Memo to the commissioner responsible for health

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Health policy in the European Union is in a stronger situation in the wake of the COVID-19 crisis and the adoption of legislation intended to ensure greater resilience and underpin the response to the next pandemic. In this context, you face challenges of ensuring that health security stays prominent on the agenda, while furthering the reform of EU pharma legislation and doing more on non-communicable diseases, including cancers, cardiovascular disease, diabetes and Alzheimer's.

You should push for greater resources for the Health Emergency Response Authority, pursue an integrated 'one health' approach that takes into account the linkages between human health, animal health and ecosystems, do more to make the EU attractive for highly innovative pharma and seek to extend the Health Union project to non-communicable diseases.

Maintain health policy as a high priority

Boost EU attractiveness for innovative pharma

Extend the Health Union to non-communicable diseases

Your predecessor's term was dominated by the management of the COVID-19 crisis, its global and European aspects and its legacy. As early as November 2020, the European Union started to re ect the lessons of the crisis in a 'Health Union' package, nalised in 2022 and intended to make the health security framework more resilient.

Although the Health Union was conceived as response to COVID-19, its perimeter is much larger. It includes initiatives on pharmaceutical markets, health data and non-communicable diseases (cancer and mental health), and a global health strategy.

During your term, decisions will have to be made on the ambitions for Health Union, whether to implement and consolidate the pipeline of ongoing initiatives, or whether to boost the project further with new proposals for a more integrated European health policy[1].

COVID-19 reminded the world of pandemic risks and made European citizens aware of the role of the EU as a partner to manage health crises. e EU did well to guay the malC20 1 11 (ar)ldone

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e most signi cant change under the Health Union was the creation of the Health Emergency Response Authority (HERA) in 2021 as a Commission directorate general. HERA was set up as a European counterpart to the United States' BARDA (Biomedical Research and Development Authority), which oversees development and purchasing of medical countermeasures (vaccines, therapeutics and diagnostics) for health crises. HERA has already a track record in setting up schemes for vaccine production (EUFABLAB), clinical trial platforms for crisis medicines and vaccines (VACCELERATE) and joint purchases. It is being evaluated and you will have to decide its future.

e COVID-19 crisis has been enlightening in terms of the capacity and limitations of pharmaceutical markets to respond to needs in crisis. e development of innovative mRNA vaccines within less than a year was an unprecedented scienti c success. e ability to ramp up vaccine production within half a year was a sign of a dynamic ecosystem. At the same time, health systems su ered shortages of basic medicines.

e COVID-19 experience shaped the far-reaching pharma reform proposed by the Commission in 2023. is reform includes framework legislation and speci c regulations, such as for orphan or paediatric medicines. It also extended the mandate of the European Medicine Agency (EMA) to include monitoring for medicine shortages. Access, a ordability, availability of medicines, innovation and the environmental impact of the industry are at the heart of the reform. Medicine shortages, which have become chronic and a ect a large part of the market are considered of utmost priority, making temporary measures necessary pending adoption of the legislation. Immediate measures have been put in place: a new alliance with all partners, regulators and industry to secure value chains; the adoption of a list of critical medicines; and monitoring of national and European markets by national medicine agencies and the EMA. Negotiations on the pharma reform; the European Parliament adopted its position on the package in April 2024.

The EU has been very effective in using its political leverage to speed up the digital transformation of health. The healthcare sector has not been an early adopter of digital technologies. But the EU made health a priority sector for the new wave of innovation brought by artificial intelligence: the European Health Data Space Regulation (EHDS), finalised in spring 2024, is the first sectoral application of the EU data strategy. It is an ambitious law that puts in place a European framework for patients' electronic health records, access to them by patients and professionals and their use for research and policy purposes. However, implementation will pose significant challenges: supporting the development of markets for interoperable IT solutions for patient data; upgrading the European platform, MyHealth@EU, an infrastructure for cross-border exchanges of patient records; coordinating the network of bodies for access to health data that member states will have to set up.

The EU has been active on the global stage during and since the pandemic. The EU was an early promoter of a World Health Organisation pandemic treaty, and a major contributor to the new international Pandemic Fund. It is also an important actor and investor in global health through the Neighbourhood, Development, and International Cooperation Instrument (NDICI).

Reference Networks (ERNs), which are 24 specialised networks covering di erent rare diseases involving 300 university hospitals, set up in 2017. ey share knowledge and provide telemedicine services for rare diseases. ey could be considered as prototypes of EU cooperation between healthcare facilities. e ERNs are being evaluated and you will decide on their consolidation and expansion.

You will have much to do to deliver on and implement the post-COVID-19 agenda. However, you may face the risk of a decline in interest in European health policy, which has never been a priority for national governments and might attract little support from a less pro-EU European Parliament. Choosing your priorities and political battles carefully will be key for success in consolidating progress and avoiding setbacks.

Pandemics are prone to 'panic and neglect' cycles and the negotiations on the Health Union package have shown that member states are lukewarm about more coordination at EU level for pandemic prevention and response.

Your rst challenge will be to develop and maintain very good and open cooperation between di erent layers: cooperation between EU countries in the Health Security Committee, interaction with the WHO and the global health community, cooperation between EU agencies (the European Centre for Disease Prevention and Control, HERA, EMA, the European Food Safety Authority, the European Environment Agency). Such partnerships are indispensable to take into account the linkages between human health, animal health and ecosystems in an integrated 'one health' approach. Over the last ve years, there have been several political commitments for countries to cooperate, but the framework remains fragmented, untested and not yet crisis-proof.

Your second health-security challenge will be to make a success

of the new authority, HERA. HERA has limited resources and draws on a few funding programmes which are not t for high-risk investment in development and production of innovative medical products for use in crises. HERA is also increasingly involved in the initiatives on medicine shortages. e previous Commission outlined a roadmap on strategic autonomy for medicines. You will likely bene t in this respect from consensus among and support from member states, and probably industry, to implement it. But there is a risk that HERA's limited resources reduce its ability to focus on crises.

e rst part of your mandate will focus on nalising the pharma reform and reversing the trend of chronic medicine shortages in the EU. e debates on the reform package are likely to remain highly contentious and it will not be easy to nalise a balanced package of obligations and incentives for the pharmaceutical industry.

e reform should preserve an innovation-friendly environment for industry. e pharma sector is very research-intensive, and the failure rate of research is high. With more complex treatments and diseases to address, the R&D costs per medicine have been increasing (Simoens and Huys, 2021) and the business model has moved from a model of blockbusters to a model of 'niche-busters', with higher prices and less scienti c certainty on medical e ectiveness. Measured by the increasing share of medicines addressing unmet needs in market authorisations (Bouwman *e a* , 2024), the trends point to a continuous increase in innovation. e

years compared to international competitors. The production of active pharmaceutical ingredients (APIs) has moved outside the EU to benefit from lower production costs in India or China. With a market share of 24 percent of API production in 2015, Europe is specialised in the high-end segment of the market. However, China and India outperformed Europe over the last 20 years and it is estimated that two thirds of API quality certificates are held by Indian and Chinese manufacturers (European Commission, 2021). Meanwhile, the US has become increasingly more attractive for innovative medical research thanks to a dynamic biotech ecosystem and a more favourable regulatory and market environment, offering a large market with much higher prices than in the EU. Europe accounted for 19.3 percent of global clinical trials activity in 2020, a decrease of 6.3 percent, compared with a 25.6 percent average over the previous decade (EFPIA, 2022).

The pharma reform is timely. It is encouraging more competition through earlier entry of generics. It is offering longer regulatory protection for medicines responding to unmet needs, and launched on the 27 member states' markets, and a transferable exclusivity voucher for new antibiotics. The negotiation will challenge this new balance of incentives.

The EU has been playing an increasingly strategic role in health security and in regulation of medical products. But its legitimacy is weaker for actions in other areas, such as non-communicable diseases, health systems and health inequality. EU action in these fields is constrained by the competences set out in the Treaty. But at the same time there is strong political pressure for action from civil society, including patients' organisations and health professional associations. In these areas, the track record of the EU

e launch of the Health Union project has created expectations and you cannot start your mandate without clear views on its development, and whether and how you want to contribute to its consolidation in these areas.

e success of your mandate will be measured by the successful delivery of the existing pipeline of policy initiatives and your ability to set the EU Health Union on a credible path.

The immediate task you will be faced with will be to put HERA on a sound footing

have records of cooperation with national counterparts. e second recommendation on health security is an ambitious 'one health' programme with enhanced member-state coordination, stronger mandates for EFSA and the EEA and direct involvement of EU representatives in global governance structures, in particular after the adoption of the pandemic Treaty.

Consider a package of measures along the

e ongoing initiatives on pharmaceutical markets, though legitimate, fail to address the structural problem of loss of competitiveness of industry, and the widening gap with the US on innovative medicines. is requires a more forceful policy response focused on cutting-edge innovation. You should consider a package of measures along the whole value chain, from research to price setting. is would combine:

Setting up an ARPA for Health

Currently, research e orts at EU level are too fragmented (ECDC, HERA, Horizon Europe, EU4Health, European institute of Technology, Innovative Health Initiative) and fail to concentrate resources on the most consensual priorities, such as research for new antibiotics. e EU needs a strong public institution for medical research with resources for top-down priorities and high risk projects – an ARPA (advanced research projects agency) for Health.

Reviewing regulatory bottlenecks to innovation

Highly innovative biological medicines fall within the framework of Advanced erapies and Medicinal Products (ATMP). ese speci c rules were not part of the pharma package and with rapid scienti c developments in this segment, it is time to check whether the legislation is t for purpose and implemented consistently across EU countries. Moreover, the pharma reform has left the clinical trial legislation untouched. Clinical trials are authorised by national regulators, which makes clinical research costly and creates unnecessary delays and bottlenecks. A centralised clinical trial protocol under the responsibility of EMA would create a regulatory environment such as that which rms face in the US, and would enhance clinical research in the EU.

Initiatives on new price and reimbursement models

Although the market for medicines is well integrated with central market authorisation delivered by EMA, prices and reimbursement decisions remain national. Such fragmentation is particularly penalising for innovative medicines that target small populations, often with limited clinical data on their e ectiveness, and which come to the markets with high prices. Radical innovation requires new pricing and reimbursement models, such as pay-for-performance and annuity models. Member states should set up pilot schemes for new nancing models. e new Health Technology Assessment framework, the group of National Competent Authorities on Pricing & Reimbursement and public healthcare payers should examine this possibility as a priority, and EU countries could launch joint public procurement for such cases.

Your ambition should be to develop a Health Union project, with clear bene fts for citizens

Your ambition should be to develop a Health Union project, which delivers clear bene ts to the European citizen. e current initiatives on rare diseases, cancer and mental health deserve to be continued. But you should extend the 'Health Union' project to non-communicable diseases (NCDs) at large, since they generate the heaviest burden for health systems, are signi cantly a ected by the way public health is addressed in EU policies and are at the heart of health inequalities.

e EU would gain from mutualising research and epidemiology for NCDs. e move towards a comprehensive European epidemiology should be a long-term goal and could rely on research funding and the experience of ECDC. e rst step in this direction is to extend the ECDC mandate to NCDs, building on the ECDC cooperation with national public health institutes and fully aligning ECDC with the role of organisations outside the EU, such as the WHO.