

Does Europe need a Health Union?

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Executive summary

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HEALTH OUTCOMES IN the European Union are good by international standards, even compared to other developed economies, and improved continuously before COVID-19. This reflects the alignment of the objectives of improving health and wellbeing with the overall socio-economic objective of prosperity, and suggests that a radical overhaul of EU health policy is not needed.

HOWEVER, THE EU could benefit from closer integration in some areas and be more effective in delivering a high level of health protection. Action could be taken in the following areas:

- The European Commission's November 2020 Health Union package to increase resilience to cross-border health threats is ambitious, in particular with the establishment of the Health Emergency Response Authority, which extends the scope of cooperation in health emergencies. The EU should pursue further the Health Union approach to address cross-border externalities and enhance health security. It could, for instance, do more to tackle anti-microbial resistance, or define minimum requirements for the resilience of health systems.
- For non-communicable diseases, the EU should tap the economies of scale of research and knowledge organised at EU level, and put in place systems for the surveillance of non-communicable diseases and consolidation of scientific knowledge. This could be achieved through an extension to non-communicable diseases of the European Centre for Disease Prevention and Control mandate.
- The 'Health in all Policies' principle is a key channel to deliver good health outcomes at EU level. EU scientific agencies provide health risk assessments in a number of areas, but the EU should better organise, coordinate and consolidate the scientific knowledge that underpins health-protection measures in sectoral legislation, and should more systematically apply better regulation rules to the health impacts of EU policies.
- The EU should support the digital transformation of health systems and set high targets for the European Health Data Space initiative, which is a critical infrastructure for the future of health research, regulation and policymaking.
- Several non-health EU policy objectives (cohesion policies, European Pillar of Social rights, economic governance) are linked to the performance of health systems. A common understanding on how to measure this performance would inform these policies in a consistent way. Moreover favourable health outcomes in the EU have not reduced health inequalities, which remain high between and within EU countries. Monitoring of health inequalities, including those related to access to and quality of healthcare, should be improved as an initial step.

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In response to COVID-19, the European Commission tabled a ‘Health Union’ package on 11 November 2020 (European Commission, 2020a). It previewed the establishment of a Health Response Emergency Authority (HERA), which was done by a decision of 16 September 2021¹. Both initiatives are close to adoption, which will be a landmark in health integration at European level. They draw on the lessons of the crisis, which has shown that saving lives and preserving the economy are interlinked challenges. The main justification for the two initiatives is to increase resilience in the face of cross-border health threats. But the Health Union communication states more broadly that “*a strong European Health Union will protect our way of living, our economies and societies*”. This raises the legitimate question of whether Health Union should be limited to crisis prevention and management, or should have a broader public health scope.

This Policy Contribution assesses the rationale for a Health Union. Section 1 provides a historical perspective on health provisions in the European Union treaties. Section 2 gives an overview of the achievements of EU health policies. Section 3 explores the need for an overall health strategy and section 4 identifies the areas that would benefit from closer integration.

1 Health in the EU treaties: a historical recap

The EU’s founding fathers did not include health as a building block of the European Economic Community. However, progress in the European project has necessitated at different times specific legislation on health, or health provisions in general or sectoral legislation. The European Coal and Steel Community, for instance, provided for health and safety rules at work. In 1965, the European Economic Community adopted its first legislation on medicines to harmonise research, manufacturing standards and licensing procedures. The harmonisation of diplomas, with the health sector a frontrunner, started in the 1970s. The EU Court of Justice (CJEU) also recognises health rights and obligations through a large body of case law.

The political recognition of health as part of the objectives of European integration started with the construction of the single market. The greater degree of integration brought about by the single market project triggered new debates, such as on social Europe and environmental protection, connected to the four freedoms of free movement of goods, capital, services and people. The 1986 Single European Act established a requirement for European policies to guarantee a high level of health protection. This laid the foundations for a European public health policy and the public health field of competence was shaped subsequently in the Maastricht Treaty in 1992 (Article 129), the Amsterdam Treaty in 1997 (Article 152) and finally in Article 168 of the 2007 Lisbon Treaty.

Article 168 established important parameters:

- It states clearly the obligation to guarantee a high level of protection in all EU policies, the so-called ‘health in all policies’ (HiAP) principle;
- It defines an extensive scope for public health policy: prevention of physical and mental illness and diseases, fighting major health scourges, with a specific reference to combating serious cross-border health threats, and combating illicit drugs;
- It defines health as a complementary competence in contrast to other sectors over which competence is shared; this means that for health “*the Commission complements national*

¹ See Commission decision establishing the Health Emergency Preparedness and Response Authority, 2021/C 393 I/02, 16 September 2021, available at [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D0929\(02\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D0929(02)).

policies and encourages cooperation between member states”. The EU can adopt incentive measures such as health programmes, and the Council may adopt recommendations;

- It provides for harmonisation of safety standards in specific areas: blood, tissue and organs of human origin, medicine and medical devices, and in the phytosanitary and veterinary fields;
- It provides an unambiguous reminder that health systems and the delivery of healthcare remain national competences.

The EU *acquis* goes beyond the public-health objective and touches on health rights for all European citizens.

The coordination of social security systems, which came into force in 1971, has organised the trans-border continuity of health coverage and cross-border access to healthcare services. Initially limited to workers, the rights were extended to all EU residents with the 2004 reform that introduced European Health Insurance Cards.

In parallel, the CJEU, on the basis of the treaties, developed jurisprudence which was codified in the 2011 directive on patients’ rights in cross border healthcare (2011/24/EU), giving EU citizens access to healthcare in other member states. This resulted in a complex set of routes for access to cross-border healthcare². But the most important lesson is that the free movement of persons has generated rights to healthcare in the EU. Although health systems remain a national competence, these rights have implications for patient safety and quality of healthcare.

Overall, between the mid-1980s and the mid-1990s, political awareness about health issues grew at the European level. The treaties have integrated the idea that the EU project cannot progress without a clear competence in the field of public health. They have left health systems out of the scope of cooperation, but this does not prohibit closer integration. All sectors covered by EU policies have had or still have to deal with big exceptions or derogations: the Economic and Monetary Union was built without a budget for the euro area and notwithstanding the Energy Union, the energy mix remains a national prerogative, for example.

2 Does Article 168 provide the foundations for a Health Union?

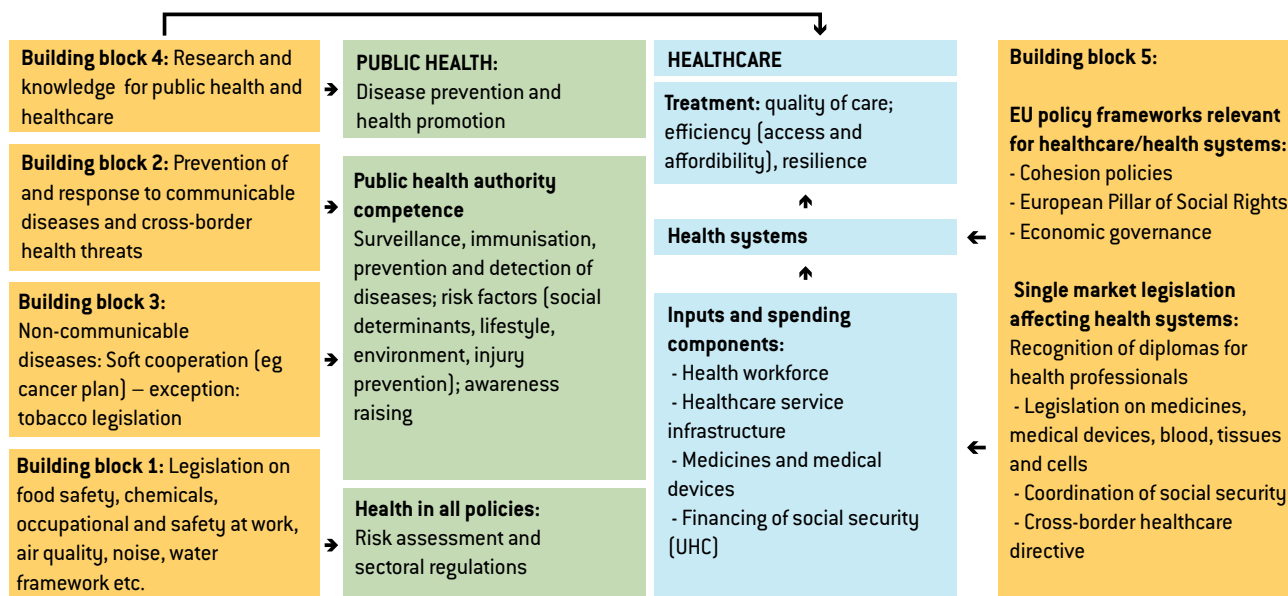
Article 168 has triggered a wide range of EU health initiatives and measures³. A simplified representation of health policy can be organised around two pillars, public health and healthcare⁴. Public health is a broad concept that includes health information systems to monitor health and wellbeing, health promotion and disease prevention, health emergencies and health protection through sectoral rules. The latter function is important because this part of public-health policy is not under the direct control of health ministries, and is wide-ranging and significant. Healthcare is the core business of health systems, although health systems are also responsible for some public-health activities, including immunisation and screening. Healthcare includes organisation of health systems in each country (hospitals, public healthcare facilities, the health services market), financing of health services for citizens, organisation of access to these services, and education and employment conditions of medical staff.

2 A simplified way to differentiate between the two bodies of legislation is to distinguish between unplanned healthcare, which activates the social-security coordination mechanism, and planned healthcare, which requires prior authorisation from the country of insurance and depends on the directive on patients’ rights.

3 For a comprehensive description see Greer *et al* (2019).

4 For a discussion on the concepts of public health and healthcare, see WHO (2018).

Figure 1: Mapping health policy



Source: Bruegel. Note: In green: general functions of public health; in blue: general healthcare organisation; in yellow: areas where the EU has competence

Positioning EU interventions in the health policy landscape shows the complexity of the division between national and European competences, with the emergence of a coherent European project made difficult by notable discontinuities. Overall, there are five building blocks for European action:

- **Building block 1:** the ‘health in all policies’ principle (HiAP) has been applied in a systematic way in EU policymaking over the last thirty years. Some sectoral rules have health as their main focus. These include laws on occupational safety and health at work, the food safety *acquis*, legislation on chemicals (REACH, the registration, evaluation and authorisation of chemicals), environmental laws, in particular the air quality, noise and water directives, and road-safety provisions.
- **Building block 2:** the most far-reaching framework for disease prevention and health promotion from a Health Union perspective is for communicable diseases. This has been built up progressively in response to crises. EU countries have established at EU level the overall health-security framework to deal with cross-border health threats⁵, to organise joint public procurement of medical supplies⁶, and to put in place EU-level surveillance by the European Centre for Disease Prevention and Control (ECDC; Regulation (EC) No 851/2004). The November 2020 Health Union package would strengthen the application of these mechanisms⁷, while the decision to establish the Health Response Emergency Authority (HERA) is an important step forward to promote research, development and manufacturing of treatments, vaccines and medical supplies for health crises. HERA will support a Europe-wide ecosystem to supply medical products in times of crisis and allow the EU to share risks with researchers and industry in the development and production of medical supplies.
- **Building block 3:** For non-communicable diseases, EU-level public-health actions rely mainly on soft coordination, with funding from the EU4Health Programme and

5 This is contained in Decision No 1082/2013/EU on serious cross-border threats to health; see <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013D1082>.

6 See https://ec.europa.eu/health/health-security-and-infectious-diseases/preparedness-and-response_en#joint-procurement-of-medical-countermeasures-ensuring-proper-preparedness.

7 For the proposal on a regulation for cross-border health threats, see <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0727>. For the revision of the ECDC mandate, see <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0726>.

its predecessors⁸. 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. The 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.

- **Building block 4:** research. An important aspect of EU health policy is the direct contribution of the research Framework Programmes, which represent a significant investment in research, notably in the fields 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. The contribution is even bigger if life-science research and environmental research are included – these have contributed to the scientific foundations of ‘health in all policies’ through research in areas such as toxicology.
- **Building block 5:** 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 influence health systems. The coordination of social security and the directive on patients’ rights in cross border healthcare have progressively established the freedom of access to healthcare services. This legislation has put in place coordination mechanisms that guarantee the freedom of movement while preserving member-state prerogatives in designing and financing benefit policies. The EU initiatives are not driving a convergence process, and cross-border access to healthcare remains in practice marginal for national health systems⁹. The 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 Networks¹⁰ 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. The 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 policy¹¹ and will be an important contribution to Health Union.

Even if not covered by the health competence as defined in Article 168, healthcare and health systems are issues in non-health policies. They 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 period¹². With the new Multiannual Financial Framework and the Next Generation EU initiative¹³, 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 benefits, 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-profile-cohesion-policy-improving-health-servic/gyuv-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.

The European Parliament and civil society have called repeatedly for stronger involvement of the EU in health¹⁴. 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, fighting climate change or reducing unemployment. Nevertheless, member states prefer a model of cooperation rather than integration. The 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 benefits of closer integration compared to the *status quo*. This 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 define 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 Health Union strategy?

Several policy initiatives have defined comprehensive global or European strategies to address health issues in a holistic way. The United Nations Sustainable Development Goals (SDGs), for example, include the health-specific SDG 3, which aims at “*ensuring healthy lives and promoting wellbeing for all at all ages*”. But all SDGs, including on poverty, nutrition and climate, influence health outcomes. Another comprehensive framework was the concept of the wellbeing economy discussed under the Finnish presidency of the EU Council in 2019 (OECD, 2019a), which underlined “*the mutually reinforcing nature of wellbeing and economic growth*”. Both frameworks demonstrate that there is a limited need for a separate EU Health Union that would develop a comprehensive public-health strategy:

- The Finnish EU presidency conclusions on the economy of wellbeing explicitly stated: “*Pursuing the concept of an Economy of Wellbeing does not require new competences or structures for Union-level actions, but it does necessitate coordinated and improved use, by the Union and its Member States, of their respective powers and calls for a renewed focus on the key drivers of wellbeing*”¹⁵.
- In terms of SDG 3 goals, the EU is in a fairly favourable position compared to the rest of the world, including developed countries (Box 1). The only worrying trend highlighted by both the World Health Organisation (WHO, 2019) and the Organisation for Economic Co-operation and Development (OECD, 2019b) is persistent health inequalities within and between countries in Europe, and signs that COVID-19 has exacerbated these trends.

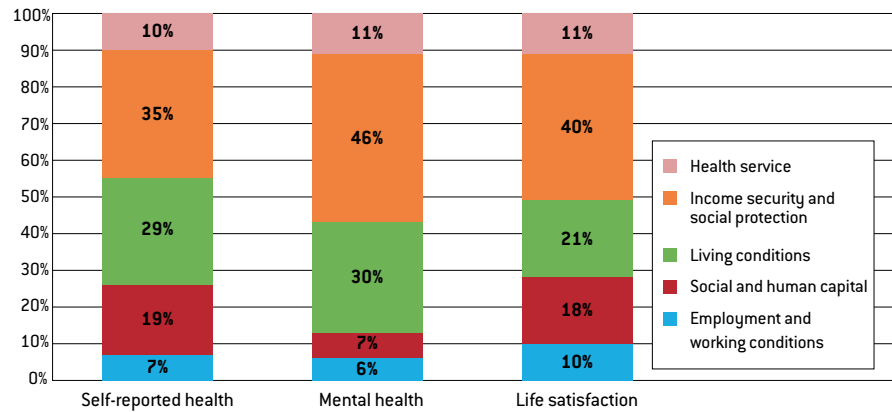
Meeting over-arching public-health objectives mainly requires better coordination between member states and properly designed economic and social policies, which take into account health issues. There is therefore not a clear push to extend the scope of Article 168 and create a dedicated framework for health policies. However, persistent health inequalities

¹⁴ A European Parliament resolution of July 2020 established a comprehensive list of policy expectations for an EU health strategy. See https://www.europarl.europa.eu/doceo/document/RC-9-2020-0216_EN.html.

¹⁵ See <https://data.consilium.europa.eu/doc/document/ST-13432-2019-INIT/en/pdf>.

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 identified 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



Source: WHO [2019]. Note: % of the gap explained by each of the five conditions.

The World Health Organisation (WHO, 2019) has quantified on the basis of microdata the contribution of different factors of health inequality in the EU. This confirms that health inequalities are predominantly a reflection of income disparities, poor housing and environmental conditions for vulnerable groups, and different degrees of health literacy, linked to educational attainment. Together, these factors explain roughly 90 percent of gaps in health outcomes in the EU.

The 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 first 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.

Box 1: Health outcomes in the EU: relatively good by international standards but health inequalities a major concern

The EU's member states are among the countries globally with the best health performance (Sachs *et al*, 2021).

In terms of more detailed indicators and trends in the EU, Eurostat (Eurostat, 2021) highlighted that all countries have made progress on nearly all health indicators and have made even significant progress on most of them. But overall progress has not reduced large disparities between countries and within countries, or between regions or income groups. This is true for the recent past but also over the longer term. Table 1 illustrates this trend for some indicators¹⁶.

Finally it should be kept in mind that these are pre-COVID-19 assessments and both the WHO (WHO, 2020), and the European Commission (2021d) have found evidence of health setbacks as a consequence of the pandemic. The high COVID-19 mortality, postponement of non-COVID-19 care and the increase in mental distress have led to deterioration in overall health performance. The OECD has also collected evidence on the disproportionate impact of COVID-19 on vulnerable groups, which also points to a widening of health inequalities during the pandemic.

Table 1: SDG on health and wellbeing

	Health outcome			Health inequalities						
	EU 27			Gaps between countries (2)			Gaps between regions (3)		Gaps between income groups (4)	
	2005	2014	2019	2005	2014	2019	2014	2019	2014	2019
Life expectancy and healthy lives										
Life expectancy at birth (in years)		80.5	81.3		8.4	8.9	3.1	3		
Healthy life years at birth (in years)	60.9	61.3	64.6	19.0	20.0	20.0				
People with good or very good perceived health (% of population)		67.6	68.6		17.8	37.7			18.6	21.7
Health determinants										
Smoking prevalence (% of population aged 15 and over)	31.0	27.0	25.0	24.0	27.0	35.0				
Obesity rate (% of population aged 18 and over)		15.4	16.5		16.6	17.0				
Exposure to air pollution particles PM2 PM5 (in µg/m3)	17.5	15.7	12.6	17.5	15.7	14.8				
Causes of death (deaths per 100,000)										
Standardised death rate due to TB, HIV and hepatitis	4.8	3.2	2.6	11.4	10.0	10.45				
Standardised avoidable mortality	281.35	260.65	252.90	419.00	376.00	349.60				
People killed in accidents at work		2.0	1.8		4.2	4.2				
Road traffic deaths	9.8	5.4	5.1	17.0	8.3	7.4				
Healthcare										
Self-reported unmet needs for medical care (% of population ages 16 and over)		3.7	1.7		12.4	15.5			4.8	2.4

Source: Bruegel based on Eurostat SDG database, <https://ec.europa.eu/eurostat/web/sdi/good-health-and-well-being>. Notes: [1] Or closest year if data for that year not available; [2] Difference between max and min values of the 27 EU countries; [3] EU average of gaps between max and min values for NUTS 2 regions within a member state and [4] EU average of gaps between the 20% poorest and 20% richest in a member state.

¹⁶ For a more comprehensive review of health inequalities, see OECD (2019), WHO (2018) and Forster *et al* (2018).

4 How can Article 168 be better implemented?

The 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. The next question is how good is the EU at protecting health in practice? In other words does the EU need to take additional steps?

The political economy of international or regional integration (Alesina *et al*, 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: “*This is why a system consisting of several regions or countries will not converge to a state of full integration*”. This is very much aligned with the WHO analysis in the specific area of health policy. The WHO (Soucat, 2019; WHO, 2021) has conceptualised the framework for health commons and has identified 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.

This section reviews the five building blocks identified in section 2 as areas for EU cooperation and the specific rationale for EU involvement.

Cross-border externalities: a strong case for Health Union for communicable diseases (building block 2)

For cross-border health threats, the protection of the population in one country depends on how the region (or the world) deals with health threats; the EU (or the world) is only as strong as its weakest country. A supra-national layer is clearly required. All countries have an interest in coordinating efforts and sharing information on emerging infections through a central surveillance function such as the ECDC.

The optimal level of coordination might not be the EU level. For outbreaks that could become pandemics, as experienced with COVID-19, the optimal level of coordination is global. But there are also more localised health threats – such as the foodborne *E. coli* outbreak in 2011 – with limited geographical impact for which the European level is the optimal level for coordination. Even in the case of a global threat, there is a need for coordination at EU level to mitigate the economic and social disruption in a more integrated region. COVID-19 has offered several examples of this, such as the need to impose green lanes to keep borders open and avoid generalised shortages, or the need to preserve cross-border movements for essential cross-border or transport workers.

Should the EU go further than the November 2020 Health Union package? The tension between European and national interests is a structural feature for health security, in particular in crisis times where national governments are directly exposed if they fail to protect the lives of their citizens. In the COVID-19 pandemic, EU countries have been reluctant to share epidemiological data and information on procurement, to harmonise COVID-19 indicators and to coordinate sanitary measures. Even for the management of their common borders, and equipped with the harmonised tool of the EU digital COVID certificate, member states have continued to deviate from ECDC/EU advice on epidemiological criteria, or to stick to national sanitary requirements for travellers. Against this background, the vaccine strategy with the joint purchase of vaccines was an exceptional solidarity decision, but was taken in the context of a global race for vaccines and under the threat of Trump-led vaccine nationalism.

As explained in section 2 (building block 2), the November 2020 Health Union package drew lessons from the COVID-19 experience and proposed a certain number of new ideas.

The 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. The 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. The former opens the way to define 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). The increasing risk of infections for which previous effective treatments no longer work because of increased resistance of pathogens to antimicrobials is a severe cross-border health threat. Fighting AMR would require binding commitments of countries to reduce the use of antibiotics. An AMR initiative, covering human health, animal health and environment policy, should include targets and monitoring of the use of antibiotics. Such a model would require a radical shift in member states' preferences and is not a short-term deliverable.

Public goods: the research-knowledge-information nexus (building blocks 3 and 4)

Like eradication of diseases, research and knowledge are typical public goods¹⁷. Because they benefit more than one country, they tend to universality and are considered as global public goods. Free markets under-provide public goods, and therefore their provision requires some collective action, including public financing and market incentive mechanisms. Both exist at EU level. But the challenge for research and knowledge in the field of health is not only to generate new research results, but also to ensure they are used in policymaking and regulation. As highlighted by the Horizon Europe cancer mission (European Commission, 2020d), making progress in the understanding of cancer, its causal factors and impact, will help design better prevention, diagnostics and treatments.

Is the current research-knowledge nexus fit for purpose? The challenge goes beyond the financing of European health and medical research. The first challenge is the immediate risk of disruption with the digital transformation of health systems, which is changing data-generation and data-sharing models, potentially creating new barriers to open research and research by university hospitals in the EU. The European Health Data Space initiative, and its related legislative proposal, is intended to address this risk¹⁸. Its success depends on the ability to enshrine public-goods features in the forthcoming legislation. In particular, it is critical that national models of data governance allow access to data by all researchers beyond

¹⁷ In the sense of being non-excludable (they benefit all) and non-rival (consumption by one does not diminish the ability of others to consume it).

¹⁸ See https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en.

national borders, facilitate the use of national data with external data sources, and cover a broad range of health data, including privately-held data. The 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 fragmented and partial way through initiatives like the European Network of Cancer Registries¹⁹. Extending the ECDC mandate to cover surveillance of non-communicable diseases would share and consolidate knowledge about disease prevalence, disease causes and scientific knowledge on these²⁰. This is necessary for the EU to fulfil its public health mandate, and would have a number of side benefits. It would help measure and monitor health inequalities, identified as a major EU challenge in the previous section. It would also be a valuable asset for health emergency prevention and response because, as experienced with COVID-19, populations with co-morbidities or social vulnerabilities are hit disproportionately by pandemics. EU-level surveillance of non-communicable diseases would also support the implementation of the HiaP principle. The ability to compare and follow over time a comprehensive mapping of health outcomes with, for instance, detailed information on environmental harms or chemical exposure, would strengthen the assessment of the health impacts of EU policies and would help identify regulatory gaps.

Economic integration and interdependencies (building block 1)

In the case of externalities and pure public goods, European coordination and integration generate economic efficiency and social welfare gains. But HiaP responds to a completely different logic: the health in all policies principle is dictated by interdependencies within the EU. This is what the WHO defines as market-shaping factors for global commons. It is a legal imperative in the EU. Given that many sectors and policies are integrated at EU level, the health protection provisions in these policies need to be defined at EU level. Section 2 showed how health protection cuts across a wide range of sectoral legislation, including environmental legislation and the single market *acquis*.

Is the HiaP principle implemented adequately? This principle is applied in a decentralised way in each policy field. Each policy field is organised to obtain the relevant scientific advice on health protection. In policy fields where the health focus is very strong, the assessment of health risks is supported by scientific agencies: the European Medicines Agency (EMA), the European Food Safety Authority, the European Chemicals Agency, the European Environment Agency. The system of scientific agencies has a number of advantages: it pools resources at EU level, avoids duplication of tasks such as information collection, and provides a one-stop shop for businesses, reducing their regulatory burden. Sharing expertise at EU level also means a more diverse set of evidence can be taken into account. It also allows the EU to influence global standards, like for food traceability, or third-country rules like the use of EMA scientific assessments in a number of non-EU jurisdictions, or open access to EU chemicals data²¹. Overall, for regulations backed by health-related risk assessments carried out by scientific agencies, the EU has a good track record of achieving a high level of health protection.

However the system does not deliver even results across the board. In relation to air quality, for example, which is the number one environmental health risk factor in the EU, the EU's legal threshold for exposure to fine particulate pollution is above WHO recommended levels. When it comes to the social determinants of health, there are some calls for more stringent regulation at EU level of markets for alcoholic drinks (EPHA, 2016) or better reflection of health risks in taxation legislation for tobacco and alcohol. Some EU policies, such as on 5G

¹⁹ See <https://www.enrcr.eu/>.

²⁰ It would be very much in line with other public health bodies like the US Centers for Disease Control and Prevention (CDC), the WHO and the African CDC.

²¹ See European Commission (2017) p324, European Commission (2018) pp76-92, Lugietti (2016).

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' project²², or the equivalent of an ageing report (see European Commission, 2021c), or via the European Pillar of Social Rights scoreboard²³. 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

This contribution takes as a starting point the current framework for health policy as a reflection 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 confirms that Health Union is more relevant for cross-border health emergencies than other public health concerns. It also confirms that greater convergence of health systems would be too costly for national governments and therefore that coordinated actions in healthcare will remain very limited. There 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 identified the need for greater political ambition in a number of areas: monitoring of health inequalities and measurement of health-system performance for a better synergy between health policies and other economic and social policy objectives; surveillance of non-communicable diseases at EU level; and an upgraded research-knowledge nexus, in particular to implement the 'health in all policies' principle.

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