
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

State of affairs

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 reflect the lessons of the crisis in a 'Health Union' package, finalised 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 policy¹.

Better prevent and manage health crises

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. The EU did well to guarantee the integrity of the internal market and adopt emergency measures to protect the economy. Citizens will remember the joint purchase of vaccines, which allowed the EU to vaccinate 70 percent of the population by the end of 2021, just one year after the market launch of new vaccines. Access to vaccines and the common digital COVID-19 certificate were critical to exit the pandemic and end restrictions on social and economic life.

Vaccine purchases were successful exceptional crisis responses. But the EU cooperation framework for health security was less effective than expected in providing a coordinated response to COVID-19. National priorities and conditions determined member states' responses to the pandemic. The EU took stock of the weaknesses in coordination and adopted the Health Union package to strengthen the existing mechanisms.

¹ In the absence of Treaty change, this is limited to supporting cooperation between EU countries on public health and cross-border health threats, and organising markets for medicines, medical devices, blood, tissues and organs. EU policy must respect the exclusive competence of member states for health policy and healthcare services.

Access to vaccines and the digital COVID-19 certificate were critical to exit the pandemic

The most significant change under the Health Union was the creation of the Health Emergency Response Authority

The most significant 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 (Bio-medical 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.

Reform of the pharma legislation

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

The COVID-19 experience shaped the far-reaching pharma reform proposed by the Commission in 2023. This reform includes framework legislation and specific 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, affordability, 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 affect 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.

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The European Health Data Space

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.

Global health

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). The EU has all the assets to play an even bigger role in global health and the Global Health Strategy (2022) identified new partnerships and contributions to global initiatives such as research, environmental health and pandemic prevention.

Other health initiatives

Several other initiatives, not less important than those above, fall within the scope of more traditional EU intervention in health: cooperation between EU countries, exchange of best practices and funding from the EU4Health programme. This includes the Europe's Beating Cancer Plan (2022), which could be prolonged, the comprehensive approach to mental health initiative (2023), which is to be implemented, rare diseases and the European

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

Challenges

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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.

Keep health security on the agenda

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 first challenge will be to develop and maintain very good and open cooperation between different 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 five 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 fit 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. The previous Commission outlined a roadmap on strategic autonomy for medicines. You will likely benefit 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.

Better functioning pharma markets

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

Pharma reform should preserve an innovation-friendly environment for industry

The reform should preserve an innovation-friendly environment for industry. The 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 'nichebusters', with higher prices and less scientific certainty on medical effectiveness. Measured by the increasing share of medicines addressing unmet needs in market authorisations (Bouwman *et al*, 2024), the trends point to a continuous increase in innovation. The pharma industry exhibits a stable profitability rate, higher than in most other sectors.

However, there is a need to tackle several unfavourable trends. Some markets, mainly in small or less-developed member states, remain underserved because industry does not consider them profitable. Mismatches between supply and demand persist with unmet needs (antibiotics; very rare diseases) or marketing of medicines with low added value. Industry sees EU markets as less and less attractive because of the oligopsony structure, with public authorities or social insurance funds negotiating prices and sales volumes. Overall, the EU pharma industry has lost ground over the

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.

Getting more done on non-communicable diseases

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 is characterised by fragmented and discontinuous actions, with uneven support from member states.

The EU4Health programme is a useful tool to support the various health policy initiatives. But there is a need to streamline actions to create a critical mass of interventions and make them visible. Rare diseases, chronic diseases, ageing, mental health and environmental health are the areas that need strategic steering.

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The 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.

Recommendations

The 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

Two 'must-dos' for health security

The immediate task you will be faced with will be to put HERA on a sound footing. Currently, HERA is being evaluated. It has limited resources relative to its responsibilities and there are overlaps in risk evaluation and management with the European Centre for Disease Prevention and Control (ECDC) for major threats, and with EMA for medicine shortages. In the current set up, HERA is not designed and resourced to support large-scale investment in research and development for counter-medical measures. HERA could host such a function, which could take the form of a European public infrastructure for pharmaceutical research and development. But it would need an adequate budget. The first recommendation is that at constant resources and mandate, HERA might be better off if merged with the ECDC. This would bring the advantage of operating as an agency without creating a new one, and it could build synergy with ECDC on risk assessment and preparedness measures.

A 'one health' approach'

The post-COVID-19 period has been rich in creating plans and partnerships at European and international levels. Emerging zoonotic pathogens and antimicrobial resistance are major threats to the EU, and require a 'one health' approach to national and international cooperation. The EU is well positioned, with competence in animal health and environment. It is also supported by a network of independent scientific agencies that

have records of cooperation with national counterparts. The 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.

Make the EU attractive for highly innovative pharma

The 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. This 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. This would combine:

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Setting up an ARPA for Health

Currently, research efforts 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. The 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 Therapies and Medicinal Products (ATMP). These specific rules were not part of the pharma package and with rapid scientific developments in this segment, it is time to check whether the legislation is fit 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 firms 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 effectiveness, 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 financing models. The 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.

A Health Union for non-communicable diseases

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

Your ambition should be to develop a Health Union project, which delivers clear benefits to the European citizen. The 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 significantly affected by the way public health is addressed in EU policies and are at the heart of health inequalities.

The EU would gain from mutualising research and epidemiology for NCDs. The move towards a comprehensive European epidemiology should be a long-term goal and could rely on research funding and the experience of ECDC. The first 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.

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