Anne Bucher (anne.bucher@bruegel.org) is a Non-resident Fellow at Bruegel

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In response to COVID-19, the European Commission tabled a 'Health Union' package on 11

- [illegible] The EU can adopt incentive measures such as health programmes, and the Council may adopt recommendations;

its predecessors[8]. Interventions are much more fragmented and lack continuity. Rare diseases and cancer are among the areas in which EU countries have shown the greatest interest in cooperation. Cancer is currently prioritised through the Europe's Beating Cancer Plan (European Commission, 2021a). In addressing common risk factors from non-communicable diseases, the EU plays a role through various laws, as noted above. But the case for cooperation at EU level to address the social determinants of health (alcohol, tobacco, physical activity, diet) is much weaker. e only exception is tobacco, for which the single market legislation for tobacco products (Directive 2014/40/EU) has introduced a stringent framework with far-reaching public health impacts.

- . r . research. An important aspect of EU health policy is the direct contribution of the research Framework Programmes, which represent a signi cant investment in research, notably in the elds of cancer, rare diseases, social determinants of health and infectious diseases. Since 2014, Horizon 2020 has invested roughly €1 billion per year in health. Its successor, Horizon Europe, is expected to increase this contribution. e contribution is even bigger if life-science research and environmental research are included – these have contributed to the scienti c foundations of 'health in all policies' through research in areas such as toxicology.
- . r . healthcare and health systems. Article 168 includes a reminder that health systems remain a national competence. In practice, there are several direct and indirect channels through which European policies in uence health systems. e coordination of social security and the directive on patients' rights in cross border healthcare have progressively established the freedom of access to healthcare services. is legislation has put in place coordination mechanisms that guarantee the freedom of movement while preserving member-state prerogatives in designing and nancing bene t policies. e EU initiatives are not driving a convergence process, and cross-border access to healthcare remains in practice marginal for national health systems[9]. e single case of concrete collaboration between national healthcare services is in the area of rare diseases, where member states see gains in cooperating at EU level and have set up European Research Networks[10] covering diagnosis and treatments.

But the major channel through which the EU shapes health systems is through pharmaceutical legislation. Medical products, which are mainly medicines, represent roughly 20 percent of health spending in the EU and EU regulation of markets for pharmaceuticals has created a central market authorisation system. e European Commission's pharmaceutical strategy (European Commission, 2020b) is an EU common response to internal market issues, but also to global competition pressure in the sector. It is part of the new EU industrial policy[11] and will be an important contribution to Health Union.

Even if not covered by the health competence as de ned in Article 168, healthcare and health systems are issues in non-health policies. ey receive funding under cohesion policies, which cover investment in health systems as part of the support provided to lagging regions and amounted to €6.6 billion in the 2014-20 programming period[12]. With the new Multiannual Financial Framework and the Next Generation EU initiative[13], funds have been massively increased and the focus on health has been encouraged. Health systems are also addressed from a policy perspective in the European Pillar of Social Rights, which has two principles related to access to healthcare and long-term care, and in the EU economic

8 See https://ec.europa.eu/health/funding/eu4health-2021-2027-vision-healthier-european-union_en.

9 Cross-border healthcare amounts to 0.4 percent of total spending on in-kind healthcare bene ts, and only 0.02-0.04 percent falls under the cross-border healthcare directive (European Commission, 2019).

10 See https://ec.europa.eu/health/european-reference-networks/overview_en.

11 See https://ec.europa.eu/growth/industry/strategy_en.

12 See https://cohesiondata.ec.europa.eu/stories/s/In-pro_le-cohesion-policy-improving-health-servic/qyuv-h9j2/.

13 Including the Recovery and Resilience Facility, the REACT-EU programme, and access to EU Structural Funds through the Coronavirus Response Investment Initiative (CRII and CRII+).

governance framework on health-sector reforms as part of structural reform.

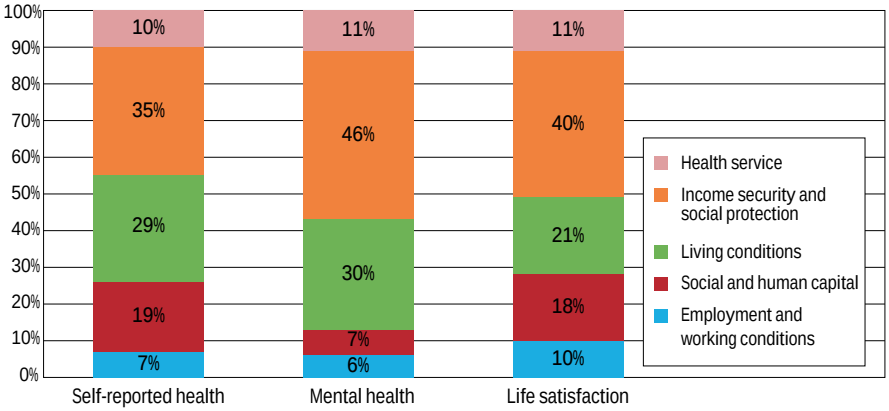
EU health initiatives have therefore developed gradually and built up a complex set of interactions between the national and EU levels.

e European Parliament and civil society have called repeatedly for stronger involvement of the EU in health[14]. In the April 2021 Eurobarometer (European Commission, 2021b), 38 percent of Europeans said they considered healthcare as the number one task of the EU institutions – more important than economic recovery, ghting climate change or reducing unemployment. Nevertheless, member states prefer a model of cooperation rather than integration. e reality is a hybrid model with substantial achievements in some areas. Could the Health Union model for health emergencies (see the introduction) be extended to respond to the political demand for a stronger role for the EU in health? Without conceptualising a full Health Union at this stage, the next two sections outline the bene ts of closer integration compared to the [illegible] . is is done from a macro perspective and from a bottom up approach by reviewing the individual building blocks of health actions listed above. Two questions are addressed: 1) how to de ne overall EU health objectives? 2) Does the political economy of integration provide a rationale for a greater role for the EU in health?

3 Does the EU need a comprehensive

against the background of more favourable health outcomes show that prosperity on its own will not deliver health for all. Health inequality weakens the long-term prospect of achieving a high level of protection, and health equity deserves to be identi ed as an explicit policy objective at EU level, even if health inequalities fall to a great extent into the area of subsidiarity.

Figure 2: Contributions to inequities in self-reported health, mental health and life satisfaction, EU countries



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e World Health Organisation (WHO, 2019) has quanti ed on the basis of microdata the contribution of di erent factors of health inequality in the EU. is con rms that health inequalities are predominantly a re ection of income disparities, poor housing and environmental conditions for vulnerable groups, and di erent degrees of health literacy, linked to educational attainment. Together, these factors explain roughly 90 percent of gaps in health outcomes in the EU.

e importance of social conditions highlights the value of EU cohesion policies and the European Pillar of Social Rights as policy responses to health inequalities. But it might be too much to expect these two policies to solve health inequalities, partly because, with limited instruments, they also deal with many competing non-health priorities. To better steer European policies to address health inequalities, the EU should rst have the means to monitor them. Given that access to, and quality of, healthcare are responsible for 10 percent of the gaps in health outcome, health systems should be part of this monitoring.

4 How can Article 168 be better implemented?

e previous section showed that a high level of health protection, combined with a focus on health inequalities throughout EU policies, provides an adequate health policy framework for the EU. e next question is how good is the EU at protecting health in practice? In other words does the EU need to take additional steps?

e political economy of international or regional integration (Alesina , 2001; Grüner, 2017) tells us that: (1) integration depends on the degree of diversity of national preferences; (2) the existence of cross-border externalities is a push factor for more integration; (3) but transaction costs to deal with cross-border externalities might discourage integration. Grüner (2017) concluded: " ". is is very much aligned with the WHO analysis in the speci c area of health policy. e WHO (Soucat, 2019; WHO, 2021) has conceptualised the framework for health commons and has identi ed three reasons for countries to act jointly in the area of health: (a) the existence of cross-border externalities; (b) some public goods in health policy with increasing returns justify action at regional or global level; and (c) market-shaping interventions can be supra-national because market forces and regulation are supra-national, regional or global.

is section reviews the ve building blocks identi ed in section 2 as areas for EU cooperation and the speci c rationale for EU involvement.

e main novelty was the establishment of HERA, which is creating EU coordination in a new area, the development and production of medical supplies. But the basic health-security model that underpins Decision No 1082/2013/EU on serious cross-border threats to health (see footnote 5) relies on the same sharing of competence: an EU-wide surveillance and risk assessment framework for cross-border health threats, but the national level remaining the centre of gravity for risk-management decisions. Many of the proposed Health Union package measures aim at increasing transparency and exchange of information, supporting the risk-assessment process. e proposals that could pave the way towards more EU integration are: 1) an EU preparedness plan based on national plans, which are audited and subject to stress tests, and 2) the exclusivity clause in joint public procurement. e former opens the way to de ne minimum requirements for preparedness and response to crises, and the latter, which forbids member states from conducting parallel procurement negotiations when engaged in a European procurement process, shifts national competence temporarily to EU level. At the time of writing, negotiations on the Health Union package are still ongoing. If these measures are adopted, it might open the way to more integration in health-crisis preparedness and response.

What would a more integrated Health Union for cross-border health threats look like? A fully integrated model for preparedness, prevention and response to health crises would require minimum standards of resilience for health systems; joint responses in some areas of common interest like travel and transport rules; more solidarity mechanisms through, for instance, cooperation between hospitals in crisis times, exchange of health professionals or more EU funding targeted at weaker health systems; and common strategies for prevention of cross-border health risks. For prevention, one obvious priority is anti-microbial resistance (AMR). e increasing risk of infections for which previous e ective treatments no longer work bEU l(or)9 (k bE)3 (U l(or)9 (k bE)3)-3.9 (e (t p)4 (ublic41 (ion) for whifts n)7 (a)7 on) for w2 (s)17 (, shif

national borders, facilitate the use of national data with external data sources, and cover a broad range of health data, including privately-held data. e national health data spaces should build a common EU research infrastructure.

On the use of research for policy and regulatory activities at EU level, a shortcoming is the absence of an integrated surveillance information system on risk factors and health outcomes. Such a system exists only for communicable disease through the ECDC, and in a

deployment or renewable energy, hit implementation bottlenecks for having overlooked citizens' concerns about electro-magnetic fields or the health impacts of wind farms. Even if these concerns do not necessarily require specific provisions in EU legislation, they should be part of the risk communication related to policy initiatives. For the credibility of EU commitments to health protection, the EU needs to be much more transparent on how it takes into account public health concerns in policymaking.

One way forward towards a more systematic HiaP approach would be to apply better-regulation principles to health impacts in impact assessments of regulatory proposals. This might help, but is not sufficient. It needs to be combined with stronger upstream scientific assessment and anticipation of knowledge gaps. The Chemicals Strategy for Sustainability (European Commission, 2020c) has identified this challenge and made proposals for upstream coordination on issues such as endocrine-disrupting chemicals and data-sharing arrangements between scientific agencies. In policy fields that do not benefit from the support of an agency, the Scientific Committee on Health, Environment and Emerging Risks (SCHEER), which provides scientific opinions for legislative initiatives on demand from the Commission services, should be consulted systematically. The combination of better-regulation rules, scientific foresight and greater coordination between scientific bodies supporting the policy-making process will enhance regulatory science and improve the scientific knowledge about the health impacts of policies. It will create a scientific conversation on public health across sectors and ultimately strengthen the HiaP principle.

More policy coordination: access to healthcare and quality of care (building block 5)

The exclusion of health systems from the scope of Article 168 leaves little room for legislative developments at EU level. As explained by the regional and international integration model, health systems are unlikely to follow a convergence path because the financial costs for national budgets would be prohibitive. However, this still leaves room for voluntary cooperation on healthcare similarly to what exists currently for rare diseases. This could be expanded to other areas with the support of the EU4Health programme (see footnote 8).

In the short term, the EU should address the growing interest in the performance of health systems under different policy umbrellas. Assessment of the resilience of health systems during health crises is part of the Health Union package. Monitoring access to healthcare and the quality of healthcare as a social rights issue is part of the European Pillar of Social Rights. Finally, assessment of the financial sustainability of health systems and the need for health reform is included in the economic governance process.

Should the EU go further? To avoid duplication and inconsistency, the EU should build a common understanding of the performance of health systems and how to define and measure it. EU policies in other fields offer different templates: it could be done through a beefed-up 'State of Health in the EU' project[22], or the equivalent of an ageing report (see European Commission, 2021c), or via the European Pillar of Social Rights scoreboard[23]. But a central exercise would avoid duplication and the risks of inconsistency between the various exercises. It would also make the assessment more transparent and could be used to measure inequalities in access to healthcare, which is one aspect of health inequality.

22 See https://ec.europa.eu/health/state-health-eu/overview_en.

23 See https://ec.europa.eu/eurostat/web/european-pillar-of-social-rights/indicators/social-scoreboard-indicators.

5 Conclusion

is contribution takes as a starting point the current framework for health policy as a re ection of the EU political compromise to balance national preferences against the economic gains from acting jointly at EU level. It questions whether EU health policy as currently implemented is delivering the treaty objective of ensuring a high level of health protection, or if further progress in integration is required. It does not seek to open a debate on the need for a treaty revision to strengthen EU competence in health beyond the current scope of Article 168 of the treaty.

Relying on the political economy principles of integration, it con rms that Health Union is more relevant for cross-border health emergencies than other public health concerns. It also con rms that greater convergence of health systems would be too costly for national governments and therefore that coordinated actions in healthcare will remain very limited. ere is no basis for extending the model of Health Union underpinning the November 2020 Health Union package to other areas of health policy.

But the analysis has identi ed the need for greater political ambition in a number of areas: monitoring of health inequalities and measurement of health-system performance for a

WHO (2020) [illegible], World Health Organisation, available at https://www.euro.who.int/en/health-topics/health-determinants/social-determinants/publications/2020/health-inequity-and-the-e_ects-of-covid19-2020

WHO (2021) [illegible], World Health Organisation, available at https://www.who.int/publications/i/item/9789240034204