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Working Paper 2023/3

EU Health Ambitions Beyond Limited Competences and Treaty paralysis.

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Introduction

Scholars have extensively searched for an answer to the question why despite the limited Treaty's competence in the health domain, the EU has been able to regulate health-related concerns. The majority agrees that the Treaties' limitations to the Union actions are not an issue.[2] In fact, the EU political activity in health even precedes the conferral of competence to the Union. Evidence that the evolution of the EU policy ambitions and action in health has been historically far more pronounced than the EU formal competence under the Treaties.[3] This characteristic of EU health law and policy has become even more evident as one looks at the EU's response to the Covid-19 crisis. The EU has launched important initiatives to address the causes of the pandemic, whose actual roots have been linked to inequalities amongst Member States' health systems.

In this view, this paper intends to explore whether a reform of the competence allocation in health under the Treaties is necessary or whether the EU health governance can successfully lead to policy transformation independently from any Treaty modification.

To address that question, the first part of this paper starts by illustrating how the EU has acted in the field of health despite Treaties' constraints. In more details, it reviews the current state of the art, discussing how literature understands the EU-driven policy developments in the health domain. Three fundamental approaches are described. First, the EU legislator exploits the transversality of health to address health-related concerns. Second, it resorts to instruments of soft law. Third, after the introduction of a new European fiscal governance system in 2010, the EU political economy of health emerged as a novel policy transformation mechanism, impacting the health sector as well.[4] Within this framework, the second part of this paper investigates in more details the regulation of health through the Recovery and Resilience Facility ('Facility' or RRF)[5] and the EU4Health Programme ('EU4Health').[6] In this context, it claims that these two instruments are drivers for the establishment of multi-level experimentalist governance architectures between the Member States and the Union. To conclude,

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[2] Tamara Hervey and Bart Vanhercke 'Health Care and the EU: The Law and Policy Patchwork' in (eds) Elias Mossialos, Govin Permanand, Rita Baeten, and Tamara K. Hervey, *University of Sheffield Health Systems Governance in Europe* (Cambridge University Press, 2010), 88-89

[3] Oliver Bartlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (2016) 5 Cambridge Journal of International and Comparative Law 50.

[4] Scott L Greer, Holly Jarman and Rita Baeten, 'The New Political Economy of Health Care in the European Union: The Impact of Fiscal Governance' (2016) 46 International Journal of Health Services 262.

[5] Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 Feb. 2021 establishing the Recovery and Resilience Facility [2021] O.J. 2021, L 57/17.

[6] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 [2021] OJ L 107/1.

this paper submits that there is no need for a reform of the EU's competence in health as long as the EU can utilise mechanisms of health governance like the RRF and the EU4Health programme.

Part I –The full potential of EU health law and policy between the frame of the Treaties' competence allocations and beyond.

The EU health governance is an elaborate project of policy design that relies on both traditional and new governance approaches, delivering the idea that EU health law is the reflection of 'the dynamic potential of EU law'.[7] This first part of the paper, therefore, maps and analyses the different EU mechanisms of health regulation.

1.1. Mainstreaming of health and soft law.

Traditionally, the legal analysis of the Union's capacity to act focuses on the assessment of the legal bases within the EU Treaties.[8] In the health domain,[9] the EU Treaty provision on public health, now Article 168 TFEU, appears a rather weak legal basis, which could be described as 'a compromise between those governments of the Member States who did not want any EU mandate in health and those who wanted to go further', similarly to the old Article 152 EC.[10] In fact, under Article 168 TFEU, the EU formally possess shared competence with the Member States to regulate common safety concerns in public health matters[11] and the power to complement national policies towards the protection and improvement of human health.[12] Following this logic, the EU powers in the health domain have been commonly taken as limited and restricted given the Member States' primary responsibility to regulate health.[13]

However, behind this weak façade hides the mainstreaming of health into other EU policies, which is enshrined in the first paragraph of Article 168 TFEU,[14] making the protection of health a cross-policy objective. In this sense, literature claims that the entire Union's action in the field of health is supported by 'a web of competence' provided by the Treaties.[15] In practice, the transversal nature of public health has permitted to adopt multiple actions by recurring to non-health-policy legal bases. For instance, the EU competence to ensure the establishment and functioning of the internal market has

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[7] Tamara Hervey and Anniek de Ruijter, 'The Dynamic Potential of European Union Health Law' (2020) 11 European Journal of Risk Regulation 726.

[8] Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health' (2020) 11 European Journal of Risk Regulation 747.

[9] For a definition of EU Health law see Tamara Hervey and Jean McHale, 'What Is European Union Health Law?,' in (eds) Tamara Hervey and Jean McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press, 2015); The authors adopt a broad definition, describing EU health law and policy has composed of various provisions belonging to different policy domains, among the others public health, internal market, social affairs, and economic policy.

[10] Tamara Hervey, 'Mapping the Contours of European Union Health Law and Policy' (2002) 8 European Public Law 69.

[11] Articles 168(4) and 4(2)(k) TFEU.

[12] Articles 168 (1)(2) and 6(a) TFEU.

[13] Paul Craig, 'EU Competences' in (eds) Dennis Patterson and Anna Södersten, *A Companion to European Union Law and International Law* (John Wiley & Sons, Inc., 2016) 83; Anniek de Ruijter and Eleanor Brooks, 'The European Health Union: Strengthening the EU's Health powers?' (2022) 28 Eurohealth 47; Tamara K. Hervey and Jean V. McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015) 69.

[14] Article 168(1) TFEU states that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'

[15] Kai P Purnhagen, Anniek de Ruijter, Mark L Flear, Tamara K Hervey, and Alexia Herwig, 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the CoviD-19 Outbreak' (2020) 11 European Journal of Risk Regulation 297.

played a central role for the development of EU health policies. The internal market Treaty provision, Article 114 TFEU, has been used to justify various measures, most notably the Tobacco Products Directive,[16] Directive 2001/83 on the Community code on medicinal products for human use,[17] and Regulation 2017/745 on medical devices.[18] Likewise, the mainstreaming of health protection can also be witnessed by looking at the integration of public health concerns within the Common Agriculture Policy (CAP), indirectly through the regulation of food safety,[19] as well as in relation to social policies under Article 153 TFEU, consumer protection, competition law, and environmental policies, among the others.[20] Despite the risks that it entails,[21] the intersection of policy areas is a common practice to address public health concerns. It is now commonly accepted that harmonising measures adopted on the basis of other provisions of the Treaties may have an impact on the protection of human health.[22] The EU openly adopts an approach that strategies the horizontal protection of health through other policies, namely 'Health in All Policies' (HiAP), and promotes the idea of 'One Health',[23] which is also reflected in many laws and programmes.[24]

More silently, soft law has also progressively become another predominant legal mechanism of health regulation. Even before the pandemic crisis, a great majority of the actions in the health domain was undertaken recurring to soft law instruments, such as guidelines, recommendations, and opinions.[25] Primarily for the flexibility of its adoption procedure, which generally escapes the interinstitutional and comitology control, but also for its capacity to overcome Treaty limitations on the EU competence in health, soft law has represented an effective supply mechanism of secondary legislation, especially in the health domain. Soft law might serve different purposes. It might represent a guidance to facilitate the enforcement of secondary legislation, such as the several guidelines issued to facilitate the interpretation and applications of the Union legislation on the marketing authorisation of medicinal products for human use.[26] As well, it might be used as a supply mechanism of secondary legislation. Emblematic is the Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control,[27] which was adopted to compensate the failure of finalising a legislation able

[16] 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 [2014] OJ L 127/1.
[17] 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 [2001] OJ L 311/67.
[18] 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 [2017] OJ L 117/1.
[19] Hervey and McHale (n 11) 31.
[20] Tamara K Hervey and Jean V McHale 'Community competence in the field of health in Tamara K Hervey and Jean V McHale, Health law and the European Union (Cambridge University Press, 2009) 85
[21] Delhomme (n 10) 747. The author highlights that the diffuse recourse to Article 114 TFEU as legal basis raises important concerns over the legal constraints that applies to the EU internal market legal action and the risk of not reaching a high level of protection given internal tensions between the interest to protect health and market integration. In other words, by recurring to other legal basis, health is rarely the main focus and objective of these policies.
[22] Case C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union (Tobacco Advertising), [2000] EU:C:2000:544, para 78.
[23] For a definition of 'One Health' see Regulation (EU) 2021/522 (n 8) Article 2(5): 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;'
[24] Francesca Coli and Hanna Schebesta, 'One Health in the EU: The Next Future?' (2023) 8 European Papers 301.
[25] Eleanor Brooks 'Europeanisation through soft law: the future of EU health policy?' (2012) 6 Political Perspectives 86.
[26] EudraLex - Volume 2 - Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use <https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en>
[27] Council Recommendation on the prevention of smoking and on initiatives to

to comprehensively regulate tobacco control.[28] Furthermore, soft law is well-suited to deal with emergencies and exceptional situations. It has been widely employed to counter the impact of the coronavirus pandemic.[29] Examples do not lack in this context. For instance, in the field of State aid, the European Commission adopted a Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak in the form of Communication.[30] As well, to regulate the increasing use of data by governments to combat the pandemic, the European Data Protection Board adopted Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak.[31] Notwithstanding its multiple advantages, important issues related to soft law-making are the lack of legitimacy and democratic credentials, as well as soft law's lack of enforceability.[32]

1.2. The economics of EU health law and policy: using fiscal and financial tools to regulate health.

The analysis above highlights that the EU governance of the health sector has been generally characterised by the continuous interplay between politics and law. The political desire of regulating health by means of law has led EU policy makers to find creative solutions in the context of the EU Treaties framework (and beyond). Within this framework, the EU fiscal policies and financial support in the form of fundings have also become determinant instruments to regulate health-related matters.

The Union fiscal governance, namely the powers of the Union to shape the fiscal policies of Member States, has been described as the third face of EU health law.[33] The post-economic crisis apparatus of fiscal governance has emerged totally renewed and various changes now attribute to the EU the power to monitor national expenditures, including health, and direct national fiscal policies towards health policy targets. Under these circumstances, it has been noted that this system has already extended until the point of regulating national health systems.[34] Illustrations of this approach are multiple. Most notably, the European Semester has been described as a tool of economic governance that has been able to impact the policy domain of health, more specifically the financing and organisation of the health care sector, which has traditionally been an area of strict responsibility of the Member States.[35] In fact, the European Semester is designed to assist Member States in planning their economic and fiscal policies, subject to EU surveillance. Over time, health and health care has progressively become part of the evaluation process.

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improve tobacco control, OJ 2003 No. L22/31.

[28] Martin McKee, Tamara Hervey, and Anna Gilmore, 'Public health policies' in (eds) Elias Mossialos, Govin Permanand, Rita Baeten and Tamara K. Hervey, Health systems governance in Europe, (Cambridge University Press, 2010) 265.

[29] Stefan Oana, 'COVID-19 Soft Law: Voluminous, Effective, Legitimate? A Research Agenda' (2020) 5 European Papers 663.

[30] Communication from the Commission Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak 2020/C 91 I/01, C/2020/1863, OJ C 91I/1.

[31] European Data Protection Board, 'Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak' (2020)

[32] Mariolina Eliantonio and Oana Ştefan, 'The Elusive Legitimacy of EU Soft Law: An Analysis of Consultation and Participation in the Process of Adopting COVID-19 Soft Law in the EU' (2021) 12 European Journal of Risk Regulation 159.

[33] Greer L Scott, *Everything you always wanted to know about European Union health policies but were afraid to ask* (2nd eds European Observatory on Health Systems and Policies, 2019) 5

[34] Scott L Greer, Holly Jarman, and Rita Baeten, 'The New Political Economy of Health Care in the European Union: The Impact of Fiscal Governance' (2016) 46 International Journal of Health Services 262; Scott L. Greer et al., *Everything you always wanted to know about European Union health policy but were afraid to ask* (3rd eds European Observatory on Health Systems and Policies), chp 6.

[35] Pierre Bocquillon, Eleanor Brooks and Tomas Maltby, 'Speak softly and carry a big stick: hardening soft governance in EU energy and health policies' (2020) 22 Journal of Environmental Policy & Planning, 843.

At the same time, there has also been an increasing number of financial incentives, especially EU funding programmes, that have contributed to pursue health objectives, directly or indirectly, including in those areas where the EU health power has been traditionally limited. For instance, the European Structural and Investment Funds rely on extremely high budgets and in this sense, can have a significant impact on national policies. These funds, more specifically the European Regional Development Fund and the European Social Fund, have provided crucial financial support to the Member States for the development of national health strategies in the health sector.[36]

In the context of the pandemic crisis, the EU has been able to mobilise unprecedent resources to fund and promote crucial long term policy transformations. Most notably, in 2021 the European Commission formally adopted the Next Generation EU Recovery Fund (NGEU) which represents an unprecedent measure to target future policy objectives in multiple fields. Through borrowing money directly from the financial markets, the NGEU intends to provide grants and loans to Member States, becoming a unique mechanism of indiscriminate financial support to the Member States and an expression of solidarity and trust.

Many elements suggest that the NGEU might have an impact on health regulation. In fact, the Recovery and Resilience Facility Regulation (RRF Regulation),[37] which is the central instrument shaping the scope and functioning of the NGEU's funds, lists health resilience as one of the policy areas of European relevance and application of the Facility.[38] Moreover, the RRF has been embedded in the European Semester. Therefore, national reform programmes are used to fulfil one of the two bi-annual reporting requirements of Member States under the RRF, besides their role in the context of the European Semester. As well, the country reports now provide for an analysis of the Member States' national plans under the Facility, on the basis of which the European Commission proposes country-specific recommendations. Under these circumstances, the integration of the RRF in the Semester will represent an important support for an effective policy coordination, including in the field of health, since through the country-specific recommendations adopted in the context of the European Semester, the EU will be able to provide guidance to Member States to respond to new challenges and adapt their policy targets and objectives.

Recent development confirms the potential impact that the RRF might have on health. Among the various national recovery and resilience programmes (NRRPs) that have been submitted, many include health as a component or sub-component.[39] For instance, the Italian National Recovery and Resilience Plan includes health as one of six missions and mainly aims at changing the structure of the healthcare services, in particular focusing on proximity networks, intermediate facilities and telemedicine for territorial healthcare, and innovation, research and digitisation.[40]

At the same time, in the aftermath of the Covid-19 crisis, the EU has also adopted the EU4Health Programme, established by means of Regulation 2021/522,[41] which remains the sole policy initiative that makes of health is exclusive and central core. The EU4Health uses Article 168 TFEU as legal basis. Despite the Treaty legal basis on public health is limitative rather than permissive as regards the

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[36] Jonathan Watson, 'Health and structural funds in 2007–2013: country and regional assessment' (2017) Brussels: DG Health and Consumer Protection. Available at: https://ec.europa.eu/health/sites/default/files/health_structural_funds/docs/watson_report.pdf

[37] See Regulation (EU) 2021/241 (n 7), Article 5(1).

[38] Ibid, Article 3.

[39] Scott L. Greer et al. *Everything you always wanted to know about European Union health policies but were afraid to ask* (3rd eds,W orld Health Organization 2022), cph 6.

[40] Italian National Recovery and Resilience Plan (2021) http://www.politicheeuropee.gov.it/media/5651/pnrr-definitivo.pdf

[41] Regulation 2021/522 (n 8).

powers of the Union, it still provides for the Union's competence to adopt incentive measures 'designed to protect and improve human health and in particular to combat the major cross-border health scourges'.[42] The understanding of the nature of the incentivising legislation remains blurry, being controversial their binding nature as their capacity of providing for policy harmonisation.[43] In practice, however, they have generally been used to adopt EU-funded programmes intended to stimulate policy developments in the field of health. The EU4Health is not a new instrument in the EU political scene. The first Public Health Programme (PHP) was created in 2003,[44] and afterwards new programmes were proposed for the 2008-2013[45] and 2014-2020 period,[46] generally relying on small budgets compared to other EU funded programmes. Their limited financial capacity has raised significant concerns, being the effectiveness of funding programmes measured on their capacity of promoting transformations through financial incentives. Through the establishment of EU-funded programmes, EU policymakers have shown the intention to inspire policy development through 'carrots' rather than 'sticks', as outlined by Hervey and Vanhercke.[47]

In this context, the EU4Health Programme sets extensive objectives, which vary from reducing the burden of communicable and non-communicable diseases, protecting people from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States, improving the availability, accessibility and affordability of medicinal products and medical devices, and finally, strengthening health systems' resilience and resource efficiency.[48] Building on these far-reaching goals, the EU4Health is likely to become an effective tool of policy transformation in the field of health.

Part II – The soft governance of health: an analysis of the RRF and the EU4Health programme.

The EU's response to the Covid-19 crisis marked without a doubt a path-breaking for health and its regulation. In fact, a great majority of the initiatives undertaken to cope with the shortcomings of the health domain in the aftermath of the pandemic is represented by fiscal and financial measures, most notably the above-mentioned Recovery and Resilience Facility and the EU4Health Programme. In that regard, important questions remain to be answered: first, which are the features of these initiatives? Second, why has the EU legislator decided to focus its post-Covid-19 health policy action on initiatives of this kind?

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[42] Article 168(5) TFEU.

[43] Oliver Barlett, 'The EU's Competence Gap in Public Health and Non-Communicable Disease Policy' (2016) 5 Cambridge Journal of International and Comparative Law 50; Kris Grimonprez 'The European Dimension in Citizenship Education: Unused Potential of Article 165 TFEU' (2014) 39 European Law Review 3, 13

[44] 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) - Commission Statements [2002] OJ L 271/1. The Programme of Community action in the field of public health replaced eight action programmes on specific topics concerning health promotion, health monitoring, communicable disease, cancer, rare diseases, injury prevention, pollution related diseases, drug prevention.

[45] 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) [2007] OJ L 301/3.

[46] 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) and repealing Decision No 1350/2007/EC Text with EEA relevance [2014] OJ L 86/1.

[47] Tamara Kervey and Bart Vanhercke, 'Health care and the EU: the law and policy patchwork' in (eds) Elia Mossialos, Govin Permanand, Rita Baetan and Tamara K Hervey, Health systems governance in Europe, (Cambridge University Press, 2010) 90.

[48] Regulation (EU) 2021/241 (n 7), Article 3.

Building on these questions, this part of the paper will explore in more details the nature and scope of the RRF and the EU4Health and discuss whether these solutions might be sufficient to alleviate the discontent of those who want more EU powers in health.

The decision of making the Recovery and Resilience Facility and the EU4Health case-study of this article is driven by the fact that, despite some differences, these two instruments are linked to the Covid-19 crisis and are explicitly intended to deliver policy transformations in the field of health (see 1.2.). In more details, while there are no doubts on the health-related focus of the EU4Health, some clarifications might be necessary on the role of health in the RRF. Lying at the heart of the Next Generation EU, the Recovery and Resilience Facility is an instrument of socio-economic recovery. In this context, it lays down several and various objectives, which vary from green transition, digital transformation, and social and territorial cohesion, among the others.[49] In this context, Article 3(e) of the RRF Regulation explicitly includes health under the scope of application of the Facility. However, health is also an important component of other areas covered by the Facility, such as digitalisation, green transition, social growth of the Member States, as well as contributing to the implementation of the European Pillar of Social Rights, which includes healthcare among its principles.[50]

2.1. The RRF and EU4Health as Experimentalist Governance Architectures.

It is not new that over the years the EU governance has experienced a radical shift towards soft governance, which responds to the logic of voluntary performance rather than mandatory regulation in order to pursue policy development. Soft governance has become a rather diffuse alternative tool of policy development also in the field of health.[51] Intended as an approach that cannot be reduced to hierarchical command-and-control models, it poses itself at odds with the traditional top-down, hierarchical and sanctionary system of regulation, being based on a collaborative and flexible model of regulation where different actors participate to achieve a common purpose.[52]

In this context, the employment of systems of soft governance for the regulation of health has become significantly diffuse.[53] In particular, the regulation by means of 'experimentalist governance', a concept elaborated by Sabel and Zeitlin in the attempt of conceptualising the large variety of mechanisms of soft governance progressively adopted by the EU in multiple policy sectors,[54] has represented an important frame in which the EU health regulatory action could be conceived. The concept of 'experimentalist governance' refers to various EU governance mechanisms characterised by a multi-level system of decision making and implementation, which connects national administrations among each other and the EU, without the necessity of establishing a clear hierarchy among them. In this structure, national units enjoy a sufficient degree of autonomy in the implementation of the objectives

[49] Regulation (EU) 2021/241 (n 7), Article 3.
[50] Ibid, Preamble, p. 42.
[51] Katherine Fierlbeck, 'The changing contours of experimental governance in European health care' (2014) 108 Social Science & Medicine 89, 90
[52] Alana Klein, Judging as nudging: new governance approaches for the enforcement of constitutional social and economic rights' (2008) 39 Columbia Human Rights Law Review 351; Arthur Benz Combined modes of governance in EU policymaking in (eds) Tömmel Verdun, *Innovative Governance in the European Union* (Lynne Rienner 2009).
[53] Application of experimentalist governance architectures in health have been already been explored see Scott L. Greer, 'The weakness of strong policies and the strength of weak policies: Law, experimentalist governance, and supporting coalitions in European Union health care policy' (2011) 5 Regulation & Governance 187; Bocquillon et al (n 37).
[54] Charles F. Sabel and Jonathan Zeitlin, 'Learning from Difference: The New Architecture of Experimentalist Governance in the EU' (2008) 14 European Law Journal 27; Charles F. Sabel, and Jonathan Zeitlin, *Experimentalist Governance in the European Union: Towards a New Architectur* (Oxford University Press, 2010).

that they contribute to shape and modify afterwards, in exchange of regular reporting and peer review of performance.[55]

In more details, the authors define four determinant elements characterising the architecture of experimentalist governance systems. First, at supranational level, the EU and the Member States by joint action decide the framework goals. Second, as expression of the principle of subsidiarity, lower units, such as Member States' competent authorities, are in charge of the implementation, and in this context, they enjoy wide discretion. Third, the bodies in charge of the implementation should report regularly on their performance. Fourth, the framework goals, and procedures for implementation are periodically revised by the actors who initially established them but also by new indispensable participants. In this frame, the concept of experimentalist governance has been described as functional, in the sense that it is applicable to different institutional and policy arrangements.[56] However, since experimentalist governance architectures might be employed in many different ways, their existence and characteristics remains largely unexplored.

Against this background, this paper submits that the Recovery and Resilience Facility and the EU4Health are drivers for the establishment of multi-level experimentalist governance architectures between Member States and the Union. This assumption takes into account that multi-level regulatory frameworks might enormously vary in forms and purposes. Nevertheless, at the heart of these systems lies the idea of establishing a model of governance that differs from a principal-agent relation and that is based on a 'a recursive process of provisional goal-setting and revision based on learning from the comparison of alternative approaches to advancing them in different contexts.'[57]

The features characterising experimentalist governance architectures can be found in the Recovery and Resilience Facility. In order to access to financial allocation at their disposal, Member States must submit national recovery and resilience plans, which set out their reform and investment agenda.[58] The national plan is drafted through the participation of central and local actors. Primarily, the European Commission's assessment of the plan is conducted in close cooperation with the Member State concerned.[59] As well, the Member States can request to the European Commission to organise an exchange of good practices among Member States. Moreover, it has also been noted that national government engages in consultation with public stakeholder, such as industry representatives, civil society, labour unions before submitting their plans.[60] Member States are fully in charge of the implementation of their NRRPs. In this context, they further delegate the implementation of the specific reforms and interventions at lower levels. However, in exchange of this discretion and trust, Member States are required to report twice a year in the context of the European Semester within their national reform programmes on the progress made in the achievement of its recovery and resilience plan. Finally, the recovery and resilience plans can be amended when the Member States realise that their targets are no longer achievable because of objective circumstances. In this case, the Member State concerned may make a request to the Commission to propose an amendment or a new

[55] Ibid.
[56] Ibid.
[57] Charles Sabel, Maurice Moore and Jonathan Zeitlin, 'Experimentalist Governance' in (eds) Thoman Risse, Tanja A. Börzel and Anke Draude, *The Oxford Handbook of Governance and Limited Statehood* (Oxford University Press, 2018) 172
[58] Regulation (EU) 2021/241 (n 7), Article 17(1)
[59] Ibid, Article 19.
[60] Mart Pilati, National Recovery and Resilience Plans: Empowering the green and digital transitions? (2021) European Policy Centre, Discussion Paper

recovery and resilience plan. The request is assessed by the Commission in collaboration with the Member State concerned.[61]

Moreover, experimentalist governance's features might be differently noticed in relation to the EU4Health Programme. This latter is indeed implemented by annual work programmes, formally adopted by means of implementing act of the European Commission. These programmes determine the actions to be undertaken and relative allocation of financial resources, and the different eligible actions. In drafting the work programme, on the one side, the Commission shall consult the EU4Health Steering Group, which is composed by the Commission and a member for each Member State.[62] Third countries associated to the EU4Health programme participate in the consultation process and observe the work of the EU4Health Steering Group. On the other side, the Commission should also consult relevant stakeholders, including representatives of civil society and patient organisations, as regards the priorities and strategic orientation of the annual work programme, and the needs and results that need to be achieved through it.[63] The work programmes provide for funding to specific legal entities, such entities from Member States, third countries associated with it, health organisations, non-governmental organisations (NGOs) and private sector, which implement the actions set in the work programme. In more details, in the preamble of Regulation 2021/522, one reads that Member States' competent authorities, namely competent authorities responsible for health in the Member States or in third countries associated to the EU4Health programme' are considered, on some specific occasions, the best-placed actors for the implementation of the programme.[64] Therefore, Article 13(5) of Regulation 2021/522 stipulates that direct grants may be awarded without a call for proposals to fund actions, under specific circumstance, when they are co-financed by the competent authorities that are responsible for health in the Member States. Moreover, the recipients of the funds have an obligation to report. Each action contains specific indicators that will be used by the beneficiaries of the funds to collect data for measuring and monitoring the progress of implementation and for highlighting the key results achieved.[65] At the same time, the governance of the programme is periodically revised by the European Commission together with the EU4Health Steering Group and stakeholders, which each year submit a new work programme. Moreover, the evaluation of the EU4Health Programme is carried out by the Commission according to Article 34(3) of the Financial Regulation.[66] In this context, the interim evaluation constitutes the basis for adjusting the implementation of the Programme and the EU4Health Steering Group shall follow up the implementation of the Programme and propose any necessary adjustments based on evaluations.[67]

2.2. The benefits of soft governance.

The second fundamental question is why the European policy makers recurred to multi-level systems of governance for the regulation of health. The answer to this question indirectly lies in the analysis

[61] Regulation (EU) 2021/241 (n 7), Article 21.
[62] Ibid, Article 15(2).
[63] Article 16
[64] Ibid, Preamble, point 38.
[65] Annex to the Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2023.
[66] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 PE/13/2018/REV/1, [2018] OJ L 193, 30.7.2018/1.
[67] Regulation (EU) 2021/522 (n 8) Article 19.

conducted above. The use of multi-level regulatory system has been generally used to overcome the political blockages to the EU action.[68] This explains why the employment of soft governance systems has been particularly useful in the aftermath of the Covid-19 crisis, where health, especially the organisation and functioning of national health care systems, has required for further regulation, while the EU action was pulled back by the EU Treaties' competence limitations. In that sense, by creating a multi-level system of governance that makes Member States crucial actors for the determination of the framework objectives and targets and for their implementation, the RRF and the EU4Health are capable of pursuing policy developments in the field of health regardless of Treaty limitations.

Concrete examples might help clarifying how EU health policies might benefit from these systems. The Covid-19 pandemic has manifested the importance of digital health technologies, which facilitate remote medical care and cross-border health responses. In this context, the EU legislator has launched a proposal for the establishment and regulation of the European Health Data Space (EHDS), using Articles 16 and 114 TFEU as legal bases. Grounded in the European Health Union and in the European strategy for data,[69] the objective of the EHDS is creating a harmonised single market for digital health and data. Despite making clear that this proposal does not aim to regulate how healthcare is provided by Member States, the major challenge that the EHDS encounters is that the development and deployment of eHealth solutions in healthcare systems remains a primary responsibility of the Member States. Therefore, the digitalisation of health care crucially depends on the willingness of Member States to reform and adapt their health care systems.

Within this framework, strengthening health systems figures as one of the four objectives of the EU4Health, alongside improving and fostering health, protecting people, ensuring access to medicinal products, medical devices and crisis-relevant products.[70] The EU4Health's work programmes of the 2021, 2022, and 2023 periods have included specific grants to establish the European Health Data Space and develop infrastructures at domestic level in order to make the EHDS operational. In more details, the Annex to the Commission Implementing Decision, which determines the work programme for the 2021 period, establishes direct grants for Member States' authorities in order to establish national contact points for eHealth (NCPeH) for the purpose of broadening the geographic scope of the MyHealth@EU Digital Service Infrastructure (eHDSI),[71] develops infrastructures that would enable patient to access to their health data,[72] and creates a standard terminology to express clinical meanings.[73] Similar objectives are recalled by the 2022 working programme, which sets direct grants in order to expand the MyHealth@EU Digital Service Infrastructure (eHDSI),[74] including new services and more Member States, and setting up of national health competent data access bodies to receive

[68] Sabel and Zeitlin (n 57) 273

[69] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a European Strategy for Data com/2020/66 final.

[70] Regulation (EU) 2021/522 (n 8), Article 3.

[71] Annex to the Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2021 [2021] C(2021) 4793 final, p. 87.

[72] Ibid, pp. 90-91.

[73] Ibid, p. 92.

[74] Annex I to the Commission Implementing Decision of 14.1.2022 on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2022 [2022] C (2022) 317 final. P. 31.

and process data.[75] As well, the 2023 work programme includes further direct grants to Member States' authorities in order to develop the cross-border infrastructure MyHealth@EU.[76]

New experimentalist institutional frameworks have the ability to regulate health issues independently from Treaty limitations. This can also be seen in relation to the Recovery and Resilience Facility, which presents all the conditions to contribute to the implementation of the EHDS. In fact, the digital transition is at the core of the RRF, which also includes health, alongside with 'economic, social and institutional resilience, with the aim of, inter alia, increasing crisis preparedness and crisis response capacity', as one of its six pillars.[77] Therefore, among the others, the Belgium's RRP addresses health in the context of digital transition, being one of the key investments directed towards the digitalisation of the health services. One can read that important ambitions in the area of e-health, such as setting up an authority competent on health-related data governance, which will facilitate the alignment with cross-border EU initiatives such the EHDS.[78] Similarly, the Italian RRP, which includes a specific mission on health, aims at digitalising the national healthcare system through measures to enhance the Electronic Health Record and modernisation of the e-health systems.[79] Under these premises, it is more than likely that the European Health Data Space might strongly benefit from the RRF.

2.3. Is there a need for a revision of the EU health competence?

The Covid-19 crisis has revived the debate on the necessity to amend the Treaties in order to expand the EU health competence. Over the years, discussions over the idea of amending the Treaties to extend the Union's capacity to act in the field of health have been numerous. Most recently, a clear proposition for Treaty change originates in the Position Paper to the Manifesto for a European Health Union.[80] The founders of this initiative, who are academics and experts in the field of health, have proposed to make health an EU shared competence and attribute broader power to the Union. In fact, a stronger competence in health has the advantage of making health an autonomous objective of EU legislation and enhance the principles of subsidiarity and proportionality.[81] Moreover, the benefit of making health a shared competence with direct harmonising powers 'would improve the clarity and legitimacy of EU action, without the limitations inherent to the use of Article 114 TFEU', Delhomme additionally submits.[82] Moreover, a recommendation to include health and health care among the shared competences between the EU and the Member States and thereby, amending Article 4 TFEU, was put forwards by a citizen-led platform for discussion and debate, also known as the Conference on the Future of Europe.[83] On the 9 June 2022, the European Parliament answered to this democratic

[75] Ibid, p. 34.
[76] Annex to the Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2023 [2022] C(2022) 8510 final, p. 110-111
[77] Regulation (EU) 2021/241 (n 7), Article 3.
[78] Commission Staff Working Document, Analysis of the recovery and resilience plan of Belgium Accompanying the document Proposal for a Council Implementing Decision on the approval of the assessment of the recovery and resilience plan for Belgium, SWD/2021/172 final, p. 31.
[79] Commission Staff Working Document Analysis of the recovery and resilience plan of Italy Accompanying the document Proposal for a Council Implementing Decision on the approval of the assessment of the recovery and resilience plan for Italy, SWD/2021/165 final, pp. 31-32.
[80] European Health Union, 'Position Paper: Treaty Change for a European Health Union'.
[81] Ibid; Giulia Bosi, 'Expanding EU Competence in Health? The Need for and Feasibility of Treaty Change' (2022) EU Law Live - Weekend Edition 2022 available at https://ssrn.com/abstract=4262725.
[82] Delhomme (n 10) 754.
[83] Conference on the Future of Europe, 'Report on the Final Outcome', 2022, p. 50-52.

call and submitted a resolution asking 'to adapt the competences conferred on the Union in the Treaties, especially in the areas of health and cross-border health threats', among the others.[84]

However, further actions in this direction have not been undertaken. There are several obstacles preventing Treaty changes from taking place in the near future. As regards health, at the root of the Treaty stagnation lies the political resistance of the Member States to abandon their primacy over the organisation and administration of health care systems and social care policies. Still anchored to idea that health care and health services reflect the welfare of nation states, Member States jealously protect their primary responsibility in determining their national health policies.[85] Despite this conviction has suddenly faced the reality when the Covid-19 crisis has shown that Member States alone are not capable of coping with health-related challenges and protect the health of their citizens, national governments have demanded for a major EU involvement in health but within the context of the current Treaty frame.
Another important problem is related to the procedure required to amend the Treaties. Aware of the importance of the amendments proposed, the European Parliament asks for a revision of the Treaties according to the ordinary procedure of Article 48 TFEU, which calls the Council to transmit the proposal to the European Council which then should decide by simple majority for the establishment of a Convention, which is generally composed of representatives of the national parliaments, the Heads of State or Government of the Member States, Parliament and the European Commission. However, this political initiative has not been taken by the recent Presidencies of the Council.[86] In other words, in clear contradiction with the above democratic requests, Member States have resisted to any proposal to change the EU Treaties' allocation of competence.

Under these circumstances, the answer to the initial question on the necessity of a Treaty reform to extend the EU competence in public health results quite elaborate. On the one hand, as noticed above, there is a democratic claim that pushes in that direction. On the other hand, the necessity to expand the EU health competence is not imminent. Taking partly inspiration from the recent State of the Union, the reality is that 'we cannot – and we should not – wait for Treaty change' to move ahead with policy developments in health.[87] In this regard, it can be asserted that the current shift towards a new and experimentalist EU health governance can successfully lead to policy transformation independently from any Treaty modification. In particular, systems of experimentalist governance, such as the one established by Recovery and Resilience Facility and EU4Health Programme, might be useful tools of policy transformation in the field of health, especially in those areas where the Union action is rather restricted.

To conclude, it is possible that the EU will gain more competence in health. This change is likely to be instigated by a Treaty amendment, although it is not expected to happen immediately. Before any Treaty adjustments, the existing structure, which relies on multi-level cooperation systems involving various actors, serves as an efficient interim solution. In fact, this setup already positions the EU within the decision-making framework for health policies.

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[84] European Parliament resolution of 9 June 2022 on the call for a Convention for the revision of the Treaties (2022/2705(RSP)), p 5.
[85] Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford, 2019; online edn, Oxford Academic, 21 Mar. 2019).
[86] Andrew Duff, 'Raising the stakes on constitutional reform: The European Parliament triggers treaty change' (2023) European Policy Centre Discussion Paper, 3.
[87] The text of the State of the Union 2023 is available at < https://ec.europa.eu/commission/presscorner/detail/ov/speech_23_4426>

Conclusions

The analysis presented in this paper is centred around a crucial inquiry: is it essential to reform the allocation of competences in public health under the Treaties? To address this question, this paper explores whether within the current Treaty framework, the EU has been able to govern health and address emerging health concerns. Initially, it analyses the traditional legal techniques used by the EU legislator to regulate the health sector. In this context, alongside recurring to non-health-related legal bases and to instruments of soft law, most recently, there has been a shift towards the employment of fiscal policies, such as the European Semester, and financial incentives like funding programmes to regulate the health sector. Following the outbreak of the pandemic, this tendency has become even more evident, and in this context, the post-2010 EU economic governance has turned to be a useful tool to cope with the consequences of the pandemic. Under these circumstances, *inter alia*, the Recovery and Resilience Facility and the EU4Health Programme have been adopted with the intention of driving policy transformation in the health domain. Considering the increasing relevance that these mechanisms occupy in the political scene and the impact that they might have on health, the second part of this paper conducts an analysis of their nature, scope, and effects on health, submitting that these instruments present many features of experimentalist governance architectures.

Under these circumstances, it is evident that the competence limits to the EU health action set by the EU Treaties have not represented an obstacle for Union-driven policy developments in the health domain. Alternative and new solutions have been constantly explored, ultimately the use of fiscal and financial tools as instruments of soft governance of the health sector. In light of the renewed relevance of the debate over the future of the EU competence in health, this paper concludes that a revision of the Treaties' allocation of competence is not an urgent political need, since the current governance of health has been able to answer to new challenges, including those posed by the pandemic.