

Towards a European Health Union - in the wake of the Corona crisis

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The current Covid D pandemic raises the question of the role of the European Union (EU) in health protection. Is the current situation the hour of the nation states and does it herald a return to national health protection efforts, or is it a window of opportunity on the way to a European Health Union? And if the latter, what can already be achieved in the existing, albeit confusing, EU regulatory framework and where do progressive changes still need to be made?

The "ideal" pandemic response process.

"After Asian countries reported timely and transparent outbreaks of a virus - which will later be called SARS-Cov-2 (Covid-19) - to the World Health Organization (WHO) under the International Health Regulations (IHR), and the WHO promptly informed its member states accordingly, European health ministers immediately met to decide on a common approach. The focus was, for example, on an agreement regarding the regulation of travel with the affected countries to be able to directly track cases of the disease and, if necessary, the possible activation of the jointly developed pandemic plan. Later, based on the cases reported to the European Center for Disease Control and Prevention (ECDC) by the top health authorities of the Member States, further measures were agreed, such as the activation of the European Registry of Intensive Care Hospital Beds and the 100-day reserve of essential medicines, medical technologies, and personal protective clothing. Thanks to national pandemic plans coordinated in key areas, disease notifications were quickly reported electronically, and measures taken by member states were compared and evaluated. This made it possible to identify disease clusters even across borders and to target them without having to close internal European borders. As more was known about the virus, decisions about containment and tracking measures were delegated to subsequent decision-making levels to address local circumstances. Close cooperation with the U.S. Center for Disease Control and Prevention (CDC) allowed European experiences to be shared with other continents and contribute to global health. Risk communication was carried out with citizens via the European Social Network, established as a European alternative to Twitter and Facebook, which provided information that was automatically and simultaneously available in all EU languages and could be commented on by citizens. Coordinated efforts to develop test diagnostics, compare therapies, and develop vaccines eventually led to the near simultaneous availability of prevention and treatment methods in all member states. The pandemic therefore had a mild course in the EU."

The Covid pandemic could have played out like this, or something similar, if we had taken advantage of what the EU already had in place. So, what prevented us from doing just that?

Europe in its diversity, with its variety of languages, with a European press that is lacking as a result, differences in the level of prosperity, the lack of a common foreign and security policy, an only partially existing monetary union without a fiscal union and with federalism and central governments - all this does not make it easy to form a union that protects and safeguards: health protection and disease treatment are essential pillars of a European Health Union. Citizens are also rightly calling on their nation state to be there for them in times of crisis. Therefore, it was possible for border closures or the short-term export ban on health-related goods to occur in the first place as a politically induced reflex. At the same time, however, the EU usually emerges stronger from a crisis. For example, the ECDC was founded based on the experience of the SARS pandemic of 2002/2003.

Possibilities for action for a European Health Union within the framework of the current Treaty

The Treaty on the Functioning of the EU describes in §168 the Public Health Mandate, which is in principle limited to coordinating and supporting measures of a more preventive health policy. Action defence in case of cross-border health threats is possible, but without any harmonization of the legislation of the member states. Special regulations concern quality and safety standards for organs and substances of human origin, health protection measures in the veterinary and phytosanitary fields, and measures to establish high quality and safety standards for medicinal products and medical devices.

None of this sounds like a broad mandate in health care. In addition, interference in the organization and financing of medical care in the member states is taboo. This does not mean, however, that there should be no concern about the organizational form and performance of the various healthcare systems in the EU. On the contrary, various expert groups are working on the question of how to keep the individual healthcare systems fit for the future. The European Semester, a framework for EU economic governance during which the EU member states coordinate their economic and fiscal policies, also takes healthcare spending into account, as it can account for up to eleven percent of a country's gross domestic product (GDP). This involves making recommendations to the member states about reforms to be introduced, but these are then usually tackled only hesitantly.

It is also true that a high level of health protection should be ensured in the definition and implementation of all Union policies and measures. This makes it possible to intervene in all policy areas in the sense of a "health in all policies" approach. However, this is not a simple procedure, since in the implementation of health-related problems it is often not possible to follow a direct line from A to B, but one must take a detour via other policy areas. In addition, the method of "health impact assessment" can be helpful, as it analyses the effects of generally planned legal regulations on health and the health system. While the impact of new regulations on various areas is already regularly studied, health issues are not systematically integrated.

At the same time, it is important to recognize that the covid pandemic has focused interest on health issues only on health protection from the virus, prevention, and treatment. Other, equally important areas of health and public health remain out of focus. If the virus had occurred due to global warming, measures to control global warming would now be number one on the hit list of political talk shows and interventions.

Focusing EU health policy only on ongoing pandemic control would therefore fall short in the medium term. One must seize this moment to anchor an EU health policy that comprehensively addresses both communicable and non-communicable diseases.

A progressive European health policy can be guided by the following three core areas:

- Health in the Member States (Public Health in Europe)
- European deepening in health (European Integration in Health)
- Global health and Europe (Global Health Europe).

Health in the Member States (Public Health in Europe).

In this area, work has been going on for a long time on a common database with comparable indicators, which then flow into health reports of the EU, the WHO and the Organization for Economic Cooperation and Development (OECD). This comparative assessment of the situation is important to be able to judge where one's own region or country stands in relation to others. It also examines and compares interventions by different member states to identify best practices and recommend them for other member states after reviewing their transferability.

First, there needs to be a willingness on the part of policymakers to take up these analyses. In many analyses, for example, a possible pandemic has been noted for years as a risk with a low probability of occurrence but a high potential for damage. Unfortunately, too much reliance was placed on the "low probability risk".

Among other things, political leadership is also important. In various analyses of "pandemic preparedness", the U.S. and the U.K. held top positions. However, politicians in these countries have made decisions that neutralized these top positions - or, precisely, the assessment of pandemic preparedness was flawed. To prevent this, one can apply the idea of regular stress tests from the banking sector to healthcare systems, which were introduced in the EU after the last financial crisis.

What could also be learned from the last financial crisis through comparative studies is that if you overdo austerity, it can have negative health consequences. However, this is not what we are seeing now, but rather we are realising that by fighting the pandemic, other important health-related measures such as screening, e.g., for cancer, and acute treatments, e.g., for myocardial infarction, are being delayed and creating a treatment backlog that will put additional strain on health systems in the future.

Looking at the development of important health indicators separately for "old" and "new" Member States, we see that they are now running rather in parallel after a phase of convergence. A convergence to close the still existing gap is proceeding rather slowly. Since economic and health developments are mutually dependent in certain areas, the health-related data from German reunification can be helpful in estimating the length of time.

European Deepening in Health (European Integration in Health).

"A child is born with a rare disease in one of the Baltic Countries of the EU. Since the population in this country is small, there is no focal clinic for this disease here. However, since one exists in Madrid, parents, and child travel to Spain after making an appointment. There, they can stay with their child during the evaluation of the findings. Translation

services are available to take the medical history and explain findings, diagnoses and therapy to the child and parents. Initial therapy takes place in Madrid, as high-tech equipment must be used that is not available in the child's home country. After treatment is completed, the child and parents travel back with a doctor's letter translated into their local language. A follow-up examination is conducted via videoconference with translation service, during which an electronic prescription is issued by the Spanish doctor for further drug treatment, which the parents can redeem at their home. The costs of the treatment are settled between the treating hospital in Spain and the parents' health insurance company. Over time, a hospital in our patient's home country has distinguished itself and joined the EU's rare disease network. Since then, the patients' data travel to external consultations rather than the patients themselves."

The facts described above correspond exactly to what a citizen of the EU expects from it: the organization of healthcare services in a European framework. And much of this is already possible now. The directive on cross-border healthcare and the case law of the European Court of Justice have opened many possibilities, including arrangements for reimbursement. Videoconferencing and electronic prescribing are now available across Europe. Focus hospitals see many cases in which they specialize and can therefore offer good diagnostics and therapy. High technology can be better utilized and becomes available for patients from member states that cannot (yet) afford it. Why, then, is this so little used? Only one percent of healthcare expenditure is incurred in cross-border care.

The main reason for this is the slow national implementation of European agreements and the regulation of detailed administrative issues that take a lot of time. European Integration in Health is about those areas where a member state is overburdened and/or where cooperation between different member states brings added value. Everything else should be dealt with at national, regional, or local level according to the principle of subsidiarity.

Europe can already be realized in the existing regulatory framework; you just must really want it. The European agencies are an example of this. They do what each member state would otherwise have to do for itself if the respective member state could do so at all due to its size and resources. Joint research activities make sense if they bring added value, and the EU is not seen by the researchers as just another source of money. European networks, such as the one on rare diseases, create conditions for learning from each other and improving care. Joint evaluation of new health-related technologies avoids duplication of effort and can make them available more quickly. Centralized purchasing of common vaccines allows for better prices and simultaneous availability in all EU countries. In the current Corona pandemic, after some teething problems, Europe has initiated joint research on vaccines and has also jointly secured vaccine doses from developed vaccines. Sometimes, however, what is simply lacking is simplicity: A registry of the availability of intensive care beds and specialized treatment equipment would make it easier to transfer patients when hospitals are overloaded.

Global Health and Europe (Global Health Europe)

How should the EU, with its approximately 450 million people, position itself in relation to other nations and continents on health issues? Here again the "Health in all Policies" approach is helpful. Since smaller EU states hardly have a chance to negotiate on an equal footing, e.g., in trade and investment agreements with large states, the EU was given the

task of taking over these negotiation processes. Health issues can and should play a greater role here. One need only recall the failed Transatlantic Trade and Investment Partnership (TTIP) with the U.S., in which the "chlorinated chicken" was seen, to media effect, as a symbol of a European health risk from chickens treated with chlorinated water. Regardless of this example, for global health development issues, these agreements are important and should be an important component of European health policy in the future. At the same time, other actors such as the OECD, the European Central Bank (ECB), the World Bank, and even the BRICS countries (Brazil, Russia, India, China, South Africa) must also be kept in mind through their influence on the EU economy. Germany, for example, made global health a top priority in its 2015 G7 presidency. A new player has joined in the Regional Comprehensive Economic Partnership (RCEP), a free trade agreement in place since 2020 between ten ASEAN (Association of Southeast Asian Nations) member states and five others in the Asia-Pacific region.

In relation to WHO, IHR are playing an increasing role as some weaknesses have been revealed in the current pandemic. Unfortunately, the willingness to transparently and openly report infectious diseases to WHO is often lacking and independent verification on the ground is almost impossible. Travel restrictions should be distinguished from trade restrictions so as not to disrupt supply chains unnecessarily. There should also be different alert levels for declaring an event of a public health emergency of international concern. In addition to these substantive issues, governance issues of WHO should also be addressed by the EU on behalf of its Member States to ensure reliable policy action.

The Erasmus+ program is known to most of us only as an exchange program, but there is also a "capacity development" area, where e.g., cooperation projects in the field of antimicrobial resistance with countries like India are funded.

European agencies

To support its member states, the EU also maintains agencies in the health sector. The ECDC was already mentioned in the introduction. Information provision and risk assessment of infectious diseases are its main tasks. It also conducts regular training programs whose graduates now hold good positions in regional and national health authorities and speak a "common" language. ECDC's task is not to break chains of infection on the ground. This cannot and should not be its job. It should remain an original task of the local health services, as they know the situation on the ground better. In general, however, the ECDC is too poorly equipped to meet the demands made on it. Furthermore, the mandate of the ECDC is limited to infectious diseases.

In general, i.e., outside of pandemic periods, the disease burden of infectious diseases is much lower than that of non-communicable diseases, but media attention is much higher in the event of an outbreak of an infectious disease. However, since many non-communicable diseases can arise due to infectious diseases, the strict separation of the two types of disease is no longer useful. Furthermore, since there is no European agency that monitors noncommunicable diseases for policy advice, the mandate of ECDC should be expanded. The EU's Joint Research Center (JRC) has recently been pooling data from cancer registries, but this should be one of ECDC's new tasks. The JRC, on the other hand, should be mandated to also investigate the future for health issues with its Institute for Prospective Technological Studies ([PTS) in Seville.

The European Medicines Agency (EMA), in turn, is responsible for the approval and safety of medicines in the EU, thus avoiding the need for each member state to regulate this itself. The decision on reimbursement of medicines remains with the member states. The future development of the EMA depends on the interest and willingness to relinquish competencies, if necessary, to delegate new tasks and to finance these. The discussion about supply shortages of medicines due to the disruption of supply chains from Asia has brought EMA into play to ensure this and to organize stockpiling if necessary. Regardless of the discussion about such supply bottlenecks, a major problem is that for cost reasons the production of e.g., generic drugs have been shifted to Asia. However, the solution of bringing drug production back to Europe is too simplistic. Globalization cannot (and should not) be reversed so easily.

The European Food Safety Authority (EFSA) also came into being because of (food) crises and was set up to analyze, advise and communicate in relation to the food chain. As such, it is part of the "One Health" approach of looking at human and animal health together with the environment. Zoonotic diseases play an important role in antibiotic resistance - now also topical when a covid mutation transmissible to humans emerged in Danish mink.

Given the number of agencies already in place, the question is whether more are needed. Now, a European version of the U.S. Biomedical Research and Development Authority (BARDA) is being discussed, in which pandemic planning and response would be done at the European level. Supporting the member states in the preparation of their national pandemic plans and coordinating the essential contents in a separate institution goes beyond what can be done now at the European working level. However, the question arises whether a new agency would not be in competition with the given institutions. It will not be able to prevent political misconduct in the event of a pandemic. It therefore depends on the concrete design whether "more" will also be "better" in this case.

A new treaty has opportunities and risks for a European Health Union.

Just a year ago, the answer to the question of unraveling the current treaty would have been a resounding "no". In view of Euroscepticism and ideas of returning some competencies to the nation states, the health sector would certainly have been a topic of discussion when it came to the contents of a new treaty. Due to its limited mandates and the rather low political importance of the Directorate General for Health (DG SANTE) in the hierarchy of Directorates General, it would have been an easy victim. Therefore, one should only unravel the contract when one knows that one can win. This moment might have come for health now: A Europe that protects and safeguards in social and health matters is starting to become feasible.

The decisive factor will be the extent to which we can "Europeanize" the EU's health systems. Not in the sense of the feared "egalitarianism and agreement on the lowest standard through harmonization", but through monitoring, consultation, and support on the way to the right health care system in each country - "right" in the sense of adapted to the social, economic, and cultural situation of each country.

The non-re-election of U.S. President Donald Trump and the looming negative consequences of Brexit could also be seen as a turning point in the success of populists who would rather see a weak EU. To what extent the internal EU conflict on the rule of law can be resolved in some member states will help determine this. It is to be hoped that the Commission

presidents will not be seen as a Ms. Chamberlain with a policy of concessions, since in general democracy is also good for health.

Until a possible modification of the treaty, the motto is therefore to muddle through, the current treaty offers enough opportunities now to do something meaningful!