EU Health Ambitions Beyond Limited Competence and Treaty Paralysis.

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ERC StG EUDAIMONIA (GA: 948473)

This project has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (grant agreement n° 948473).

Overview of the Presentation

1. Research questions.
2. EU competence in health under the EU Treaties.
3. Union action despite limited competence.
4. The regulation of health through fiscal policies and financial incentives in the aftermath of the Covid-19 crisis - the Recovery and Resilience Facility.
5. Final considerations on Treaty amendments.

Research Questions

→ Is a reform of the competence allocation in public health under the Treaties necessary?

OR

→ Can the current EU health governance successfully lead to policy transformation independently from any Treaty modification?

EU Competence in Health under the Treaties

1) Treaty of Maastricht (1993) → Article 129 EC Treaty
2) Treaty of Amsterdam (1999) → Article 152 EC

→ Treaty of Lisbon (2009) → Article 168 TFEU

- *Mainstreaming of health.*
- *Clarifies the nature* of the EU health competence – 1) generally, complement national policies, namely support, coordinate or supplement the actions of the Member States (see also, Article 6 TFEU); 2) exceptionally, shared competence to adopt harmonization measures in the areas covered by Article 168 (4) TFEU (see, also Article 4(2)(k) TFEU).
- *EU action: incentive measures* to protect and improve human health and in particular to combat the major cross-border health scourges and *measures* 'concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol'.
- *Subsidiarity*.

Following an analysis of the legal basis on public health, the EU powers in health can be described as limited and restricted, remaining the regulation of health a primary responsibility of the Member States.

However, in practice, the EU has been able to addressed multiple health-related concerns. How?

1) *Mainstreaming of health into other EU policies.*

2) *Soft law instruments.*

3) *EU fiscal governance and financial support in the form of fundings.*

1) Mainstreaming of Health

- Article 168 (1) TFEU: 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.

- Article 9 TFEU - 'In defining and implementing its policies and activities, the Union shall take into account requirements linked to […] protection of human health.'

Instead of exclusively relying on Article 168 TFEU, the transversality of the interest to protect human health means that the EU policy makers can recur to other legal bases to address health concerns.

Example → The internal market provision, Article 114 TFEU, has been used to justify various measures, most notably the Tobacco Products Directive, Directive 2001/83 on the Community code on medicinal products for human use, and Regulation 2017/745 on medical devices.

2) Soft law

Soft law instruments (recommendations, opinions, communications, and guidelines) are non-legally binding and hardly judicially enforceable (see *Senden, Soft Law in European Community Law (Hart Publishing 2004) 55-56*).

Being adopted through flexible procedures that escape comitology and parliamentarian control, soft law has the capacity to overcome Treaty limitations on the EU competence in health.

How has been employed in relation to health matters →

- guidance to facilitate the enforcement of secondary legislation (example: *guidelines issued to facilitate the interpretation and applications of the Union legislation on the marketing authorization of medicinal products for human use.*
- supply mechanism of secondary legislation (example: *Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control*, which was adopted to compensate the failure of finalizing a legislation able to comprehensively regulate tobacco control).
- Emergencies (measures adopted in the immediate outbreak of the Covid-19 pandemic).

3) The Union fiscal governance

- The EU fiscal policy has been described as 'the third face of EU health law' (*Greer L Scott, Everything you always wanted to know about European Union health policies but were afraid to ask, 2019*)

- Fiscal policy defines the powers of the Union to shape the fiscal policies of Member States, through the monitoring of national expenditures, including health, and directing national fiscal policies towards specific policy targets.

How does fiscal policy relate to health?

→ Health is part of an important part of the expenditure of the Member States → Ex: European Semester
The EU assists Member States in planning their economic and fiscal policies and surveille national expenditure.
Over time, health and health care has progressively become part of the evaluation process.

EU Funding Programmes

EU funding programs are financial incentives that the EU makes available in different forms (grants and loans) and in almost every policy field (research, humanitarian aid, internal market, etc).

Health concerns might directly or indirectly benefit from these programs.

Examples:

→ European Structural and Investment 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.

→ EU Public Health Programmes which have supported a broad range of actions in the field of health.

Covid-19 – new challenges but old solutions

We have seen that the EU has recurred to different strategies to act in the field of health, regardless of the limited competence.

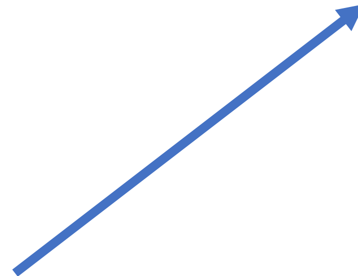
Are these solutions adequate to cope with health-related post Covid-19 challenges?

The Covid-19 crisis has highlighted many shortcomings of the capacity and preparedness of the Member States' health systems to respond to emergencies, as well as the inequalities among different national health systems.

The Interplay of Fiscal and Financial Tool in the Aftermath of the Covid-19 crisis

Despite the call for a stronger EU's intervention, once terminated the state of emergency caused by the pandemic, the Union's capacity to act in the field of health has remained unchanged.

The legacy of the Covid-19 crisis has been however an outstanding economic budget at the disposal of the EU, which represents an extraordinary leverage at disposal of the EU policy makers for the achievement of specific targets and policy objectives, including in the field of health.



To understand the EU-driven policy transformation in the field of health in the post-pandemic period, one should primarily look at EU funding programmes and other financial tools.

This research focuses on the Recovery and Resilience Facility and the EU4Health Programme.

Recovery and Resilience Facility

- Budget of €723.8 billion
- Central instrument shaping the scope and functioning of the Next Generation EU Recovery Fund (NGEU)
- Health resilience is one of the areas of application of the Facility (Article 3 of Regulation (EU) 2021/241)

How can the RRF have an impact on health?

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.
Furthermore, 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.

Questions:

→ Which are the features of these economic initiatives (RRF and EU4Health)?

→ Why has the EU legislator decided to focus its post-Covid-19 health policy action on initiatives of this kind?

Which are the features of these economic initiatives?

This paper submits that the RRF and EU4Health are drivers for the establishment of multi-level experimentalist governance architectures between Member States and the Union.

The concept of 'experimentalist governance' has been elaborated by Sabel and Zeitlin in the attempt of conceptualizing the large variety of mechanisms of soft governance progressively adopted by the EU in multiple policy sectors.
It is characterized 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.

Four determinant elements characterizing the architecture of experimentalist governance systems:

1) at supranational level, the EU and the Member States by joint action decide the framework goals.
2) 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.
3) the bodies in charge of the implementation should report regularly on their performance.
4) the framework goals, and procedures for implementation are periodically revised by the actors who initially established them but also by new indispensable participants.

Case Study: the RRF

1. In order to access to financial allocation at their disposal, Member States must submit national recovery and resilience plans (NRRPs), which set out their reform and investment agenda. 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. As well, the Member States can request to the European Commission to organize an exchange of good practices among Member States. (Article 19 of Regulation 2021/241)
2. 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.
3. 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. (Article 27)
4. The recovery and resilience plans can be amended when the Member States realize 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 recovery and resilience plan. The request is assessed by the Commission in collaboration with the Member State concerned. (Article 21)

Why has the EU legislator decided to focus its post-Covid-19 health policy action on initiatives of this kind?

The use of multi-level regulatory system is generally used to overcome the political blockages to the EU action. 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 organization 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.

→ 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, both the RRF and the EU4Health are capable of pursuing policy developments in the field of health regardless of Treaty limitations.

Examples → *establishment of the European Health Data Space (EHDS).*

- The Italian RRP 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 digitization. In that context, it aims at digitalizing the national healthcare system through measures to enhance the Electronic Health Record and modernisation of the e-health systems.

- The Belgium RRP addresses health in the context of digital transition, being one of the key investments directed towards the digitalization 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.

Does the EU Need a Revision of its Health Competence?

In the aftermath of the Covid-19 crisis, the question of a revision of the health competence allocation under the Treaty has returned prominent in the political and academic scene.

- Position Paper to the Manifesto for a European Health Union.
- Conference on the Future of Europe (Recommendation n. 49)
- Resolution of the European Parliament of 9 June 2022 on the call for a Convention for the Revision of the Treaties.

Obstacles persist:

- Political resistance of the Member States.
- Procedures required to amend the Treaties.

No further action in the direction of amending the EU competence in health has been recently taken.

Amending the Treaties in order to enhance the EU competence in health is not a political priority (at the moment).

WHY?

In the light of the analysis above, 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 RRF and EU4Health, might be useful tools of policy transformation in the field of health, especially in those areas where the Union action is rather restricted.

Hypothesis → the area of health will be subject to a transformation from an area controlled by Member States to a supranational policy area. This transition will be probably driven by a Treaty modification, but it will not be imminent. Under these circumstances, the current set-up based on multi-level systems of cooperation between different categories of actors represents an intermediary phase, being the European Union, together with the Member States, already involved in the decision-making process in policy areas of health traditionally belonging to the Member States.

Thank you for your attention!