

ESEC PLENARY MEETING - EUROPEAN HEALTH SYSTEM

TUESDAY 12 APRIL 2022

CONTRIBUTION OF THE RAPPORTEURS IN RELATION TO THE POWERPOINT

1- INTRODUCTION

- During the previous term of office, ESEC made recommendations on the vaccination campaign. On that occasion, we pointed out the need for a more coordinated European Health System. Today, this draft opinion on the European Health System draws on the findings of the pandemic but is part of a broader context that we, and Benoit Miribel, will now present to you.

2- CONTEXT

- The EU has no exclusive competence but plays only a supporting role in the field of health, thus demonstrating that it had not been a central theme in the European integration process.
- During the 2008 financial crisis, the EU's austerity and public deficit reduction policies even led Member States to cut back on health spending, leading to underfunding. But in the wake of this global financial crisis, Article 6 of the Treaty on the Functioning of the European Union (TFEU) in 2009 gave the Union the competence to *"take action to support, coordinate or supplement the activities of the Member States, in particular in the field of the protection and improvement of human health"*.
- The European public is divided on the effectiveness of the EU's action during the COVID-19 crisis, not least because it was slow to act in a rapid and concerted manner. But this pandemic has created very high expectations among citizens regarding health. It has now become a priority for ¾ of them and the French Presidency of the European Union (FPEU), the first for 13 years, is a real opportunity.
- Several European ministerial meetings are addressing this issue of a European Health System and it is important that civil society does its bit. It is in this context that we have worked here at ESEC to draw up this opinion in order to make progress in building a European Health System, starting with the actions put in place by the EU during the pandemic.

[1st video clip: Ambassador Stéphanie Seydoux : EU responsiveness and solidarity during the pandemic](#)

3- EU ACTIONS/PANDEMIC (slide 4-Catalina) (2 mm)

In response to the pandemic, a number of actions, which would have been difficult to manage at national level, have been launched at European level: grouped purchases of vaccines, distribution between Member States, digital health pass to preserve free movement.

The European Union has encouraged cooperation and coordination between states through inter-governmental measures provided for in the treaties.

It has also innovated by strengthening the health agencies (we can note in this respect the important role played by the European Medicines Agency (EMA) in examining the results of clinical trials presented by laboratories) or by suspending the stability pact to allow States to support their economies. This led Mrs Kyriakides, European Commissioner for Health and Food Safety, to say that “the package lays the foundations for our Health Union”.

It is therefore by relying on existing legal and institutional tools that the EU has taken a first series of measures:

- From January 2020, activation of the EU Integrated Political Crisis Response (IPCR) has ensured harmonisation at the highest political level and coordination of cross-sectoral actions: health, consular protection, civil protection and economy.
- Mobilisation of the EU Civil Protection Mechanism has allowed 100,000 citizens to return to their homes.
- Tests, PPE and countermeasures were purchased and strategic reserves of medical equipment were hosted by Member States through an Emergency Support Instrument (ESI), with, at the same time, a relaxation of regulations for vital purchases.

However, at the beginning of the health crisis, despite this willingness to coordinate, European citizens noted disparate national strategies between states and strong competition in the purchase of health equipment and products.

In terms of vaccine strategy, the EU has played a positive role in accelerating, developing, manufacturing and deploying vaccines with rapid and fair access between countries, while leading an international solidarity effort.

The results are in. As of 12 January 2021, 80.4% of the European population had been vaccinated (compared to 62% in the USA) despite disparities between Member States not linked to the availability of doses. The EU is now the world’s largest exporter of vaccines: 1.7 billion doses to 150 countries.

4- TACKLING COVID

- From the start of the epidemic, which was declared a global pandemic by the WHO on 11 March 2020, the European level quickly proved to be indispensable in responding to this transnational threat. A number of measures that would have been difficult to manage at national level have indeed been launched at European level. They are the first step towards an EU health system:
 - the creation or strengthening of specialised agencies dedicated to health (the European Health Emergency Preparedness and Response Authority – HERA;
 - the European Centre for Disease Control and Prevention - ECDC;
 - the European Medicines Agency - EMA);
 - the implementation of an enhanced EU4Health programme dedicated to health

These measures and initiatives are all assets for building a European Health System.

- Although the EU only plays a supporting role in the health field, the COVID-19 crisis meant that it was quickly seen as an appropriate level to provide a coordinated response to this pandemic. It prompted Member States to find collective responses through the EU, and there is now a general awareness of the need to go further in the construction of a European Health System, which calls for many challenges to be faced.

5- CHALLENGES

Before a European Health System can be constructed, there are a number of challenges to tackle:

- Political
- Governance
- Inequalities in access to care within the different Member States
- Investment in research
- Industrial capacity
- Data management
- But also public health.

Faced with these challenges, which we have identified, the draft opinion formulates recommendations to overcome them.

6- POLITICAL CHALLENGES

- In the current context, there seems to be general agreement that health should be a real priority on the European agenda but, at the political level, the reality seems more complex. Remember that when the President of the European Commission, a medical doctor by training, presented six priorities for her term of office (2019 - 2024), health was not explicitly mentioned. But in 2021, during her State of the Union address, health was put on the agenda because of the health crisis.
- In response to the pandemic, the EU relied both on what the treaties allowed it to do, i.e. coordination between states and inter-governmental measures, but also innovated by strengthening or creating health agencies or suspending the stability pact to allow states to support their economies.
- However, the EU's scope for action and, above all, for initiative remains limited, as it is always in support of the Member States and in compliance with their responsibilities in this area. Moreover, the "scattering of health competences in the treaties creates a legal fragmentation that does not facilitate the visibility of action, nor the capacity to act".
- Beyond the legal mechanisms, it is important to underline that during the pandemic, the main difficulties observed originated in governance, with a lack of articulation between the national and European levels. In some cases, EU action has been marked by a lack of anticipation and coordination without any real overall logic. There are also questions about a lack of transparency in governance.

- It is regrettable that a single institution or an identified person is not responsible for embodying the European Health System, steering the European strategy and coordinating existing structures. The creation of a political steering committee for health issues at European level could remedy this shortcoming, provided that its governance is transparent and involves all health stakeholders, including all civil society organisations.

[2nd video clip: Christine Colin-Oesterlé: EMA limit \(stocks, budget, etc.\) and HERA limit](#)

7- PUBLIC HEALTH CHALLENGES

In the field of public health, a coordinated approach within the framework of a European Health System would make it possible to meet the major challenges. Beyond the fight against major pandemics, the EU must strengthen its actions in other areas.

For ESEC, the EU health system should be inspired by the integrated and universal vision of health, the sustainable development goals and the One Health principle: a concept that aims to highlight the relationships between human health, animal health and ecosystems and thus to link ecology and human and veterinary medicine.

Article 168 of the Treaty on the Functioning of the EU allows it to act to coordinate Member States' action on prevention.

The EU can put in place actions to address key health determinants related to lifestyle and to economic and environmental factors.

The EU faces a number of public health challenges:

- Mental health, a major concern during the COVID-19 pandemic, which now particularly affects young people (suicide is the 2nd leading cause of death among 15-29 year olds).
- The lack of consideration of gender in the design of public health policies does not allow for the reduction of gender inequalities in exposure to risks and access to care.
- Environmental and social inequalities that exacerbate health inequalities are not sufficiently taken into account.
- Occupational health. The protection of people from health and safety hazards is an essential part of ensuring decent working conditions for the 170 million workers in the EU over the long term, regardless of their status. Although the EU has set up the European Agency for Safety and Health at Work and adopted several directives, for example on the protection of pregnant women and on work-life balance, certain issues have not been sufficiently addressed: arduous working conditions, to which women are particularly exposed, psychosocial risks and the recognition of burn-out.

Europe must therefore set priorities for action on public health.

[3rd and 4th video clips with Julien Vermignon and Gérard Reymond \(France Assos Santé\)](#)

8- RESEARCH CHALLENGES

- Before the pandemic, it should be remembered that the EU had been disengaging for several years from basic research, which is essential because it has a major impact on the innovation process. ESEC had already noted in previous opinions that the EU, and France in particular, is falling behind in research.
- Nevertheless, the commitment made at the Lisbon Council in 2020 was renewed in the Horizon Europe research funding programme, with a budgetary target of 3% of each Member State's GDP.
- Since 2020, a real effort has been made to support R&D in the EU and the topic of health has become more visible in research programmes. The EU4Health programme, presented as one of the EU's responses to the COVID crisis, will invest €5.3 billion in health, and the HERA agency, bestowed with €6 billion over 6 years, includes among its remit support for research and innovation to develop new medical countermeasures, in particular through networks of EU-wide clinical trials, and the stimulation of industrial capacity.
- Beyond the level of budgetary effort to be achieved, particularly in terms of public research, there is also the question of the R&D players to be supported.
- Aspiring to an effective EU health system means facilitating joint research at European level and enhanced cooperation in this field. This point was made at the ESEC hearing by Professors Karin Sipido, Detlev Ganten and many others within the research community. They note that research in the EU is still compartmentalised by country and support the creation of a European body that could synthesise all health-related research. Health research must be conceived in a multidisciplinary way in order to develop real prevention policies and be part of the One Health framework.
- In ESEC's view, in order to consolidate the entire European R&D ecosystem, a European entity should be set up for health research, involving organised civil society and guaranteeing a multidisciplinary approach (networking, large-scale clinical trials, etc.).
- Patent protection is an essential component of a stable regulatory framework for industry and R&D players to reassure industry and investors in the context of pharmaceutical research and to ensure the supply of quality products. The business model of this sector has its own specificities linked to the long research and development processes and the determining role of the European social protection systems.
- While more than half the world's population has received at least one dose of the COVID-19 vaccine, only 8.8% of the African population is vaccinated. The lifting of patents could be one way of facilitating access for non-vaccine producing countries, as health is a global public good.

[5th video clip of Philippe Lamoureux – LEEM](#)

9- INDUSTRIAL CHALLENGES

- The EU is a strategic market for health. Here are some key figures: healthcare represents 10% of the European GDP, 8% of the working population and €190 billion of expenditure
- The top 5 players in the sector account for 22% of the global market and of the 10 major players, only one is European: SANOFI.
- It should also be noted that 80% of active pharmaceutical ingredients and 40% of medicines sold in the EU come from India or China.
- The COVID-19 crisis has highlighted both the EU's dependence on health products, particularly from Asian countries, and its supply problems.
- To address the shortages that were exacerbated during the pandemic, the EMA's mandate was expanded to enable it to collect data more efficiently and to have a better view of the status of stocks. However, this mechanism only applies in the event of a health emergency, and drug shortages do not only occur in this context.
- ESEC believes that more needs to be done to avoid shortages. It is also necessary to strengthen the European industrial fabric and supply chains for health goods via a system of direct aid to relocate part of the production or to help local players of sufficient size emerge. This aid could be part of the Important Project of Common European Interest (IPCEI) on health, which provides for significant funding compatible with the European state aid regime.
- France thus wishes to advance its IPCEI project intended to support the development of innovations in health, the aim of which is to strengthen the European Union's health sovereignty by relocating, for example, the production of certain strategic active ingredients that are currently produced mainly in Asia.
- ESEC proposes recommendations to meet these industrial challenges, which we are going to cover in the second part of our presentation.

10- DIGITAL CHALLENGES

- During the COVID-19 crisis, the lack of interoperability in the transmission of information and difficulties in sharing data at European level complicated the monitoring and surveillance of the pandemic. Furthermore, the implementation of an interconnected system giving access to comparable and interoperable health data across the EU would be a real multiplier for research.
- The aim is to improve the exchange of and access to health data, both for the provision of health care (primary use of data) and to support research and health policy development (secondary use of data). The development of remote medicine must also be accelerated.
- The EU faces many challenges, not least the challenge of ensuring strategic sovereignty in data hosting and management in the face of digital giants. As ESEC already recommended in its opinion on the Economy and Governance of Data, the European Union must speed up the investment needed for a sovereign European cloud, which is a prerequisite for its technological independence.

- During his hearing, the Chairman of FEFIS, Olivier Bogillot, reiterated the importance of a European health data hub for scientific research purposes. Indeed, to develop a new drug, it is essential to have a substantial database and significant computing capacity, either autonomous or shared.
- European Health and Digital Executive Agency (HaDEA), which oversees the deployment of the EU4Health programme.

11- 5 CHALLENGES AND 17 RECOMMENDATIONS

12- POLITICAL RECOMMENDATIONS

- The European Health System must be developed around a common model and in this respect, although the 27 Member States each have their own health system, they share values and principles which can serve as a matrix. Willingness to commit to the UN Sustainable Development Goals (SDGs), the One Health concept, and health as a common good are all coherent foundations for promoting a European health model.
- Here are 4 points extracted from the recommendations in relation to the political challenges (reading of extracts displayed on the screen).
- We recommend that maximum use be made of all the opportunities offered by the treaties. The Treaty on European Union (TEU) thus allows “Member States which [so] wish to establish enhanced cooperation between themselves within the framework of the Union’s non-exclusive competences” (Article 20 TEU). This procedure can be used if at least 9 EU Member States volunteer for this cooperation, thus creating a real knock-on effect on the other States. This type of enhanced cooperation would allow both concrete actions and a first step towards a consolidated EU health system.
- ESEC therefore believes that the EU must define its international health priorities, which will then enable it to adopt positions that reflect the will of its Member States. To launch this initiative, the EU could take as a basis the Council Conclusions on the EU role in Global Health, which were drawn up in 2010. This document was indeed an outline of the EU’s international role.

[6th video clip: Joël Destom ESEC: involving civil society](#)

13- PUBLIC HEALTH RECOMMENDATIONS

By 2030, 25% of the European population will be over 60 years old, the dependency ratio will almost double by then. Two million people die each year from cardiovascular disease and 5% suffer from diabetes.

Mental health has become a major concern. In line with the Mental Health Action Plan 2013-2020, this issue should become a major focus of future EU health policy and should be integrated into prevention policies.

It should be remembered that women are particularly exposed to certain diseases, including chronic diseases, and to the deterioration of their mental health, which was exacerbated during the pandemic.

It is therefore essential to take gender into account when designing public prevention policies.

ESEC believes that a coordinated approach within the framework of an EU health system would address the major public health challenges.

Recommendation 4 therefore proposes:

- “that the public health prevention policy becomes a priority and that it is broken down into thematic action plans (cardiovascular diseases, mental health, cancers, infectious diseases) led by the European Commissioner for Health and Food Safety. In each of the areas identified, ESEC recommends that prevention policy take into account the gender dimension of access to health. Lack of awareness of certain diseases among women remains a major cause of poor and/or late treatment of women affected by these diseases”.

In the field of occupational health, the EU has developed rules introducing minimum rights on working conditions, but without developing an ad hoc directive. ESEC is calling on France to make this a priority during the FPEU. The European Parliament has adopted a resolution on a new strategic framework for occupational health and safety. This aims at better protection against exposure to harmful substances, stress at work and musculoskeletal disorders. This resolution invites “the Commission to propose, in consultation with the social partners, a directive on psychosocial risks and well-being at work”.

A request that the opinion supports in its recommendation 5.

Finally, it should be noted that a European Labour Authority should be operational by 2023, in its recommendation 6.

“ESEC recommends that the future European Labour Authority be mandated from 2023 onwards to ensure that occupational health issues are integrated into the relevant European public policies.”

[7th and 8th video clips from Benjamin Roche and Amandine Gautier](#)

14- RESEARCH RECOMMENDATIONS

- Taking into account the analysis in the report on the challenges related to Research, here are 2 extracts from the recommendations (oral reading).
- The issue of patent removal alone cannot solve everything. The transfer of technology and production capacity are indeed essential and must be at the centre of the debate, as we heard from Dr Sall of the Pasteur Institute in Dakar.

[9th video clip Amadou Sall](#)

15- INDUSTRIAL RECOMMENDATIONS

As we have seen, the health market is a strategic market for the EU. The pandemic has highlighted the need to secure our health product supplies and make this a priority. This implies moving towards joint management of stocks to reduce the shortages we have been facing since 2010.

The European Commission, in its pharmaceutical strategy, has focused on ways to strengthen the industrial fabric and supply chains for health goods. ESEC believes that these ideas are relevant, but that it is necessary to go further and restore greater autonomy to the EU in this strategic sector.

The weight of this sector must be strengthened by encouraging a partial relocation of production to European soil, including VSEs/SMEs.

In order to strengthen the EU's health sovereignty, the draft opinion proposes the following:

“Based on the important projects of common European interest (IPCEIs), ESEC recommends promoting the relocation to European soil of the production of health protection equipment and certain medicines of major therapeutic interest. The list of these products must be regularly updated in consultation with the health professionals and associations concerned and validated by the European Parliament”.

16- DIGITAL RECOMMENDATIONS

- Taking into account the analysis in the report on the challenges related to digital and data management, here are 2 extracts from the recommendations (oral reading).
- The aim is to respond to this expectation with a Europe that can provide “more and better”, in particular by providing health security and a framework conducive to the development of everyday good health.
- While health has not been a central theme in the process of European integration as it is still only a supporting competence, it must now become the basis for a new impetus for Europe.

17- CONCLUSION

In conclusion, the opinion promotes an inclusive European global health model based on the values of solidarity and territorial social inclusion, drawing on the expectations of European citizens and involving organised civil society.

To achieve this, ESEC recommends strengthening the health element of European social rights to produce a health roadmap that can then be translated into directives to bring about convergence of health situations in the Member States.

The EU should define its international health priorities, building on the Council Conclusions on the EU role in Global Health developed in 2010, which outline the EU's role internationally.

We would like to thank President Cambou, who organised the debates in a calm atmosphere that respected the positions of all parties, as well as all the members of the Commission for their valuable contributions, without which this opinion would not have been possible, and the people who agreed to be heard or interviewed and whose expertise was invaluable to us. Finally, thanks to Jean-Baptiste, Marion and Catherine for their availability and efficiency, without whom nothing would have been possible.