FONDATION ROBERT SCHUMAN

POLICY PAPER

Health Europe: from dream to reality?

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Françoise GROSSETÊTE

No one imagined at the dawn of the year 2020 that such a small but dangerous coronavirus could revolutionize the world to the extent that it has. The Covid-19 health crisis has repeatedly rekindled fundamental debates, calling into question sometimes globalisation, sometimes the inaction of the European Commission, and sometimes the lack of European solidarity.

Indeed, from the very beginning of the epidemic, when its enormous contagion was impossible to imagine, Eurosceptic voices were raised to denounce the European Union's unduly late response. It is true that at the time Europe gave a divided image between the countries of the North, less affected by Covid-19, and the countries of the South, which were in greater difficulty.

When we talk about Europe, whom are we talking about? The European Commission? The European Parliament? The European Central Bank? These institutions succeeded in providing a massive and unprecedented response to the crisis. The Member States are the only ones to bear the responsibility for a fragile European Council... and for their lack of solidarity.

THE FUTURE OF HEALTHCARE WILL BE EUROPEAN OR NOT

While the organisation of health care systems remains an exclusively national competence, the regulation of medicines and medical products depends largely on the European Union.

A quick overview of the challenges facing our healthcare systems is enough to realise just how essential European cooperation is, because these are challenges that cannot be solved at national level alone. Indeed, health budgets are under increasing pressure, while disruptive innovations, which are necessarily much more costly, are coming onto the market. Research is focusing on increasingly complex therapeutic areas. Patient populations are often fragmented. This is the case, for example, for those suffering from rare diseases. Epidemics know no borders. This also raises the question of vaccination policy, which one day will have to be common. Patients are increasingly mobile, ready to go elsewhere to seek expertise or treatment that does not exist at home. Health professionals are being led to train or practise abroad.

The single market for medicines and medical devices has been created to ensure that they meet the same norms and standards throughout Europe. The digital and robotic revolution, the development of artificial intelligence, the collection and analysis of big data is also forcing us to change scale.

The evidence is clear: everything is pushing us towards greater cooperation, harmonisation, pooling of resources and knowledge, and therefore towards an Europeanisation of health policy. Health policy cannot be conducted in a bubble, sheltered from the fundamental changes affecting our economy and society. This Copernican revolution, although it is now relatively well understood by everyone, seems to be opposed to the many conservative tendencies that are affecting many of our countries and in which everyone is playing their part.

In the field of health care, France, for example, has for too long remained stuck on its principles and certainties, convinced that it had the best health care system in the world, and with little or no lessons to learn from others, wanting to use its own health care model as one for the emerging European system.

The health crisis that we are experiencing is rich in lessons. While we must salute the incredible energy and efficiency of health workers who have had to deal with the worst situations, we must acknowledge that, in many Member States, health systems have been challenged. Admittedly, situations have been very disparate, with the epidemic striking with varying degrees of intensity depending on population densities and the emergence of clusters. Hence, there is an urgent need for us to learn to question ourselves and to work together more constructively. The underlying problem is the lack of trust between Member States and national health authorities, each fearing that they will be dispossessed of their own turf. This is nothing new. When the European Medicines Agency (EMA) launched and the centralised procedure for the marketing authorisation of medicinal products established, whose efficacy is undisputed, it faced a certain amount of reticence. But can we continue for long with these quarrels, these rear-guard battles, when we are being outpaced by China, the United States or the so-called GAFAM companies? Should we continue to shoot ourselves in the foot when there is an urgent need to build, together with all of our European partners, the critical mass that should allow Europe to ensure our health and scientific sovereignty?

This sovereignty, be it health, industrial or digital sovereignty, is unanimously agreed upon, but it must be to the benefit of the European Union so that all the Member States are protected!

HEALTHCARE, A COMMUNITY COMPETENCE?

While " Europe of health " has never really existed despite numerous advances made through the EMA and very specific legislation responding to the needs of the internal market, can we hope that this global health crisis will be the trigger for action that is already shared by the Commission, the Parliament and some of the Member States? It would appear that "thanks to" Covid-19, European leaders have decided to make health one of the pillars of Community action. So far, the Lisbon Treaty states that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". Thus, the European Union is playing a role in improving health, preventing and managing diseases and harmonising national policies through various programmes that pursue three objectives:

- Promoting good health through disease prevention and the promotion of healthy lifestyles, while taking account of the ageing of the population;
- Protecting citizens against threats, pandemics, bioterrorism, and new health challenges such as climate change;
- Taking into account the mobility of patients and health personnel.

This health policy is a consequence of the free movement of people and goods within the internal market, with proposals based on a high degree of protection. It was following the bovine spongiform encephalopathy (BSE) crisis in the 1990s that consumer protection became a priority. From then on, and despite an unclear legal basis, European health policy was strengthened in several areas: medicines and medical devices, research and mutual assistance between Member States in the event of disasters and serious diseases (swine flu, H1N1 flu, Zika virus). Under pressure from the European Parliament, initiatives have multiplied, whether it is regarding "cancer, AIDS or Alzheimer's plans". *"Similarly, improving patient safety has led to the strengthening of legislation on clinical trials, medical devices and anti-bio resistance."* The H5N1 avian influenza episode of 2005 was decisive for a new approach to pandemics. State preparedness plans were drawn up in conjunction with the Ministries of Defence. It is interesting to reread the "Pandemic Plan" of 2011 to find all the measures recommended to fight against Covid-19 and which already raised the question of health care dependency on China. However, the H1N1 flu, which was less serious than expected, caused a boomerang and led to demobilisation and cuts in health budgets in some Member States, including France. The culture of preparing for a health crisis had thus disappeared and health policies were then built on accounting schemes, considering stocks and reserves as useless fixed assets.

The European Union is already learning the lessons of this crisis and the lessons of its over-dependence on China for health care. In response, it is proposing a plan to combat shortages of strategic stocks, which should be backed by a plan for equitable access to medicines at affordable prices. To support research, it has committed €100 billion in funding, mainly for vaccines, in response to the global challenge of producing a vaccine that is rapidly accessible to all the world's citizens.

Finally, a draft European health plan levelling up health systems will be launched to help Member States to go digital and move more towards prevention. Everything possible must be done to prevent a future pandemic: reinforcing the strategic reserve of medicines, providing for a European emergency medical corps, ensuring full coordination to ensure that solidarity is better enforced. To finance this plan, the European Commission has proposed a health budget of almost €10 billion, not based on a new tax... but on the pooling of investments.

WHAT ARE THE FUTURE DEVELOPMENTS FOR A REAL EUROPEAN HEALTH PROJECT?

Subsidiarity is a fundamental rule of the European Union, which should also apply to the governance of health. It is a political and social principle according to which a central authority can only carry out tasks that cannot be carried out at local level. The European Union must therefore act where there is real added value. For example, combating a pandemic, or legislating on the medicinal products market, must be at European level, since these are challenges that transcend national borders. In this case, we do better together, by pooling our resources and expertise. The European level is then relevant. The European Reference Networks for Rare Diseases are a striking example. But Europe is not meant to be hyper-centralising. It plays a coordinating role, while leaving flexibility to the territories. This means trusting each other and learning to work together.

There must therefore be political will, a form of humility also in the decision-making process, believing that we can be enriched by the vision and practices of others. This is the exercise to which Europe is pushing us. This is why the European Commission has proposed to harmonise, the clinical part of medical technology assessment (MTA) to a certain extent. The aim is to speed up market access for innovative products and to strengthen the evaluation process in all Member States. However, the idea of accepting a binding evaluation raises the problem of trust between States and scepticism regarding the idea of divesting oneself of certain competences.

This health crisis is therefore forcing us to take a new European approach to healthcare policy. First of all, it must be based on strategic health autonomy strengthening our sovereignty in the industrial and digital field so as to reduce Europe's dependence. We must therefore give priority to our research and development (R&D) capacities in the field of vaccines and medicines, while setting up common strategic stocks.

Europe must also be able to speak with one voice to the pharmaceutical industry. To this end, health must be seen as a priority economic sector with a future, a source of jobs and wealth. Accounting approaches alone are no longer a viable option.

The objective is clear: the creation of a genuine Task Force on Health. To achieve this, we must upgrade health careers and make progress in the mutual recognition of diplomas, so that mobility of health professions is more effective and better responds to the need for European solidarity.

Health policy must be carried by all EU policies; this was the message at the press conference held by Angela Merkel and Emmanuel Macron on 18 May. Over and above the Recovery Fund and the totally new financial proposals made by the European Commission and the ECB, a whole new strategy must be put in place to give Europe competences in the field of health: reducing our dependence on the outside world, protecting our businesses, relocating fundamental investments in Europe, reviewing the rules of world trade - that is the immense task awaiting the Commission. It is a boost to

the modernisation of the European economy that will be needed to rebuild our societies. The Commission had, in a premonitory way, entitled its health programme for 2014-2020 "health for growth". The good health of a population is presented as a sine qua non for achieving the basic objectives of prosperity, solidarity and security.

A few days ago, four States, France, Germany, Italy, the Netherlands and Germany announced the creation of an "Inclusive Covid-19 Vaccine Alliance" whose objective is to pool resources to develop a vaccine and guarantee its supply so that all Europeans have equal access to this vaccine.

The opportunities ahead and their implications in the health sector are therefore incalculable. The stakes are compelling. The European legislator must really understand the extent of these changes. They must be approached on a scientific basis with rationality, far from ideology. Policy-makers, like citizens, must be better equipped to strengthen everyone's critical thinking and scientific culture. Let us oppose reason over emotion, and let us not leave the monopoly of indignation to those who pretend to know everything without knowing anything.

Health policy, like European policy in general, needs a direction, a vision and consideration of the long term. This is the price to pay for a Europe of health that will no longer be a dream, but one which will become a reality.

Françoise Grossetête

MEP (1994-2019)

Special Advisor to the Foundation

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