THE PROMISE OF A EUROPEAN HEALTH UNION

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Summary: In order to cope with current and future crises, individual welfare states need transnational collective action, that is, solidarity. The 'European Health Union' should organise such collective action in support of shared goals of public health and national healthcare systems. The Belgian presidency will give a strong signal that health should be a top priority for the next European Commission’s agenda. The key policy challenges to be addressed by the future Commission answer three broad and interconnected aspirations: a Europe that cares, prepares and protects.

Keywords: European Health Union, Solidarity, Health Workforce, Needs-driven Innovation, Medicines Shortages, Access to Healthcare

Introduction

At the time of writing, the Ukrainian war has been going on for a year and a half, armed conflict has erupted in the Middle East, the world is experiencing record temperatures, and patients face severe medicines shortages. Meanwhile, we are still dealing with the aftermath of the most serious health crisis in a century, which has added to the fatigue of a health and care workforce already under stress. Such international crises and emergencies are no longer an exception, they have become part of life as we know it. No country can overcome large-scale transnational crises on its own: they require international collective action or, in other words, solidarity.

Solidarity proved to be essential to respond to the COVID-19 pandemic, both at the national and the European level. At the national level, the in-built solidarity of inclusive welfare states with accessible healthcare and universal sickness benefits is crucial for a society to be economically and socially resilient when it is hit by such a shock. However, European solidarity was needed to complement and reinforce the response capacity of the individual European welfare states. Fortunately, the EU’s reaction to the pandemic was a deliberate choice for collective action and solidarity, more explicitly and more boldly than in previous economic and financial crises. Traditional concerns about the risk that solidarity might be ‘misused’ were quickly – and rightly – set aside. This crisis was caused by a public health shock which hit all countries in the same way, no country could be held ‘responsible’. There was no issue of moral hazard, the adequate response was straightforward solidarity.

A European Health Union

In the past I coined the expression ‘a European Social Union’ to describe the role the EU should play in the domain of social policy: the EU should be a true...
union of welfare states, notwithstanding their different historical legacies and institutions. In a Social Union, the EU should support national welfare states and guide their substantive development on the basis of common social standards and in pursuit of upward convergence. Simultaneously, a European Social Union maintains subsidiarity as an organising principle with regard to the ways and means of welfare state solidarity. The European SURE initiative, which was launched to support national job retention schemes, such as short-time working arrangements, when the pandemic hit, is a prime example of what a true Social Union is about. SURE could be understood as the prefiguration of a European ‘interstate insurance’ to buttress the stabilisation capacity of national welfare states. Next to providing such systemic support, a Social Union should be a norm-setter that defines common social standards, so I argued.

The mission of a European Health Union, as presented in official EU documents, indeed refers to a broad range of actions on health, “in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer”. Notwithstanding its broad mission statement, the initiatives taken under the umbrella of the European Health Union mostly focused on preparedness and response, and less on the overall resilience of public health systems.

The Conference on the Future of Europe noted this strong emphasis on crisis-related aspects of health policy and called for the establishment of a “right to health” by ensuring that all Europeans have equal and universal access to affordable, preventive, curative, and high-quality healthcare, by improving the quality and resilience of our healthcare systems, and by adopting a holistic approach to health, and ensuring access to healthy food. The Conference also called for the integration of health and healthcare among the shared competencies between the EU and EU Member States.

Still, I believe that the key, above all else, is political will, with consensus-building as the essential component. A change of the Treaty on the Functioning of the European Union (TFEU) would certainly provide the occasion to create a stronger legal basis for the work on health, but COVID-19 showed us that EU collaboration in health can already be extensive within the current legal framework.

Moreover, we know that the EU’s current impact on health policy is much broader than what one might expect when reading article 168 of the TFEU. Many health-related provisions can be found in the legislation of other policy areas (such as food safety, safety at work, chemical products, environment …). In particular, the internal market legislation and the EU fiscal policy framework have a crucial impact: think about pharmaceutical products, health professionals and the European Semester (the EU’s framework for the coordination and surveillance of economic and social policies). Furthermore, the EU’s various funding instruments are also of increasing importance, especially when they are used to leverage the implementation of policy priorities defined in the European Semester.

In short, if we argue for a broad understanding of the European Health Union’s mission, we are in good company when reading the results of the Conference on the Future of Europe. But such a broad understanding does not presuppose Treaty change acknowledging that the current Treaty already grants important legal competences to the EU in policy domains that bear significantly on national public health and healthcare policies.

A Europe that cares, prepares and protects

The Belgian Presidency of the Council of the European Union coincides with the conclusion of the von der Leyen Commission’s term. Hence, during our presidency we propose to identify and discuss the priorities for the next Commission’s agenda with regard to the European Health Union. These priorities can be grouped in three thematic clusters: “care”, “preparedness” and “protection”.

A Europe that cares

All countries face health workforce challenges: shortages associated with the increasing needs of an ageing population and waves of retirement of health workers in changing labour markets, uneven geographical distribution, mismatches in skill-mix, difficulties to develop skills to meet new healthcare needs and new technologies. To face the health workforce crisis, action is necessary at all levels, both national and European. Whilst fully respecting national competences, the EU can do much more to support Member States in the development of strategies to ensure the availability of sufficient and well-skilled healthcare workers.

What is an optimal division of tasks between professionals with different qualifications? What is the role of
technological innovation and new medical devices? To address such – shared – questions national policy-makers can learn much from each other, and the EU can contribute significantly to the exploration of new frontiers of innovation. However, next to taking up such a supportive strategic role, the EU already has a crucial legal impact on the organisation of the healthcare professions, through the EU legal frameworks regulating health professions, in particular – but not only – the Professional Qualifications Directive (PQD). We call for a critical examination of these legal frameworks from different angles, even if they might seem to pull the debate in opposite directions. On the one hand, the PQD may be too rigid and formalistic to accommodate the continuous dynamic development of competencies and the flexibility and new models of cooperation needed in the future organisation of the health workforce. On the other hand, the current legal frameworks seem ill-equipped to address challenges related to specific contexts, in particular short-term mobility of health workers and telemedicine, which raise specific issues of quality assurance and patient protection.

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Research and development are obviously crucial to continuously improve healthcare systems and shift their frontier. However, research and development must not be driven by what can generate significant profits, but rather by current (unmet) health-related needs in society, and therefore needs from patients. The EU plays an important role in orienting research and development through its research funding programs and through regulatory incentives built into the pharmaceutical legislation. Therefore, the Belgian presidency will launch a debate on the notion of a ‘needs-driven approach’ of healthcare policy and research and development. That is, we need a common methodology to identify and assess disease-specific unmet needs and define priorities in an evidence-based manner. On that basis, the Commission must be able to draft an EU strategic plan to adequately and effectively respond to the identified patient and societal needs. Such a strategic plan should consider all types of health interventions (rather than only pharmaceuticals), and coordinate all kinds of public support and incentives.

While there are already many sound arguments for the prevention of non-communicable diseases (related to health, budgetary matters and economy of well-being), COVID-19 added one more argument to this list: healthy populations are also more resilient to different types of crises. But then, first of all, people must have the opportunity to lead a healthy life. Here too, the EU has an important role to play given its already existing legal competences: just think about its policy levers with regard to food, tobacco and alcohol. There is a significant acquis, but the EU must continue to work on the prevention of non-communicable diseases and raise its level of ambition. More concretely, we want to bring the negotiations on the Council Recommendation on vaccine-preventable cancer and the Council Recommendation on a smokefree environment to an adoption by the Council, as well as organise a stock-taking exercise on the Europe Beating Cancer Plan, with a specific focus on legislative measures. Consequently, this could lead to a call to continue action on non-communicable diseases.

A Europe that prepares

We need to implement the lessons learned from the COVID-19 pandemic in order to be ready for the future. With the adoption of the Health Union legal package and the creation of the Health Emergency Preparedness and Response Authority (HERA), the work related to health emergency preparedness has only started. These swift initiatives were badly needed, but are we now really prepared for the next crisis? The Belgian Council Presidency will launch a stock-taking exercise of the post-pandemic EU health emergency governance framework. We propose to address five sets of questions. In the event of a new health emergency, will the EU be able to rely on: (i) the right tools and procedures to deal with the crisis; (ii) the financial means to effectively secure adequate resources; (iii) the structures and institutions to develop coordinated, multi-level response strategies; (iv) the means and advice to speak with authority and legitimacy to the general public; and (v) sufficient intelligence to collect data and relevant information, and translate it into actionable insights? In a nutshell, who does what exactly at what time? And how do we ensure that everyone is on board in time?

In this context, we will also examine how the EU’s capacity to conduct large scale clinical trials can be expanded. During the pandemic, the World Health Organization (WHO) recorded over 18,000 COVID-19 clinical trials, the vast majority (95%) of which are thought to have contributed nothing to the evidence base due to failure to complete enrolment or poor design features. An unprecedented number of academic clinical trials have also been launched in the EU to speed up COVID-19 treatment and prevention. Despite these efforts, a lack of coordination across Member States resulted in a chaotic landscape with numerous underpowered trials that could not provide meaningful results and a duplication of research activities. The Presidency will work on the development of concrete actions for strengthening the European ecosystem for public clinical trial platforms.

Additionally, the Presidency will continue the work of the Swedish and Spanish Presidencies on the silent pandemic of antimicrobial resistance (AMR). The European Centre for Disease Prevention and Control (ECDC) estimates that 35,000 people die each year in the EU from antimicrobial-resistant infections. We intend to discuss the EU’s AMR governance, the development and implementation of effective, results-driven, policy measures to optimise use of
located in another country.

intermediate inputs, even if they are sourced from China. Furthermore, almost all API producers depend on China for its medicines supply, adding imports from a few manufacturers and detrimental effects for patients.

In several Member States, parallel exports, impedance and regulatory measures, factory closures or relocations, have been faced. The reasons for shortages are complex and range from unexpected increases in demand to manufacturing and quality issues, factory closures or relocations, bottlenecks in the supply chains, and regulation and reimbursement policies. In addition to these problems, the EU is becoming increasingly dependent on exports from a few manufacturers and regions for its medicines supply, adding a security dimension to the question. In 2019, globally more than 40% of Active Pharmaceutical Ingredients (APIs) were sourced from China. Furthermore, almost all API producers depend on China for intermediate inputs, even if they are located in another country. Next to the geographic concentration, there is also a concentration of manufacturing sites: for more than 50% of APIs globally, less than five manufacturers with a Certificate of Suitability (CEP) exist. As a result, Europe (and the world) depend on a few manufacturers for a large bulk of their medicines supply.

To tackle these problems, Belgium launched a non-paper on security of medicines supply, which was signed by 23 Member States. The non-paper proposed three measures to help relieve the worst effects of shortages on patients, as well as to provide a structural answer to the underlying causes, namely: 1) a voluntary solidarity mechanism to address acute shortages, 2) a European list of critical medicines whose supply, production and value chains must be monitored, and 3) a Critical Medicines Act to strengthen Europe’s manufacturing base for critical medicines and reduce dependencies and market consolidations. The initiative has been followed up by a comprehensive Commission Communication, published on 24 October 2022. The Communication puts forward a broad set of short-term and longer-term actions to address shortages of medicines and enhance their security of supply in the EU. Concretely, the Commission immediately put into action proposals to establish a voluntary solidarity mechanism to share medicines between Member States in case of acute shortages and to carry out a risk assessment of the supply chains of a list of critical medicinal products. The Commission also announced an industrial plan for the production of older, less-profitable but critical medicines, the launching of a public-private cooperation under a ‘Critical Medicines Alliance’ and of a study to prepare a future ‘Critical Medicines Act’.

Putting these actions into practice will be challenging, yet necessary. For instance, several Member States have started rigorous stockpiling programmes as a response to shortages, which can have further negative consequences for the fair distribution of medicines on the European market. A solidarity mechanism should be able to counteract some of these problems, but only provided that Member States do not have export restrictions in place to put up a barrier for solidarity, and that there are procedures in place that can efficiently move stock without excessive legal and logistical burdens. In a nutshell, in an interconnected market we must help each other out: the stockpiles of the rich must not create the shortages of the poor.

The same goes for the government support programmes under the ‘Critical Medicines Alliance’ and the future ‘Critical Medicines Act’, which will require tight coordination on the medicines that are primarily targeted, finding the necessary public and private financing, and defining the public services that are asked from producers in return.

Healthcare as a social right and a social investment

During the Belgian Presidency, we want to reaffirm the European Pillar of Social Rights as an overarching compass for the EU’s action in the social domain. Principle 16 of the Pillar proclaims that “everyone has the right to timely access to affordable, preventive and curative healthcare of good quality”. The Pillar has generated highly valuable policy spillovers since its first proclamation in 2017, but, so far, principle 16 has not triggered specific implementation initiatives. In our view, a European Health Union should also be inspired and driven by this important principle 16 of the Pillar. A Health Union is also about access to healthcare and equity: therefore, the Pillar of Social Rights should be one of the key references and benchmarks of the European Health Union.

Linking the European Health Union to the Pillar not only underscores the importance of equal access to healthcare as a fundamental social right. Establishing that link will also bear on the way healthcare spending is treated in the EU’s economic and budgetary governance; at least that is our ambition. During our Presidency, we will argue that the EU’s economic governance and budgetary policies should now take due consideration.

† A non-paper is an unofficial document, a paper that has not been through a formal adoption procedure.
‡ This work will be carried out under the Belgian Council Presidency, but not be further elaborated on in this publication.
of the European Pillar of Social Rights. The review of the EU’s Economic Governance, which is currently on-going, has to recognise that investments in well-organised social policies are an asset and not a liability, a productive factor rather than a cost. The concept ‘social investment’ is well-known in the European policy debate, but it has been used most often with reference to early childhood education and care, education, training and active labour market policies. Investment in health and healthcare are prime examples of investment in human capital and should be included in the concept of social investment. The review of the EU’s Economic Governance offers an opportunity to highlight the role of investment in healthcare as a condition for growth, competitiveness and sustainable public finance. That opportunity must not be missed.

Conclusion

As we navigate global challenges, from conflicts to health crises and climate emergencies to medicine shortages, it is evident that European collective action on health – a true European Health Union – is not optional but imperative. We urgently need more debate on the ways forward to a Europe that cares, prepares and protects. That is why we commissioned this special Eurohealth issue. It is an invitation to dialogue, highlighting some key areas where the Union can make a substantial impact, from bolstering the healthcare workforce to adopting a needs-driven approach to research and development. The contributions also emphasise the importance of reinforcing prevention and promoting healthier lifestyles. And while the views presented are solely those of the authors and do not engage the Presidency, we will work hard with the Commission, the Parliament and Member States to take the objectives that inspire these contributions on board in our work on the European Health Union.

References