tobacco products,[8] cross-border healthcare,[9] and cross-border health threats.[10] The EU has also addressed a series of recommendations on public health, like, for example, on the prevention of health-related harm associated with drug dependence and on patient safety.[11] Furthermore, the EU is particularly active in the area of digital

[2] Tamara K. Hervey and Jean V. McHale, *European Union Health Law: Themes and Implications*, Cambridge University Press, 2015, p. 69.

[3] On the scope and content of the EU health law and policy see Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*, Oxford University Press, 2019, pp. 1-15; Mary Guy and Wolf Sauter, 'The History and Scope of EU Health Law and Policy', in Tamara Hervey *et al*., *Research Handbook on EU Health Law and Policy*, Edward Elgar Publishing, 2017; Tamara Hervey and Bart Vanhercke, 'Health Care and the EU: The Law and Policy Patchwork', in Elias Mossialos *et al*., *Health System Governance in Europe: The Role of European Union Law and Policy*, Cambridge University Press, 2010.

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136.

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

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

[7] Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ 2010 L 207; Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ 2004 L 102; Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ 2002 L 33.

[8] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ 2014 L 127.

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

[10] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ 2013 L 293.

[11] Council Recommendation 2003/488/EC of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence, OJ 2003 L 165; Council Recommendation 2009/C 151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections.

health.[12] For instance, the eHealth Digital Service Infrastructure allows for the exchange of e-prescriptions and patient summaries across countries.[13]

The role of executive agencies in the health sphere should be pointed out. These include the European Medicines Agency, the European Centre for Disease Prevention and Control, the European Chemical Agency, and the European Food Safety Authority. The EU also provides several resources with a view to improving health research, health infrastructures, and the availability and affordability of medicinal products. These funds come from the EU4Health programme, Horizon Europe, the EU cohesion funds and the Resilience and Recovery Facility. In addition, over time, the Court of Justice of the EU has delivered leading judgments that shaped subsequent EU health legislation, for example on cross-border healthcare.[14] Therefore, it is not surprising that Purnhagen *et al*. observe that, in the health field, 'legal impediments to Union action are less restrictive than is commonly understood'.[15]

The European Health Union

The framework above has recently seen the introduction of another set of health-related normative proposals. In 2020, after the first wave of the pandemic, the Commission came up with the idea of building a European Health Union (EHU). The aim is to better protect European citizens' health, be better prepared for future pandemics, and strengthen the resilience of European health systems.[16] Alemanno identifies the 'EU's limited and imperfect competences in public health' as the reason that 'very quickly prompted political calls for the urgent creation of a European Health Union'.[17]

The EHU is based on three main pillars: (1) measures on crisis preparedness and response, (2) the pharmaceutical strategy, and (3) Europe's Beating Cancer Plan. Some of the steps that have already been taken under pillar (1) include the establishment of a new European Health Emergency preparedness and Response Authority (HERA), which was created last year,[18] and the adoption of a Regulation reinforcing EMA's role in crisis preparedness and management of medicinal products and devices, which became applicable as of 1

[12] Communication COM/2018/233 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.
[13] European Commission, 'Electronic Cross-Border Health Services'.
[14] Court of Justice of the European Union, 'The Court of Justice and Healthcare', 2018.
[15] Kai P. Purnhagen *et al*., 'More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', *European Journal of Risk Regulation* 11, 2020, pp. 297-306.
[16] European Commission, 'European Health Union'.
[17] Alberto Alemanno, 'Towards a European Health Union: Time to Level Up', *European Journal of Risk Regulation* 11(4), 2020, pp. 721-725.
[18] European Commission, 'European Health Emergency Preparedness and Response Authority (HERA): Getting Ready for Future Health Emergencies', 16 September 2021.

March 2022.[19] It can be affirmed that through the EHU, EU health law is once again growing. Yet, it must be highlighted that all the EHU proposals are envisaged 'within the current Treaty provisions', 'fully respecting' the competence of the Member States in the area of health, as explained by the Commission.[20]

Calls for increasing EU competence in health

Various actors believe that this is not enough, and that EU competence in health should be expanded. Since this can be done only through a revision of the EU Treaties, several calls have been made for that to occur. The most notable initiative in this regard is the *Manifesto for a European Health Union*, which was launched in November 2020 and has been signed by almost 1300 individuals from different professional backgrounds (academics, MEPs, hospital workers, NGOs employees, etc).[21] The Position Paper annexed to the Manifesto proposes to amend EU treaties eliminating letter (a) from Article 6 (the 'protection and improvement of human health' as a supplementary competence) and substituting current letter (k) under Article 4 ('common safety concerns in public health matters') with the expression 'European Health Union'.[22] Other changes suggested concern Article 3 TEU and Article 168 TFEU.

Even relevant political figures did not exclude the need for Treaty change with a view to increasing EU health competence. In April 2021, at an event organised by the European People's Party, the then-German Chancellor Angela Merkel stated: 'I believe that Europe needs more competencies in the area of health. This will probably also require changes to the treaties'.[23]

In the same vein, the Plenary of the Conference on the Future of Europe, a citizen-led series of debates and discussions involving people from across Europe to discuss the future of the European Union,[24] recommended the inclusion of 'health and healthcare among the shared competencies between the EU and the EU Member States by amending Article 4 TFEU'.[25] This proposal was first put forward by the European Citizens' Panel 3 on climate change, environment and health, which explained that:

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[19] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ 2022 L 20.
[20] European Commission, 'Questions and Answers: Building a European Health Union: Stronger Crisis Preparedness and Response for Europe', 11 November 2020.
[21] European Health Union, 'Manifesto for a European Health Union'.
[22] European Health Union, 'Position Paper: Treaty Change for a European Health Union'.
[23] Hans Von Der Burchard, 'Merkel: EU "Probably" Needs Treaty Changes, Especially for Health Policies', *POLITICO*, 21 April 2021.
[24] European Commission, 'Conference on the Future of Europe'.
[25] Conference on the Future of Europe, 'Report on the Final Outcome', 2022, p. 50, 52.

> '[…] currently the European Union does not have enough competencies to legislate on healthcare. Covid-19 pandemic has proven the necessity of a stronger EU presence in health policies. This treaty change will allow the EU to do more to guarantee healthcare for all EU citizens and to issue binding regulations and decisions'.[26]

Many Europeans seem to think in a similar way. According to a Eurobarometer survey conducted last year, 74% of Europeans want the EU to have more competences to deal with crises such as the Covid-19 pandemic.[27]

The need for a treaty change

Among the calls for expanding EU competence in health, the clearest in terms of the legal reasons why a change is needed, is the one provided by the aforementioned Position Paper annexed to the Manifesto. For this reason, this contribution will focus on it. The main argument presented in that document is that 'the EU's limited competence in health has not stopped EU law from encroaching on health policy through other fields'.[28] Health has become an 'ancillary objective' of other policy agendas and, as a result, the national health representation at the EU level has been disempowered.

The Position Paper then describes what the benefits of having more EU competence in health would entail. For instance, a Council configuration exclusively dedicated to health might be created (right now, health is under the EPSCO Council, which also deals with employment, social policy, and consumer affairs). The Position Paper also argues that there would be a more detailed debate on the application of the principle of subsidiarity and proportionality, with national health ministers having a stronger say to evaluate whether these principles are respected or not when EU health legislation is adopted.[29] In the light of the above, it is concluded that having a reinforced EU legal basis for health, would, counter-intuitively, enhance the power of the Member States, rather than that of the EU.

Analysis of the main arguments in favour of Treaty change

The Position Paper is correct in affirming that health has often become an ancillary objective of other policy agendas. As proved by a 2019 European Observatory on Health Systems and Policies report, 'much of the EU's positive effect on health is through

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[26] Conference on the Future of Europe, 'Report on the Final Outcome', 2022, European Citizens' Panel 3: "Climate change and the environment / Health", Recommendation 49, p. 163.
[27] European Parliament, 'Spring 2021 Survey – Resilience and Recovery: Public Opinion One Year into the Pandemic'.
[28] European Health Union, 'Position Paper: Treaty Change for a European Health Union', p. 2.
[29] European Commission, 'Subsidiarity'; European Commission, 'Proportionality'.

regulations grounded in the internal market', and similar considerations can be made for other non-health areas.[30] This was explicitly accepted by the Court of Justice of the EU itself. The Court claimed that the prohibition of harmonisation of laws to protect and improve human health (Article 168(5) TFEU) does not mean that other harmonisation measures, adopted under other provisions of the Treaties, cannot have any impact on the protection of human health.[31] Since more EU competence in health might lead to a more prominent role of health as an autonomous objective in EU legislation, Treaty change can be desirable. As it is sustained in the Position Paper, it is also plausible that, because of increased EU competence in health, more attention will be paid to the principles of subsidiarity and proportionality. Even more, this kind of debate could have the potential to enrich other EU policies as well. This is another reason why Treaty revision could be advisable.

Would an expansion of the legal basis for health produce the counterintuitive effect of giving more powers to the Member States rather than to the EU, as affirmed in the Position Paper? The answer depends on the meaning given to the expression 'more powers to the Member States'. It is physiological that a stronger EU legal basis would presuppose a wider role for national health ministers. In this sense, it is true that increased EU health competence would entail 'more powers to the Member States'. Therefore, the answer to the question above would probably be yes.

If, instead, the expression 'more powers to the Member States' refers to the fact that, as a consequence of the Treaty change, fewer EU law rules on health would be adopted, the answer is different. In other words, it is unlikely that an expansion of the EU legal basis for health would give more powers to the Member States in the sense that less EU health law would be adopted. This idea that more EU power in health might mean less EU law was upheld by de Ruijter, one of the co-initiators of the Manifesto, during her keynote speech at the Eighth European Conference on Health Law in Ghent (Belgium), in April 2022.[32] This view can be disputed: in the past, the clarification and expansion of EU competences in the field of health through Treaty change did not not hinder the development of EU health law and policy, quite the contrary. This conclusion seems to be supported by de Ruijter herself in her seminal monograph *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*.[33] In that book, she notes that, paradoxically, the fact that States tried to curb the role of the EU in public health

[30] Scott Greer *et al.*, 'Everything You Always Wanted to Know about European Union Health policies but Were Afraid to Ask', European Observatory on Health System and Policies, 2019, p. 152.
[31] Judgment of the Court of Justice of 5 October 2000, *Federal Republic of Germany v European Parliament and Council of the European Union* (Case C-376/98, para 1, 77-79). On the point see Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health', *European Journal of Risk Regulation* 11(4), 2020, pp. 747-756, p. 749.
[32] European Association of Health Law, 'Eighth European Conference on Health Law: Ghent, 20-22 April 2022'.
[33] Anniek de Ruijter, *supra* note 3.

through the creation of a Treaty competence 'including provisions restating the limitations of this competence', actually had the 'opposite effect' over time.[34] Why should this time be different and more EU competences in health lead to less EU law legislation on health rather than more? One answer could be that historical circumstances are different, and thus this analogy is misplaced. Yet, also leaving the past aside, the recent European Health Union proposal and its implementation seems to suggest that the direction is already to have more EU health law rather than less, let alone if the EU had increased competence in the field.

The feasibility of Treaty change

Is Treaty revision likely to occur in the foreseeable future? On 4 May 2022, the European Parliament adopted a resolution supporting the outcome of the Conference on the Future of Europe and asked the Committee on Constitutional Affairs to prepare proposals to reform the EU Treaties.[35] Statements in favour of updating the Treaties to make the EU 'more transparent and accountable, and perhaps more crucially, more nimble when responding to crises such as the COVID-19 pandemic and Russia's war in Ukraine' have recently been made by French President Emmanuel Macron, Italian Prime Minister Mario Draghi, European Commission President Ursula von der Leyen and European Parliament President Roberta Metsola.[36]

However, to assess whether Treaty change will actually happen, it must be recalled that amending the Treaties requires that Member States unanimously agree to do so.[37] This is not impossible, but, considering the current circumstances, it seems to be implausible. Amendments of the Treaties in the health field remain quite difficult as health is commonly perceived as a domestic issue and States are not usually keen on giving away sovereignty in this area, as underlined by De Pasquale.[38] Moreover, there are already numerous uncertainties that the Member States have to deal with at the moment, above all the war in Ukraine and the consequences of the pandemic. Negotiating Treaty change could also be particularly challenging considering the bitter disputes between the EU, on one side, and Poland and Hungary, on the other, on issues such as the independence of the judiciary and LGBTI rights.[39]

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[34] *Ibid*, p. 78.
[35] European Parliament, 'Treaty Review Necessary to Implement Conference Proposals, Parliament Declares', press release, 4 May 2022.
[36] Alice Tidey, 'Explained: Why EU Countries Are at Odds over Treaty Changes', *Euronews*, 11 May 2022.
[37] Article 48 Treaty on European Union.
[38] Patrizia De Pasquale, 'Le Competenze dell'Unione Europea in Materia di Sanità Pubblica e la Pandemia di Covid-19', *DPCE On Line* 3(2), 2020.
[39] Stephanie Bodoni, 'EU Triggers $42 Billion Budget Fight With Hungary's Orban', *Bloomberg*, 27 April 2022. The Commission has recently triggered a procedure that could cut funding to Hungary following concerns that there have been violations of the rule of law in the country.

Therefore, it does not come as a surprise that a few weeks ago 13 EU countries stated they would not support 'unconsidered and premature attempts to launch a process towards Treaty change'.[40] Furthermore, how the political leaders in favour of Treaty change would amend the treaties is far from clear. In any case, a revision of the Treaties would take several years. Negotiations for the Treaty of Lisbon began in 2001, the text was adopted in 2007 and entered into force in 2009.

Other options for health policymakers to have a stronger say on EU law affecting health

Even without a revision of the Treaties, there could be ways to empower national health representatives. For instance, the synergies between national health policymakers, in particular the civil servants of the ministry of health, and their respective counterparts in the other ministries could be reinforced. If this type of collaboration is enhanced, ministers participating in Council configurations other than EPSCO, such as the Competitiveness Council, might pay specific attention to the public health implications of the legislation they adopt and could be ready to discuss it further with their national health policymakers. To give an example, in those cases when an EU policy has a strong impact on health, members of the Competitiveness Council could arrive at Council meetings after having debated health-related issues of the law object of debate with the health ministry of their country.[41]

Another option, but perhaps more difficult to be realised, could be to increase the interaction between ministries at the European level, between EPSCO Council and other Council configurations. The need for more interplay between health and other ministries has already been taken into account in other policy platforms, such as the G20, where joint Finance and Health Ministers' meetings regularly take place.[42]

These solutions are far from perfect and can be criticised for adding an extra layer of complexity to an already extremely intricate institutional system. Nevertheless, it is necessary to be pragmatic. If we want national health policymakers to have a proper say in the development of EU legislation with a significant health impact, we must start looking for solutions which respect the current legislative and institutional boundaries.

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[40] 'Non-paper by Bulgaria, Croatia, the Czech Republic, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, and Sweden on the Outcome of and Follow-up to the Conference on the Future of Europe', 9 May 2022.

[41] Greer *et al.*, *supra* note 30, affirm that the Council of the EU 'relies on effective coordination at national level to ensure that the positions expressed in one Council [Configuration] take account of the full range of views domestically (e.g., if health related expenditure is being discussed in the Economic and Financial Council)', p. 44.

[42] G20 Indonesia 2022, 'The Joint Finance and Health Ministers' Meeting'.

Conclusion

Overall, the need for Treaty change to expand EU competence in health might be desirable to avoid health remaining mainly an 'accessory' objective of other policies, and that health legislation is produced in fora that do not include the participation of national health policymakers. The validity of this statement will depend on the actual amendments that are proposed, and it is beyond the scope of this contribution to evaluate the ones already suggested or to put forward new ones. Generally speaking, the reasons mentioned above are strong enough for wanting more EU competence in health. If made, such Treaty change might lead to an empowerment of national health representation, but not necessarily to less EU legislation on health. In any case, a revision of the Treaty, which requires that all EU countries must unanimously agree on it, seems unlikely at the moment. Indeed, several Member States are not in favour of Treaty change. Even if the Treaties (and consequently EU competence in health) remain as they are now, the role of national health representatives in EU policy making could be enhanced by reinforcing the synergies between ministries of health and other ministries.