OPINION

ECONOMIC, SOCIAL AND ENVIRONMENTAL COUNCIL

How can we build a Europe of Health?

April 2022

2022-06
NOR: CESL1100006X
Tuesday 12 April 2022

OFFICIAL JOURNAL OF THE FRENCH REPUBLIC

2021-2026 Term – Meeting of 12 April 2022

HOW CAN WE BUILD A EUROPE OF HEALTH?

Opinion of the Economic, Social and Environmental Council on the proposal of the **permanent committee on European and International**

Affairs RAPPORTEURS: BENOÎT MIRIBEL AND CATHERINE PAJARES Y SANCHEZ

Question referred to the Economic, Social and Environmental Council by decision of its office of 30 November 2021 pursuant to article 3 of order no. 58-1360 of 29 December 1958, as amended, on the Organic Law on the Economic, Social and Environmental Council. The office entrusted the permanent committee on European and International Affairs with preparing an opinion on *How can we build a Europe of Health?* The permanent committee on European and International Affairs, chaired by Mr Serge Cambou, appointed Mr Benoît Miribel and Ms Catherine Pajares y Sanchez as rapporteurs.

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SUMMARY OF THE OPINION

Health has become a priority in Europe in the wake of the Covid-19 crisis. It has created very high expectations with regard to the European Union (EU). However, the latter has only a supporting function in this area.

The construction of a Europe of Health is therefore a very ambitious project that could relaunch the construction of Europe. To achieve this, there are numerous political, governance, inequality of access to care within different states, research investment, industrial capacity, data management and public health issues to be addressed. In the long run, the EU is well placed to offer its own health model. This could be based on its values and on the integrated "One world, one health" approach to global health. It should be based on multidisciplinary research and on a health democracy open to the international community.

The various measures taken due to the Covid-19 crisis are the first step towards an EU of Health: the creation or strengthening of specialised agencies dedicated to health (the European Health Emergency Preparedness and Response Authority – HERA; the European Centre for Disease Prevention and Control – ECDC; the European Medicines Agency – EMA) and the implementation of a strengthened *EU4Health* programme dedicated to health are all assets for building a Europe of Health. The very strong engagement of civil society during the health crisis must also be taken into account, in order to benefit from its know-how and feedback in building this EU of Health.

This opinion contains 17 recommendations which aim to meet the five major challenges to build an EU of Health: the political, research, industrial, digital and health data challenges of public health. The following recommendations can be highlighted from among the CESE's recommendations.

- **4 recommendations related to political challenges**

Recommendation 1: Propose to all the Economic and Social Committees (ESCs) of the European Union and to the European ESC that they give priority to the issue of a Europe for Health with national and European political bodies.

Recommendation 2: Intensify enhanced cooperation procedures between Member States (e.g. cross-border cooperation, health prevention policy).

Recommendation 13: Develop a health democracy in the EU (to ensure better representation of citizens and organised civil society in the governance system of European health agencies).

Recommendation 16: Define a European health strategy that will strengthen Europe's voice on the international stage.

- **3 recommendations related to public health challenges**

Recommendation 4: Make public health prevention policy a priority and decline it into thematic action plans (cardiovascular diseases, mental health, cancers, infectious diseases, etc.) led by the European Commissioner for Food Health and Safety.

Recommendation 5: Support the resolution voted on by the European Parliament on 10 March 2022 regarding a new EU strategic framework for health and safety at work after 2020, which calls on the European Commission, in consultation with the social partners, to propose a directive on psychosocial risks and well-being at work.

Recommendation 12: Build a common European health model based on the EU's values of solidarity and social and territorial cohesion, its international commitments (Sustainable Development Goals) and integrating interactions with animal health and the environment.

- **2 recommendations related to research challenges**

Recommendation 7: Application by the European Commission of Regulation No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on the granting of compulsory licences for patents for the manufacture of pharmaceutical products intended for export to countries experiencing public health problems and providing third countries with capacity to manufacture and administer vaccines.

Recommendation 8: Assess the European Health Emergency Response and Preparedness Authority (HERA) by 2025, under the control of Parliament and in association with civil society organisations.

- **1 recommendation related to industrial challenges**

Recommendation 10: Foster the relocation to European soil of the production of health protection equipment and certain medicines of major therapeutic interest, relying in particular on Important Projects of Common European Interest (IPCEI).

- **2 recommendations related to digital and health data challenges**

Recommendation 9: Establish a common database at European level, under the responsibility of the European Medicines Agency (EMA), in order to have an accurate real-time view of the state of stocks thanks to an early warning system in the event of insufficient stocks or strains on supply chains and based on a list of medicines of major therapeutic interest.

Recommendation 11: Ensure that health data have highest levels of security by hosting them in Europe and comply with EU regulations on the protection of personal data.

OPINION[1]

Introduction

The Covid-19 crisis has created very high expectations among the general public regarding health. The European Union (EU), which only has supporting competence in this area[2], was quickly seen as being at an appropriate level to provide a coordinated response to this pandemic.

The political moment represented by this social, economic and health crisis is the right time to respond to their aspirations, and the French Presidency of the EU (FPEU) must make health a priority. The aim is to respond to citizens' expectations for *"more and better from Europe"* and to show them that Europe can be effective and provide them with health security and well-being in their daily lives.

Today, 74% of Europeans want the EU to acquire more competence to deal with health crises, including future pandemics[3]. At the Conference on the Future of Europe, the citizens' panels gathered at the event clearly stated their wishes[4]: more harmonisation, cooperation and integration at a European level, increased investment in health research, answers to the issue of ageing populations, more prevention, for example with the right to a balanced environment that respects health, etc. However, at the same time, just 48% of Europeans feel satisfied with the EU's action during the pandemic[5], especially because it was slow to act in a rapid and concerted manner.

This recognition of the need for a stronger EU of Health, which seems unquestionable today, was not self-evident before this epidemic. Indeed, after the 2008 financial crisis, austerity and deficit reduction policies in the EU led central governments to cut back on health spending, leading to underfunding. This had dramatic consequences on the health systems of some countries, such as Greece[6]. In 2019, during the renewal of the European Commission, there were even suggestions at one time to discontinue the post of European Commissioner for Health and Food Safety and the Directorate General dedicated to this theme[7].

Building an EU of Health today is therefore an ambitious project – spanning economic[8], social and environmental matters – that is capable of relaunching European construction.

1 **The opinion as a whole was adopted by 145 votes for and 24 against (See Vote page).**
2 Article 168 of the Treaty on the Functioning of the European Union.
3 The European Parliament's *Eurobarometer* , June 2021.
4 Third Interim Report, November 2021, *Multilingual Digital Platform of the Conference on the Future of Europe*.
5 Same source.
6 *The impact of the financial crisis and austerity measures on the health status of Greeks and the healthcare system in Greece*, Charalampos Economou, Revue française des affaires sociales, 2015.
7 *The European Union could do without its Health Commissioner*, *Le Soir* newspaper, 9 May 2019.
8 Health expenditure represents 10% of global GDP, source: Toute l'Europe.

This project is not limited to the fight against epidemics, although this objective is entirely legitimate in itself. It aims to meet the needs of populations: access to a quality healthcare system for all citizens, development of prevention policies, access to cross-border care and freedom of movement for professionals and patients.

To build this EU of Health, it will first of all be necessary to take up numerous challenges in politics, governance, inequalities in access to care within the various States, investment in research, industrial capacities, data management and also public health. In the long run, the EU is well placed to offer its own health model. This can be based on its values and on the "One Health"[9] integrated approach to foster global health. It will be based on multidisciplinary research, including on the exposome[10], and on a health democracy open to the international community.

The various measures taken due to the Covid-19 crisis are the first step towards an EU of Health: the creation or strengthening of specialised agencies dedicated to health (the European Health Emergency Preparedness and Response Authority – HERA; the European Centre for Disease Prevention and Control – ECDC; the European Medicines Agency – EMA) and the implementation of a strengthened *EU4Health* programme dedicated to health are all assets for building a Europe of Health. It will also be necessary to take into account the very strong mobilisation of civil society (NGOs, associations, healthcare professionals, businesses, trade unions, civil protection, frontline and second line workers, etc.) during the pandemic, in order to benefit from its know-how and feedback to build this EU of Health.

In light of the lessons to be learned from the management of the Covid-19 pandemic, the high expectations of our fellow citizens with regard to European health and the start of the FPEU, the CESE wanted to address this matter in order to issue recommendations on the actions that could form the basis of a Europe of Health.

9 The "One Health" concept aims to highlight the relationships between human health, animal health and ecosystems and to link ecology with human and veterinary medicine.

10 The exposome concept was born out of the need to better understand the influence on health from all of the exposures to which an individual is subjected throughout their life, taking into account environmental exposures to chemical, physical and biological agents and socioeconomic factors, a definition produced by work by the French National Agency for Health, Food, Environment and Occupational Safety (ANSES).

I - LIMITED EU COMPETENCE IN HEALTH BUT STRENGTHENED DUE TO THE COVID-19 CRISIS

A. Limited EU competence in health

1. A slow assertion of health competence

Rather than exclusive competence, the EU has supporting competence in the field of health. Indeed, health has not been a central theme in the European integration process. The French National Assembly even refers to it as a *"peripheral aspect of European construction"*[11]. However, over the course of European history, the EU's health competences have gradually been strengthened.

One example is the French attempt in 1952 to create a European Community of Health (ECH), but at the time many governments were opposed to any transfer of sovereignty, saying that this area of intervention was *"essential to the legitimacy of governments"*[12]. Indeed, they are considered to be the main bodies accountable to citizens for the implementation of public health policies.

Similarly, the founding European treaties, in particular the 1957 Treaty of Rome, made no mention of health. However, the latter did mention limiting the free movement of workers or goods for public policy, public safety and public health reasons, thereby recognising the importance of health conditions for the proper functioning of a common market[13].

However, it was not until the Maastricht Treaty of 1992 (following the contaminated blood affair) that it was recognised, albeit in a limited and conditional way ("if necessary"), that *"The Community shall ensure a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lend support to their action"*[14].

With the Amsterdam Treaty of 1997, the EU also obtained competences, although they were still restricted and in support of Member States in the veterinary and phytosanitary fields[15].

Lastly, more recently the EU Charter of Fundamental Rights (2009) established health as a fundamental right for all EU citizens. It recognises that *"everyone has the right of access to preventive health care"* and *"a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"* (article 35 of the charter).

11 French National Assembly information report on the coordination by the European Union of national measures to manage the pandemic, 7 July 2021.
12 *The European Health Community*, Alban Davesne and Sébastien Guigner, L'Harmattan, 2013.
13 Information Report by the French Senate on the European Union and Health, 16 July 2020.
14 Title X: *Public health* and Article 129 of the Maastricht Treaty.
15 Article 152: *"Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and disease"*.

2. The EU's current prerogatives: a supporting competence while respecting Member States' responsibilities

In 2009, the Treaty on the Functioning of the European Union (TFEU) clarified the EU's current supporting competence in the field of health. As such, the Union has the competence to *"carry out actions to support, coordinate or supplement the activities of the Member States [... in particular in the field of] the protection and improvement of human health"* (Article 6(a) of the TFEU).

In substance, the objectives are ambitious, as the EU must, in defining and implementing all of its policies and actions, ensure a *"high level of human health protection"* (Article 168-1 TFEU), thereby coming closer to the concept of *"One Health"*, which promotes an integrated, systemic and unified approach to public, animal and environmental health.

The areas of action in which the EU can act are also varied and Article 168 of the TFEU lists them:

- the improvement of public health and the prevention of human illness and diseases, and of sources of danger to physical and mental health;
- the fight against major diseases, by promoting research into their causes, transmission and prevention, as well as information;
- health education;
- monitoring serious cross-border health threats, alerting in the event of such threats and combating them;
- reducing the harmful effects of drugs on health, including through information and prevention.

Despite this broad list and extensive areas of competence, the EU's scope for action and, above all, initiative is limited, as it is always in support of States and in compliance with their responsibilities in this area. Moreover, the *"scattering of EU health competences in the treaties creates a legal fragmentation of the Europe of Health"*, which does not facilitate the visibility of its action or its ability to act[16].

16 French National Assembly information report on the coordination by the European Union of national measures to manage the pandemic, 7 July 2021.

3. EU principles and regulations have created an environment favourable for the development of an EU of Health

In practice, the health dimension of the European Union has mainly developed in support of the key elements of European integration, namely the internal market and the single currency. The EU's main operating principles have therefore created a framework conducive to the existence and development of health measures.

Firstly, the principle of the free movement of goods and people has implications for health. As such, health products are considered as goods and the free movement of goods regime is applicable to them. However, in view of the specific nature of this type of product, the EU has put in place specific legislation requiring the verification of the quality of products through marketing authorisations as a condition for their free circulation[17] [18].

The EU also recognises the freedom of establishment and the freedom to provide services (Articles 23 and 56 TFEU). In the field of health, the principle of the "free movement of professionals and the mutual recognition of qualifications" is therefore established. In the EU, diplomas, certificates and other evidence of professional qualifications as issued in the different Member States should be mutually recognised and any national provisions governing access to the different professions should be coordinated and harmonised[19].

However, this harmonisation work is currently an unresolved issue, as the agreements reached within the EU concern the validation of minimum competences, whereas a reflection on the content of training courses, their duration and their recognition should be carried out. This also has impacts on the mobility of health students, and therefore on this free movement retrospectively[20].

As the National Association of Medical Students of France (ANEMF) reminds us, *"the harmonisation of medical skills is necessary to encourage mobility"*[21], and thereby implement this desire for a Europe of Health.

In application of this principle, we can cite, for example, in the field of health, Directive 2005/36/EC of 7 September 2005, which guarantees *"persons having acquired their professional qualifications in a Member State to have access to the same profession and pursue it in another*

17 Regulation No. 2017/745 of 5 April 2017 on medical devices, which aims to ensure the proper functioning of the internal market for medical devices, based on a high level of health protection for patients and users.

18 Regulation 726/2004 of 31 March 2004 lays down EU procedures for the authorisation and supervision of medicinal products for human and veterinary use, and establishing a European Medicines Agency.

19 https://www.europarl.europa.eu/ftu/pdf/fr/FTU_2.1.6.pdf.

20 Just 6,200 French students in medical or paramedical training stayed abroad for a period between 2014 and 2020: Sorbonne Appeal, 15 December 2021.

21 https://www.letudiant.fr/educpros/actualite/appel-de-la-sorbonne-la-necessite-de-construire-une-europe-de-la-sante-pour-les-universites.html.

Member State with the same rights as nationals". In practice, however, this mutual recognition of qualifications is complex and many diplomas or health professions recognised in some countries are not recognised in others. Indeed, most of the recognition of the equivalence of diplomas takes place sector by sector, which is very tedious[22]. It is therefore necessary to speed up the process. In addition, the large number of doctors from the East of the EU coming to practise in the West destabilises the healthcare system of these States. As such, Romania lost more than 50% of its doctors between 2009 and 2015[23]. This highlights the imbalances within EU Member States between the doctor training effort and the needs of populations.

Similarly, the principle of the "free movement of patients" is based on the principle of freedom of movement within the EU. Although a framework has been established for the system of cross-border care[24], in practice the advance payment of medical costs can be seen as a major obstacle to patient mobility[25].

4. Health actions already implemented in support of States

Rather than being limited to crisis management, the EU's action also promotes common public health objectives[26]. The EU is therefore carrying out promotion (sport, a diet rich in fruit and vegetables, etc.), screening (cancer or HIV/AIDS, etc.) and prevention (combating smoking, alcohol and drug consumption) actions. In February 2020, the European Commission unveiled its anti-cancer plan (budget of €4 billion). The EU also ensures affordable access to safe and effective medicines[27]. In November 2020, it adopted a pharmaceutical strategy for Europe to create a regulatory framework and help industry promote research and technologies for patients to meet their therapeutic needs while addressing market failures[28].

It should also be noted that in the French outermost regions (ORs), the EU intervenes both by financing health structures through European

22 Fact sheet on the European Union, *The mutual recognition of diplomas* https://www.europarl.europa.eu/factsheets/fr/sheet/42/la-reconnaissance-mutuelle-des-diplomes.

23 *Le passage West of Eastern European doctors*, Libération, 14 September 2020.

24 As such, Directive 2011/24/EU of 9 March 2011 specifies the application of patients' rights in cross-border healthcare and aims to ensure patient mobility and the free provision of health services.

25 Thesis *The free movement of patients in the European Union: room for improvement in the legal framework*, Anne-Laure Philouze, IEP Strasbourg, June 2015.

26 The functioning of the Europe of Health https://www.touteleurope.eu/fonctionnement-de-l-ue/le-fonctionnement-de-l-europe-de-la-sante.

27 Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

28 However, in France's outermost regions, drug price issues are further exacerbating inequalities and can have serious consequences on an already worrying health situation. Indeed, the price of medicines is set by applying geographical mark-up coefficients, which results in a higher cost than in France.
For these territories, the issue concerns the pricing of medicines, as without ensuring the necessary price regulation, there is a risk of increasing health divides and discrimination in access to care.

funds and by mobilising funds to support international cooperation in the event of an epidemic in regional areas. Although insufficient, one example is the REMPART anti-vector project (Réseau d'Expertise et Mobilisation PARTicipatif), which combines regional technical expertise with the implementation of actions at an EU level.

The EU, which also has regulatory powers (Article 168(4) of the TFEU), particularly in the field of *"measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health"*, therefore has a role in harmonising national health policies. Examples include national tobacco regulations that are based on European standards limiting tar content and mandating prevention messages on cigarette packs. The REACH regulation is a major example of the traceability and control of CMR products[29].

A. Responses to the Covid-19 crisis: the beginnings of an EU of Health?

From the start of the epidemic, which was declared a global pandemic by the WHO on 11 March 2020, the European level quickly proved essential in responding to this transnational threat. A number of initiatives that would have been difficult to manage at a national level were launched at the European level, such as grouped purchases of vaccines and their distribution, the development of electronic health passes to preserve free movement within the EU, etc.

The EU relied on what the treaties allowed it to do, i.e. coordination between central governments and inter-governmental measures, but also innovated by strengthening or creating health agencies or by suspending the stability pact to allow central governments to support their economies. Stella Kyriakides, European Commissioner for Health and Food Safety, says that *"the package of measures implemented during the crisis lays the foundations for a health union"*[30].

1. Health measures

Building on existing legal and institutional tools, the EU has taken a first set of measures in the health field.

29 CMR products are substances that are carcinogenic, mutagenic and toxic to reproduction, CESE opinion, *REACH and chemical risk management: a positive assessment, a tool to be improved,* January 2020. https://www.lecese.fr/travaux-publies/reach-et-la-maitrise-du-risque-chimique-un-bilan-positif-un-outil-ameliorer.

30 Speech by Ms Stella Kyriakides, European Commissioner for Health and Food Safety, at the Sciences Po symposium "Towards a European Health Union", 12 January 2021.

Policy measures based on the implementation of existing legal tools

On 28 January 2020, the EU's Integrated Political Crisis Response (IPCR) mechanism in "information sharing" mode was activated, enabling the EU to ensure harmonisation at the highest political level and coordinate cross-sectoral actions (health, consular protection, civil protection, economy).

The EU also mobilised the EU Civil Protection Mechanism[31], which enabled more than 100,000 citizens to return to their homes.

Movement restrictions: disparate national measures in the absence of a European strategy

EU governments also reached an agreement to strengthen external borders by applying a coordinated temporary restriction on non-essential travel to the EU from March 2020. As such, Europe temporarily abandoned the abolition of internal border controls, the founding principle of the Schengen area. However, at a national level, central governments made haphazard arrangements with varying degrees of restrictions on population movements[32]. Moreover, in the absence of a common health strategy at the beginning of the crisis, the EU was split in two: on the one hand, those that supported the herd immunity strategy, such as Sweden and the Netherlands, and, on the other, those that tried to halt the circulation of the virus, including France and Germany.

Equipment procurement: between coordination and disparate national measures within a dependent EU

Measures were also taken in the area of common equipment. An Emergency Support Instrument (ESI) was used to procure tests, countermeasures and strategic stockpiles of medical equipment that were hosted by Member States. However, despite this desire for coordination by Europe and the lack of a strong EU of Health, this did not prevent fierce competition between European States, particularly at the start of the pandemic. Some analysts even described it as a "Wild West" or "jungle[33]".

For example, it can be pointed out that Member States and the EU lacked coordination in the procurement of healthcare equipment and products, and *"representatives of medical equipment manufacturers received French and European tenders for the same orders with different requirements"*[34].

To be reactive, the EU has nevertheless considerably relaxed the regulations on vital purchases, medical equipment and medicines at the risk of being suspected of favouritism and corruption due to public orders without prior calls for tenders, through direct-agreement procedures.

31 The Civil Protection Mechanism enables the EU to provide a coordinated response to natural and man-made disasters.

32 While the European Commission can issue recommendations on this issue, these are not binding and it is up to Member States to decide whether or not to implement them.

33 *Covid-19: how the European medical equipment market became a "Wild West"*, France Culture, 6 April 2020.

34 French National Assembly report, cited above.

In addition to these procedural problems, this crisis has above all highlighted the EU's dependence on South-East Asian countries, in particular for many healthcare products, as well as the disappearance of a European health industry.

Vaccination strategy and digital Covid certificate: the EU's positive role

On 17 June 2020, the EU vaccination strategy was approved by all Member States. The aim was to accelerate *"the development, manufacture and rollout of vaccines; to ensure their quality, safety and efficacy; and to ensure rapid and equitable access for all Member States and their populations while leading the global solidarity effort"*. The European Commission, mandated to do this, contracted with seven companies[35] to provide a total of up to 406 billion doses. These advance purchase agreements have allowed the EU to be supplied quickly and to generate economies of scale and lower costs.

As the French National Assembly recalls, however, the EU was criticised when it emerged that the US, the UK and Israel had concluded their negotiations in the spring of 2020, whereas the EU finished negotiations in November. The rollout of the vaccine campaign also encountered logistical problems, which indicate the need for increased European cooperation. Lastly, unlike the UK, the EU does not have an emergency procedure for the market launch of vaccines, meaning that the EMA had to resort to a longer authorisation procedure[36]. The lack of transparency regarding contracts was also highlighted by MEPs, who only had access to partial contracts and some of the information had been concealed[37].

However, the EU has now become the world's largest exporter of vaccines (1.7 billion doses to 150 countries[38]) and at least 500 million doses will be donated to the least developed countries. This solidarity policy is to the EU's credit. By way of comparison, the US has been much less supportive in this area.

The overall outcome of the campaign is positive, with the EU having the highest vaccination rate in the world: 80.4% of the population was fully vaccinated as of 12 January 2021[39] compared to 62% in the US on the same date[40]. Within the EU, however, there is a disparity in this rate between the countries of Eastern Europe, which are much less vaccinated, and those in Western Europe, where the percentage of injections for the second dose is 79.5% in the West compared with 43% in the East.

35 These seven companies are BioNTech and Pfizer, Moderna, CureVac, AstraZeneca, Johnson&Johnson, Sanofi-GSK and Novavax.
36 French National Assembly report, cited above.
37 Hearing at the CESE on 11 January 2022 of Ms Colin-Oesterlé, MEP.
38 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_fr#exportations-de-vaccins.
39 Source: vaccine manufacturers and ECDC data.
40 Source: Johns Hopkins University (JHU).

This vaccination policy was accompanied by the introduction of the digital Covid certificate, which has become a model for third countries. It came into force on 1 July 2021 and was intended to facilitate free movement within the EU. By 18 October 2021, the Commission announced that 591 million digital Covid certificates had been generated in the EU, 45 countries were connected to the EU system and 60 third countries were interested in joining the system[41].

2. The legislative package: institutional measures to respond to Covid-19 and plan ahead for future crises

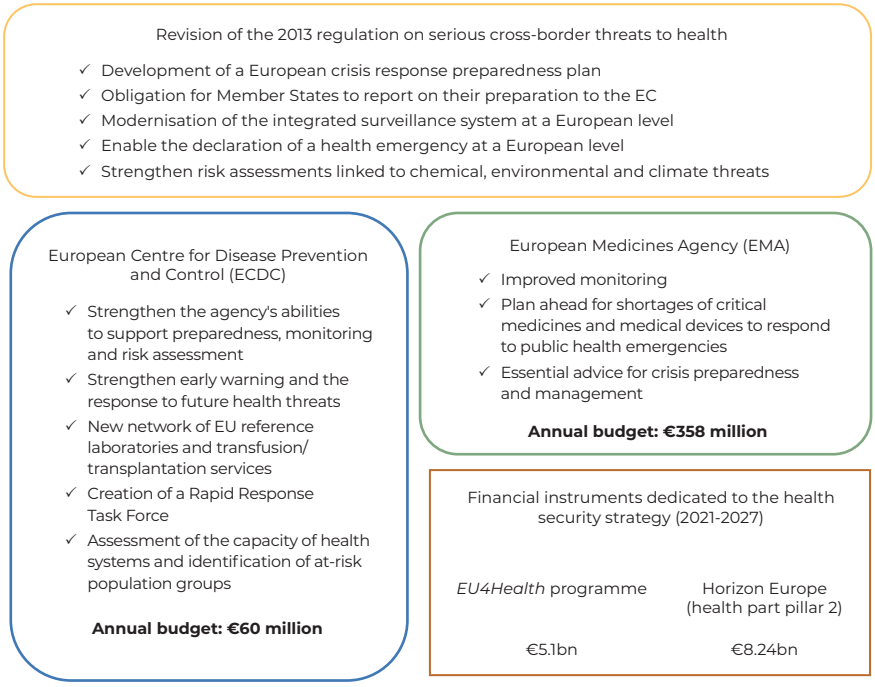
At the beginning of the crisis, the Commission was criticised for not having been proactive enough and for not sufficiently taking into account previous pandemics. The European Commission, supported on this issue by France, then presented several major proposals in November 2020, aiming to consolidate the Europe of Health through measures to prepare for and react to pandemics. For example, it proposed[42] three draft regulations in the so-called health security legislative package. These texts were in the final stages of adoption in the first quarter of 2022[43].

41 CESE hearing of Ms Ruiz from the European Commission's representation in France.

42 Communication *Building a European Health Union: strengthening EU resilience to cross-border health threats* of 11 November 2020, (COM/2020/724 final).

43 The proposal for a regulation on serious cross-border threats was approved by the Council on 23 July 2021 and is awaiting the Parliament's position in the first reading / The proposal for a regulation of the European Parliament and of the Council of 11 November 2020 amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control was provisionally agreed between the Parliament and the Council on 29 November 2021. The regulation must now be formally adopted by the Council and the Parliament/ The proposal for a regulation of the European Parliament and of the Council of 11 November 2020 on a strengthened role for the European Medicines Agency was provisionally agreed between the Parliament and the Council on 28 October 2021. An agreement must now be approved by both institutions before the formal adoption procedure can be launched.

Presentation 1: Legislative package and financial instruments of the EU health security strategy



Source: French Ministry for Solidarity and Health and CESE

The first proposal is an upgrade of Decision 1082/2013/EU on serious cross-border threats to health. Its aim is to strengthen the EU's preparedness for health crises and pandemics, enhance surveillance using artificial intelligence and other advanced technologies, and improve data communication. Member States will have to provide indicators on their health systems to better manage crises: availability of hospital beds, capacity for specialised treatment and intensive care, identification of medically trained staff.

The second proposal is to strengthen the mandate of the European Centre for Disease Prevention and Control (ECDC) to consolidate the Union's defences against infectious diseases. It was set up in 2005 in response to the SARS outbreak and its role is to identify and assess the threat posed by these diseases. The European Parliament and the Council reached a political agreement on this proposal on 29 November 2021. The ECDC's revised mandate will enable the agency to more actively support the EU and its Member States in preparedness, surveillance, risk assessment, early warning and the establishment of laboratory networks to monitor alerts.

The ECDC's effectiveness has been limited until now due to its limited budgetary resources and its difficulty in obtaining the scientific data needed for epidemiological data from Member States[44].

Lastly, the final proposal concerns extending the mandate of the European Medicines Agency (EMA). Established in 1995, the EMA is responsible for the scientific evaluation and monitoring the safety of innovative medicines for human and veterinary use in the EU. The Parliament and the Council reached a political agreement on this text on 28 October 2021. The points negotiated concerned the improvement of surveillance, with anticipation of shortages and essential advice for crisis management preparation, particularly on medicines that can treat, prevent or diagnose the diseases that cause these crises. The Agency could coordinate vaccine safety and efficacy studies and clinical trials.

Furthermore, in its Communication "Pharmaceutical Strategy for Europe" of 25 November 2020 (COM/2020/761 final), the European Commission announced the creation of a European Health Emergency Response Authority (HERA), aimed at being the equivalent of the US BARDA[45] and designed to fill a major gap in the EU's crisis preparedness and response infrastructure. The HERA, the anticipatory authority[46], was created in September 2021 and has a budget of €6 billion in the current multiannual financial framework for 2022-2027. Its main objectives are to prevent, detect and respond promptly to health emergency emergencies. In doing so, the authority will work closely with other national and international health agencies, as well as with industry. It will conduct threat assessments and by 2022 will have to identify and act on at least three far-reaching threats[47].

3. Budgetary measures: with the Covid crisis, the EU has shown a budgetary effort in the field of health

To mark the EU's commitment to health, the renamed *EU4Health* programme aims to prepare the Union's health systems to face future threats and is the main instrument used by the European Commission to implement the EU health strategy.

It has a €5.1 billion budget for the 2021-2027 period and entered into force on 26 March 2020. Presented as having a budget ten times larger than the previous year, it has four main objectives: strengthen health systems to cope with epidemics and long-term challenges; ensure the protection

44 *Increasing the capacity of the European Centre for Disease Prevention and Control*, *Eyes on Europe*, 22 January 2021.

45 The Biomedical Advanced Research and Development Authority (BARDA) is an office of the US Department of Health and Human Services (HHS) responsible for the acquisition and development of medical countermeasures.

46 The HERA has two modes of operation: non-crisis periods and crisis periods. During crisis periods, the HERA coordinates the rollout of response plans that have been prepared in non-crisis mode.

47 The HERA will be responsible for the development, production and distribution of drugs, vaccines and other medical countermeasures, such as gloves and masks, in the event of an emergency. It will also support research and innovation through clinical trial networks.

of citizens against cross-border health threats; create stockpiles of medical supplies and personnel to respond to crisis situations; and support greater production and management of medicines[48].

Health is also funded through the EU's Horizon Europe research and innovation framework programme. With a budget of €95.5 billion for 2021-2027, the health part of pillar 2 totals €8.24 billion, while the funds dedicated to health in the former Horizon 2020 amounted to €7.4 billion.

At the same time, the EU has rolled out a €4 billion plan to fight cancer.

The agencies, which are the EU's armed wing in the fight against epidemics as well as in preparing for the future, also have their own budgets: €60 million for the ECDC in 2020 and €358 million for the EMA. The HERA's budget is in another category altogether, totalling €6 billion from the current multi-annual financial framework for the 2022-2027 period, part of which will come from the EU recovery plan.

II - THE COVID-19 CRISIS: AN OPPORTUNITY TO BUILD A EUROPE OF HEALTH

A. Many challenges in building an EU of health

In the wake of the Covid crisis, citizens' expectations of a stronger and more protective EU of health have been expressed, as shown by the contributions of the citizens' panels at the Conference on the Future of Europe[49]. However, the challenges in building it are numerous, although surmountable if the political will is there. As highlighted in the CESE's resolution *2022: relaunching the European project?*[50], the current context is an opportune time to generate support and renewed enthusiasm for the European idea by building on this desire for an EU of Health.

1. Political challenges

In the current context, there seems to be general agreement that health should be a genuine priority on the European agenda. However, at the political level the reality seems more complex. The President of the European Commission, Ms Ursula von der Leyen, a medical doctor by training, presented six priorities for her term of office (2019 - 2024), which did not explicitly include health. However, in 2021, during her State of the Union address[51], health was put on the agenda due to the pandemic.

Similarly, President Macron, when he spoke of the French priorities for the FPEU on 9 December 2020 under the slogan *"recovery, power, belonging"*, did not mention health issues either.

48 Source: https://www.touteleurope.eu/l-europe-et-moi/lue-pour-la-sante-eu4health/.
49 https://futureu.europa.eu/processes/Health/f/3/.
50 CESE resolution, October 2021, rapporteurs: Mr Didier Kling and Ms Françoise Sivignon.
51 Speech delivered on 15 September 2021.

Organised civil societies therefore have a key role to play in taking into account citizens' concerns to make health a real political priority, starting with the FPEU. The EU ESCs could take the importance of this issue into account now so that they can propose a European-level action plan for this priority at their next annual meeting. In this respect, they could draw on the European ESC's 2021 opinion on the Europe of Health[52].

Recommendation 1

Propose to all of the Economic and Social Committees (ESCs) of the European Union at the next annual meeting in the second half of 2022 and to the European ESC to bring the issue of a Europe of Health to the attention of national and European political bodies as a priority.

- ***The treaty issue***

As soon as the question of a strengthened EU of Health is raised, the question of treaty reform immediately arises. For example, should Article 168 of the TFEU, which gives the EU *"only one supporting competence"* in health, be rewritten? This debate cannot be avoided and leads to several options.

The first is to draw on existing texts and apply all of their possibilities. The treaties already open up many possibilities, not all of which are being utilised. The EU has a supporting competence, while respecting the powers of central governments, but one that allows it to act when the political will of States is clear. As such, who would have imagined a few years ago the European Commission concluding group purchasing contracts for vaccines for the whole of the Union? Existing legal instruments and recent decisions taken by the EU (creation of ad hoc health agencies, *EU4Health* programme, etc.) therefore already offer significant opportunities for action and reform that must be seized.

However, the question of treaty reform remains if we are to go much further. Indeed, the EU of Health is considered by some legal experts as being *"torn apart"*[53] between different articles of the treaties and the major Community policies (free movement, free trade, competition, etc.) without having any obvious visibility and legal coherence.

However, it should be remembered that the procedure for amending the treaties is lengthy and complex[54].

In the medium term, therefore, if the EU of Health is to be strengthened and made effective, it seems that this option alone should not be relied upon.

52 *Building a European Health Union* European ESC opinion of 27 April 2021.
53 *European law and health protection*, E. Brosset (Dir,), edited by E. Bruylant, 2015.
54 Indeed, any draft revision, submitted by the European Parliament, a Member State or the Commission, must be examined by a Convention comprised of European and national parliamentarians, government representatives and the Commission. The text adopted by the Convention leading to an amendment of the treaties must then be ratified and adopted unanimously by the Member States, meeting in an "Intergovernmental Conference". https://www.touteleurope.eu/fonctionnement-de-l-ue/l-epineuse-question-de-la-reforme-des-traites-divise-l-union-europeenne/.

- ***A pragmatic solution: moving forward on health through enhanced cooperation***

The CESE believes that maximum use should be made of all the opportunities offered by the treaties. As such, the Treaty on European Union (TEU) allows *"Member States which wish to establish enhanced cooperation between themselves within the framework of the Union's non-exclusive competences"* (Article 20 TEU).

In concrete terms, this legal support makes it possible to not hinder the action of countries wishing to make faster progress on a subject or ready for stronger integration while avoiding a long and complex modification of existing treaties. This procedure can be used if at least nine EU Member States volunteer for this cooperation, thus creating a real knock-on effect on the other States.

For the CESE, this type of enhanced cooperation would enable both concrete actions and a first step towards a consolidated EU of Health. There are many conceivable areas. The strengthening of cross-border cooperation, which was very useful during the crisis, could be an appropriate subject for experimentation. Beyond the States, this cooperation would enable national health actors (hospitals, clinics, associations, NGOs, etc.) to work together on common projects.

Indeed, during the Covid crisis, *"the majority of actions deployed were above all a matter of cooperation between States outside a binding framework"*[55] and the Director General of the HERA, Pierre Delsaux, noted strong bilateral or multilateral solidarity between the majority of States during the crisis (donations of vaccines, reception of cross-border patients, etc.)[56]. In addition, the *EU4Health* programme provides EU support to interested parties with a view to transnational cooperation[57], which may facilitate the implementation of such collaborations. However, care must be taken to ensure that rather than creating a two-speed Europe, this type of action serves as a means of gradually involving all States.

Recommendation 2

The CESE proposes using the enhanced cooperation procedures between Member States, provided for in Article 20 of the Treaty on European Union (TEU), in particular by stepping up cross-border cooperation and the prevention policy regarding health.

55 *The EU of Health under the Covid lens; what progress has been made?*
56 Sciences Po conference, *Towards a European Health Union*, 12 January 2021.
57 *EU4Health* regulation.

2. The issue of governance

- ***The need for political leadership at the highest level of the Europe of Health***

During the pandemic, the main difficulties observed were due to a lack of coordination between the national and European levels. In some cases, EU action has been marked by a lack of forward planning, coordination with actors on the ground and integration into an overall logic. In the early days of the vaccination campaign for example, the division of labour between the European level, which was responsible for authorising the vaccines and then for group purchasing, and Member States, which were rolling out the campaign on the ground, was not easy, with delivery delays and coordination problems.

The EU's supporting competencies in health explain much of these relative failures[58], as it did not necessarily have the capability to lead this overall effort. The EU's missions in this area remain fragmented, as does its machinery[59]. More so than existing European structures, each of which was able to carry out its tasks in accordance with its competences, it was the urgency of the situation and political involvement at the highest level, both from the viewpoint of the Council and the Commission, that made it possible to develop a coherent European response to the Covid-19 crisis.

However, regarding the conduct of health policies in normal times, in the absence of health emergencies and specific arrangements to deal with them, it is regrettable that a single institution or an identified figure is not responsible for embodying the Europe of Health, steering the European strategy and coordinating existing structures.

As with any European policy, EU action on health needs to be visible to and understandable by citizens. During the Covid-19 crisis, European Commissioner Thierry Breton was appointed head of the European task force on vaccines and was well identified by the general public as the leader of this policy.

Regarding the Europe of Health, it would therefore be necessary to have a person to embody the EU's actions and reforms.

During the hearings organised for this opinion, the idea of appointing a European figure or ambassador for health was raised[60], but the CESE believes this appointment could compete with the European Commissioner for Health and Food Safety, Ms Stella Kyriakidou, and national ministers.

58 After a slower and more complex implementation than in the US and the UK, the EU population is now the most vaccinated in the world (80% of the adult population).

59 This is emphasised by the French National Assembly in its information report on the EU coordination of national health crisis management measures (July 2021), as well as by Jérôme Creel, Francesco Saraceno and Jérôme Wittwer in the article *To the good health of all Europeans! For a single European health agency* (OFCE *Policy brief*, May 2021).

60 Hearing at the CESE on 9 November 2021 of Ms Stéphanie Seydoux, ambassador in charge of global health issues at the Ministry of Europe and Foreign Affairs, Inspector General of Social Affairs.

In the current state of EU competences, strengthening the position of the European Commissioner for Health and Food Safety, for example by giving her the rank of Vice-President of the European Commission, would be a pragmatic solution.

At the institutional level, the resources of the Directorate-General for Health and Food Safety need to be strengthened. In charge of implementing European policies in the field of health and food safety, the capacity of this Directorate-General to act is limited compared to the ambitions it is hoped that this policy would have. As such, the current Directorate-General for Health and Food Safety will have 724 members in 2020, including 594 officials, which is 2.2% of the Commission's staff – relatively low compared to the other Directorates[61]. It is worth noting that in 2019, with the reduction in the number of Commissioners, this post of Commissioner for Health and Food Safety was even under threat of being abolished, which seems incongruous after the Covid-19 pandemic crisis[62].

However, we can be pleased that the Directorate-General for Health now incorporates food safety concerns, although an approach to health that encompasses links with animal health, for example with the risks of zoonoses and environmental concerns, would require advocating for a large *"Directorate-General for Health"* or at least for greater cooperation between the various *"Directorates-General"* covering this issue.

- ***The interconnection of action by the various EU agencies***

Strengthening the mandate of the ECDC and the EMA, as well as the creation of the HERA, also raises questions about the management of health issues at a European level and the coordination of the actions of all European structures.

In addition to these three agencies, which are particularly involved in the pandemic response, the rollout of European health policies primarily relies on the European Commission's Directorate-General for Health and Food Safety, as well as the European Health and Digital Executive Agency (HaDEA)[63], which oversees the rollout of the *EU4Health* programme. Other bodies such as the Agency for Safety and Health at Work complete the system.

This raises questions about the coordination of actions by all these structures and, in some cases, about the transparency of their mode of governance. For example, the HERA is already being criticised for not involving civil society organisations or even the European Parliament in its governance, while several associations are calling for more transparency in the conduct of clinical trials by the EMA[64]. The fact that it is chaired by a senior civil servant rather than a healthcare professional is also a subject of debate.

61 *The Europe of Health under the Covid-19 lens: what progress has been made?* Gaël Coron, IRES, 2020.
62 Same.
63 This agency is the successor to the Consumers, Health and Food Executive Agency (CHAFEA).
64 Around 30 French associations, including Médecins du Monde and France Assos Santé, made this appeal by letter to the Council of the EU in September 2021.

It will therefore be necessary to ensure that all civil society stakeholders (associations, trade unions, industrial players, etc.) are genuinely involved in the HERA.

In any event, in order to create synergies between the actions of these different structures and prevent overlapping, it will be necessary to coordinate their management, if necessary by a political decision-making coordination body.

As such, the creation of a political steering committee for health issues at a European level could remedy this shortcoming, provided that its governance is transparent and involves all health stakeholders, including civil society organisations. Like the Health Security Committee (HSC), which had little involvement before the pandemic but enabled the pooled purchase of vaccines by Member States, this structure could allow for more agile governance of health issues in the EU. In its Communication 724 of 11/11/2020, the Commission proposed strengthening the HSC, although it seems that this informal committee is not the most appropriate structure to coordinate the political steering of health issues. It will therefore be necessary to be vigilant about its interconnection with existing agencies.

Furthermore, as the acceptability of health policies is a condition for the support of the policies deployed, particularly in the field of prevention, it is important to involve organised civil society and citizens in this steering committee (see also II - B: health democracy).

Recommendation 3

The CESE recommends that the European Commissioner for Health and Food Safety be given a mandate to be responsible for coordinating the EU's health agencies, under the supervision of the European Parliament, and to promote coordination with other European public policies.

3. The public health challenge

Although each State is sovereign in its health policy, a coordinated approach within the framework of a "Europe of Health" would be an undeniable asset in rising to major public health challenges together. Beyond the fight against major pandemics, which has been very visible and concrete since the Covid-19 crisis, the EU must strengthen its actions in other sectors. Article 168 of the TFEU (see part I) enables it to act to coordinate the action of Member States in many areas of public health, such as disease prevention and dangers to physical and mental health, the reduction of drug-related harm, including through information and prevention, health education, etc. The EU can also intervene to address the main health determinants linked to population lifestyles, as well as to economic and environmental factors (pollution caused by pesticides, impacts of air and water pollution, heavy metals, endocrine disruptors, etc.).

The challenges are therefore immense. The CESE believes that an ambitious EU of Health must have several key priorities.

Prevention policies are a first challenge. Indeed, apart from an ambitious and essential *Cancer Plan*, prevention remains the poor relation of public health. However, this should be seen as a long-term investment rather than as an increase in expenditure. In light of underlying trends such as the ageing of the European population[65] and the prevalence of chronic diseases (which account for 86% of early deaths in the EU)[6667], European policies must focus on prevention in public health. They must also incorporate social and gender environmental inequalities, which are factors that exacerbate health inequalities.

The second challenge is mental health, which became a major concern during the Covid-19 epidemic. Indeed, mental health is one of the main reasons for applying for sick leave, early retirement or disability pension. It should also be noted that young people are particularly affected[68], with suicide being the second most common cause of death among 15 to 29-year-olds. In line with the European Mental Health Action Plan 2013 - 2020, this issue should become a major focus of the future EU health policy and should be incorporated into prevention policies. It should also be noted that women are particularly vulnerable to certain diseases, including chronic diseases, and are twice as likely as men to lose their job and suffer substantial loss of income. They are also at greater risk of a decline in mental health, which was exacerbated during the Covid-19 pandemic[69]. The failure to take gender into account in the design of public health policies does not make it possible to reduce gender inequalities in exposure to risks, access to care and quality of care.

Recommendation 4

The CESE recommends that public preventive healthcare policy be made a priority and that it be broken down into thematic action plans (cardiovascular diseases, mental health, cancers, infectious diseases, etc.) led by the European Commissioner for Health and Food Safety. In each of the areas identified, the CESE recommends that the prevention policy take into account the gender dimension of access to health. Lack of awareness of the signs of certain diseases in women remains a major cause of poor and/or late management of women affected by these diseases.

65 By 2030, it is estimated that around 25% of the European population will be over 60 years of age, and 7% will be over 80. Forecasts indicate that the dependency ratio could almost double by then, *Population ageing: what is the European Union doing for the elderly?*, 2008, "Pour la solidarité" think tank.

66 *Health: the European Union's major struggles*, source: Touteleurope.eu.

67 Two million people die each year from cardiovascular disease and 8% of the population suffer from diabetes, *Health: the European Union's major struggles*, source: Touteleurope.eu.

68 Hearing at the CESE of Mr Julien Vermignon, co-leader and co-rapporteur of the Europe/International Commission and treasurer of the French Youth Forum (FFJ).

69 COCLICO survey, conducted from 3 to 14 April 2020 among 3,200 adults living in mainland France.

Lastly, the third challenge involves occupational health. Protecting people from health and safety hazards in their workplaces is a key element in ensuring decent working conditions for nearly 170 million workers in the EU over the long term[70]. Action has been taken by the EU, for example with the creation in 1996 of the European Agency for Safety and Health at Work (dedicated to sharing knowledge and information), to promote a culture of risk prevention. Several directives have also been adopted, such as the Health and Safety Directive laying down the general principles relating to minimum health and safety requirements[71], the directive on the protection of pregnant workers[72] and the directive on the work-life balance of parents and carers[73]. Rules introducing minimum rights on working conditions have also been defined, although without an *ad hoc*[74] directive. The CESE supports the provisions of the European Union's Strategic Framework on Health and Safety at Work for the 2021-2027 period and calls on France to make this a priority of the FPEU[75].

For the CESE, various issues relating to health at work have not been sufficiently addressed, such as psycho-social risks, the arduousness of work, to which women are more highly exposed[76], and the recognition of burn-out. On this subject, MEPs recently called for a European directive on psychosocial risks and well-being at work as part of the own-initiative report by MEP Marianne Vind[77]. The European Trade Union Confederation, heard at the CESE, supports this initiative[78]. The European Parliament also adopted on 10 March 2022 a resolution on a new EU strategic framework for health and safety at work after 2020. It aims to achieve better protection for workers against exposure to harmful substances, work-related stress and musculoskeletal disorders. This resolution calls on *"the Commission to propose, in consultation with social partners, a directive on psychosocial risks and well-being at work"*. The CESE also believes that the European Labour Authority, which is to be up and running by 2023, could be given a mandate to ensure that occupational health issues are incorporated into European public policies on work and employment.

70 https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52021DC0323&from=EN.
71 Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.
72 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
73 Directive (EU) 2019/1158 of the European Parliament and of the Council of 20 June 2019 on work-life balance for parents and carers and repealing Council Directive 2010/18/EU.
74 The right to fair working conditions is set out in the European Charter of Social Rights and in the Charter of Fundamental Rights of the European Union.
75 https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52021DC0323&from=EN.
76 HCE, Taking sex and gender into account for better care: a public health issue, November 2020. See DDFE observation note.
77 Europe Daily Bulletin of 2 February 2022, *Employment: MEPs call for EU directive on psychosocial risks and well-being at work.*
78 Hearing with Cyrille Duch, Europe - International Federal Secretary at CFDT Santé Sociaux.

Lastly, addressing public health issues through the lens of inequalities is another challenge.

Recommendation 5

The CESE supports the resolution approved by the European Parliament on 10 March 2022 on a new EU strategic framework for health and safety at work after 2020, which calls on the European Commission, in consultation with social partners, to propose a directive on psychosocial risks and well-being at work.

Recommendation 6

The CESE recommends that the future European Labour Authority be given a mandate from 2023 to ensure that occupational health issues are incorporated into the relevant European public policies.

4. The research challenge

The European Commission has communicated extensively since 2020 on its efforts to support R&D in the EU and in particular in the field of health. The efforts are indeed real and the theme of health has become more visible in the research programmes.

It should be recalled that the *EU4Health* programme, presented as one of the EU's responses to the Covid crisis, will invest €5.3bn in health, and the HERA agency, with €6bn in funding over six years, includes among its remits support for research and innovation with a view to developing new medical countermeasures, in particular through clinical trial networks on an EU scale, and the stimulation of industrial capacity.

However, behind these figures, which show a strong increase, the budget increase needs to be put into perspective.

Concerning the budgets released during the crisis (*EU4Health* and agency budgets), MEP Colin-Oesterlé put the effort into perspective. She reminds us that *"under pressure from the European Parliament, the health budget has been increased tenfold for the 2021-2027 period compared to the 2014-2020 period, but if the funds for the HERA and the cancer plan are removed from this budget, just €1.2bn to €1.3bn remains for other projects"*. She also points out that some of the funds come from budgetary redeployments.

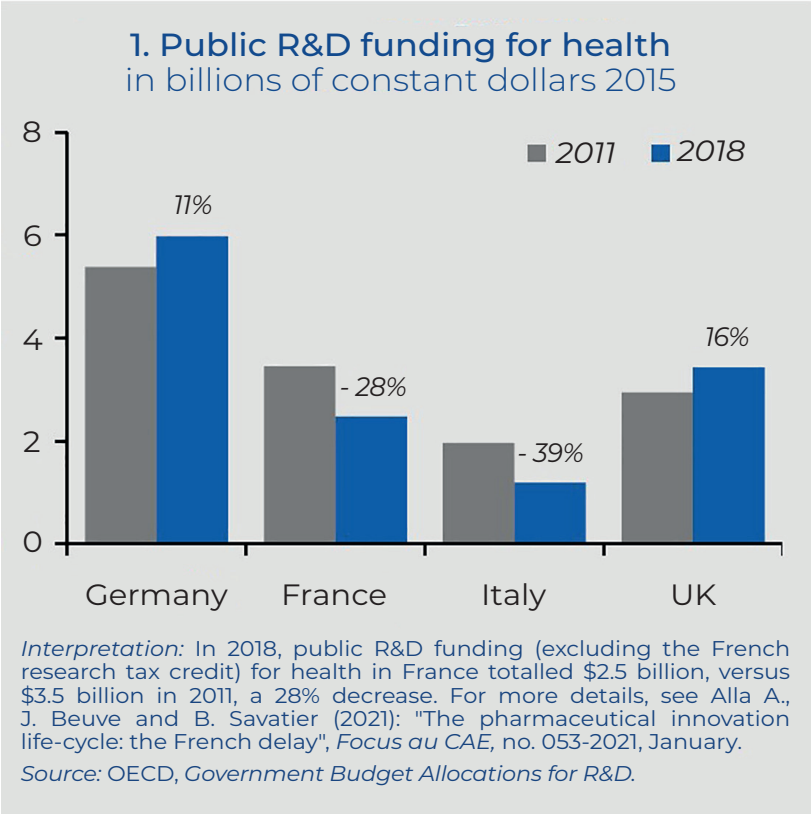
At the EU level, it is also worth noting a withdrawal from basic research for several years[79]. The National Assembly observes that France and the EU (excluding Germany) are lagging behind due to under-investment in basic research (which is essential as it has a major impact on the innovation process). In the field of health, within the EU there was even a decline in investment between 2011 and 2018 of 28% in France, excluding the research

79 French National Assembly report, already cited.

tax credit, and 39% in Italy. Only Germany and the UK (now outside the EU) have increased their spending.

In addition, in the report by the Commission of Inquiry to assess research, prevention and public policies to combat the spread of Aedes mosquitoes and vector-borne diseases, the French National Assembly recommended *"making research in the field of vectors and emerging diseases a priority for the European Union"*. The ORs should eventually become *"European research centres"* if France and the EU build research centres for vector-borne diseases and the biology of Aedes mosquitoes by relying on the trio of sustainable funding, international visibility and knowledge sharing[80].

Graph 1: Research and Development expenditure in health in Germany, France, Italy, UK



Interpretation: In 2018, public R&D funding (excluding the French research tax credit) for health in France totalled $2.5 billion, versus $3.5 billion in 2011, a 28% decrease. For more details, see Alla A., J. Beuve and B. Savatier (2021): "The pharmaceutical innovation life-cycle: the French delay", *Focus au CAE,* no. 053-2021, January.

Source: OECD, *Government Budget Allocations for R&D.*

Source: Economic Analysis Council (CAE), Xavier Jaravel and Isabelle Méjean, What resilience strategy in a globalised world?, CAE Notes, no. 64, April 2021.

This withdrawal observation contradicts the European commitments made at the Lisbon European Council in March 2000 with the *"Lisbon Strategy"*. The latter was adopted to combat the significant gap that

80 Report by the Commission of Inquiry to assess research, prevention and public policy to combat the spread of Aedes mosquitoes and vector-borne diseases, 29 July 2020.

was growing between Europe and the United States, particularly in R&D. It planned to allocate 3% of its GDP to the research budget, and today we can see that it failed. Indeed, the EU as a whole spent just 1.9% in 2018 (with significant differences between countries: 3.95% for Sweden in 2006 versus 2.16% for France and 1.1% for Italy). This compares to 2.6% in the US and 3.15% in Japan[81].

The CESE has already noted in previous opinions[82] that the EU, and France in particular, is falling behind in research. However, it welcomes the fact that the budgetary target of 3% of each Member State's GDP is being maintained under the Horizon Europe research funding programme[83]. Nevertheless, its concrete realisation seems difficult but unavoidable in order to achieve an autonomous and independent EU of Health. With a view to controlling their public spending, European States must also assess the effectiveness of public support for R&D in order to redirect aid, if necessary, to make it more efficient.

Beyond the level of budgetary effort to be achieved, particularly in terms of public research, there is also the issue of the R&D players to support. In terms of health, the pharmaceutical strategy adopted by the Commission on 25 November 2020 sets clear objectives, including supporting the competitiveness, innovation and sustainability of the EU pharmaceutical industry.

For Mr Bogillot, President of the French Federation of Health Industries (FEFIS), heard at the CESE[84], support for industrial players must be provided in several ways. He notes three conditions to be met to make the EU attractive for the health industry: support for R&D, a stable regulatory framework (avoiding EU-wide red tape but also regulatory barriers within each State) and patent protection. Concerning support for R&D, he feels it is necessary to support the entire health ecosystem and in particular start-ups, which have a strong innovation potential to bring new products to market and often struggle to find adequate support in the EU. One example is the French start-up Valneva, supported by the UK to develop a vaccine. Similarly, it can be noted that the pharmaceutical company Moderna (one of whose founders in 2010 in the US is France's Stéphane Bancel) has received long-term support from America's BARDA[85].

81 Figures from the Vie Publique website: https://www.vie-publique.fr/parole-dexpert/38558-de-la-strategie-de-lisbonne-la-strategie-europe-2020.

82 CESE opinion on the budgetary planning of the draft law on multi-annual research planning, June 2020, reported by Ms Sylviane Lejeune.

83 See Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing "Horizon Europe" – the framework programme for research and innovation, laying down the rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, which include the objective of at least 3%, and article 1 of Law No 2020-1674 of 24 December 2020 on research planning for 2021 to 2030 and on various provisions relating to research and higher education: *"The objective of increasing domestic research and development expenditure by governments and businesses to at least 3% of annual gross domestic product [...] is approved"*.

84 Hearing on 20 January 2022 at the CESE.

85 French National Assembly report, already cited.

- ***Patent policy: a debate between incentives to invest and access to vaccines and medicines worldwide***

Patent protection is a central theme in health R&D policies, as it provides a strong incentive for private research.

The French players in the pharmaceutical industry heard at the hearing stressed that returns on investment can be long, in the order of several years, in the pharmaceutical field and that the protection of innovation is an essential factor for investment[86]. Mr Lamoureux, General Manager of the organisation "Les Entreprises du Médicament" (LEEM)[87], says it is obvious that *"no one will seek a therapeutic solution for new variants of Covid-19 or any other pathology if they do not have the guarantee of their intellectual property"*. Furthermore, the lifting of patents and the transfer of technology require the creation of satisfactory production conditions in third countries. As a developing country, India has succeeded in becoming a major producer of medicines and vaccines[88], although this dynamic has yet to be taken to a more widespread scope.

As such, patent protection is a key 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 high-quality products. This sector's business model has its own specific characteristics, linked in particular to the long research and development processes and the decisive role of European social protection systems.

However, in the context of the current pandemic and the asymmetrical access to vaccines worldwide[89], the issue of patent clearance is regularly raised. Indeed, while more than half of the world's population has received at least one dose of the Covid-19 vaccine, just 8.8% of the African population is vaccinated. The lifting of patents could be one way to facilitate access for non-vaccine producing countries, as health is a global public good.

In the event of a major health crisis, such as a global pandemic, health countermeasures (tests, vaccines, drugs) must be accessible to all populations[90].

To address significant uncertainties about the capability of patent-holding manufacturers to provide the expected supplies, public health interests require all legal, technical and industrial means to be assessed and implemented to produce the necessary quantities of vaccines and medicines in the largest possible number of production units.

86 During his hearing at the CESE, Mr Bogillot referred to the seven-year period required for an industrial research programme in the pharmaceutical sector to reach the market.

87 Mr Philippe Lamoureux, General Manager of the LEEM, was heard at the CESE hearing on 14 December 2021.

88 This is the world's largest supplier of generic medicines, accounting for 20% of global supply by volume, and also meets 62% of global vaccine demand. India ranks third worldwide for production by volume and 14th by value (source: https://www.investindia.gov.in).

89 Figures from Africa CDC as of 21/12/2021 (African Centres for Disease Control and Prevention, a public health agency of the African Union).

90 Global public goods are *"the set of goods accessible to all States that do not necessarily have an individual interest in producing them"*, according to Charles Kindleberger *"International public goods without international government"*, *American Economic Review*, no. 76, 1, 1986.

During the Covid-19 crisis, the issue of relaxing access to patented inventions from a public interest perspective, through the introduction of an ex officio licence, was raised.

This mechanism enables a public authority, when justified in the interest of public health, to grant authorisations to exploit a pharmaceutical patent without having to obtain the patent holder's agreement. However, this is neither an expropriation nor a waiver of the patent, as the patent holder retains all of its rights, with the exception of the monopoly of exploitation. Each entity wishing to benefit from a licence must pay a fee to the patent holder. As such, the main objective of the ex officio licence is to improve the dissemination of the invention.

Although this licence does not seem very well suited to emergency situations, such as the Covid-19 crisis, particularly due to the lengthy implementation procedures, it has already been used, for example, by Germany in 2016 (Raltegravir®) and Israel in 2020 (Kaletra®) in connection with AIDS treatment.

Legally, it is also possible for the EU to implement this automatic licensing principle. Indeed, Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) expressly allows signatory states to *"adopt in their laws and regulations measures necessary to protect public health, provided that such measures are consistent with the provisions of this agreement"* and *"allows other uses of the subject matter of a patent without the authorisation of the right holder, including use by public authorities or third parties authorised by them"*[91].

In France, a bill on ex officio licensing of patents was tabled in the Senate on 8 April 2021, demonstrating the acuteness of the subject, but without reaching a legislative agreement[92].

However, the sole issue of lifting patents cannot solve everything. The transfer of technology and production capacity is indeed essential and must be at the centre of the debate, as Dr Sall of the Pasteur Institute of Dakar stressed. In summary, lifting patent protection is only a valid solution if third countries have the know-how to manufacture vaccines, for example against Covid-19[93].

In the context of the current pandemic, the export and donation of vaccines (via the COVAX initiative) and aid to the least developed countries are only a short-term solution. The CESE believes that long-term action is

91 This agreement was the subject of Regulation 1/200 of the European Parliament and of the Council of 1 May 2003, which establishes a compulsory licensing procedure allowing the manufacture and sale of pharmaceutical products where these products are intended for export to eligible importing countries in need of such products to address public health problems.

92 The Senate, recalling *"that it should not be forgotten that patents reward research, which is often long and costly, with a temporary exclusivity of exploitation of the invention made [...]"*, specifies that *"it is certainly possible to make access to patented inventions more flexible in the general interest by enabling companies to manufacture vaccines and treatments developed by others via the establishment of an ex officio licence"*.

93 Mr Bogillot, President of the FEFIS, and Mr Lamoureux, President of the LEEM, as well as Dr Sall from the Pasteur Institute of Dakar.

needed to help ensure that these countries have the capacity to produce, store and deploy vaccines, and have trained personnel, to enable them to better cope with future health emergencies.

Recommendation 7

The CESE calls on the European Commission, in the face of epidemic situations and in the event of a health emergency, to apply, without restriction, Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. It would also like the EU to strengthen partnership policies aimed at providing third countries with the capabilities to manufacture and administer vaccines.

- ***Decompartmentalising national and European research and encouraging cooperation between States***

Aiming for an effective EU of Health requires facilitating joint research at a European level and enhanced cooperation in this field. This point was made at the CESE hearing by Professors Ganten and Sipido[94], as it was by many other research actors. They note that research in the EU is still compartmentalised by States and that, for example, during the Covid-19 crisis, *"many small studies were carried out at a national level and did not reveal what needed to be known about Covid-19"*. Olivier Bogillot also noted at his level *"curbs on marketing and obstacles to innovation due to the 27 national laws on the marketing of medicines that are still applicable even after having obtained an approval from the EMA"*.

- ***Several avenues for strengthening cooperation in Europe should therefore be encouraged***

Firstly, the EU needs leadership in research at a European level. In the US, this competence is handled by the National Institute for Health, a governmental institution that handles medical and biomedical research, under the US Department of Health and Human Services. The French equivalent is the INSERM, although the question arises of creating such a body within the EU. Professor Karin Sipido therefore proposed[95] the creation of a European Council for Health Research, which would enable the development of a strategy and policy in this field and would take into account the views of all stakeholders (civil society, governments, academia, industry, etc.).

Strengthening networking is another way to consolidate research cooperation. One example is the European Reference Network (ERN) for rare diseases, which enables professionals and hospitals to cooperate on

94 Hearing at the CESE on 14 December 2021 of Professors Detlev Ganten, founder of the World Health Summit, and Karin Sipido, head of the experimental cardiology department at KU LEUVEN.

95 Same hearing.

research and patient treatment. The first 24 networks launched in 2017 have been very successful and could serve as a model for other research cooperations. These networks facilitate the exchange of information on rare diseases, and with this organisation a doctor in one Member State can request information on a given disease from a centre in another Member State. Health research must also be conceived in a multidisciplinary way in order to develop genuine prevention policies. Indeed, after much research on the genome, it is known that just 5-10% of diseases developed are genetic in origin, with the rest being due to the environment to which people are exposed[96]. The exposome is therefore not limited to chemical substances: it must also take into account physical and biological exposure by considering psychosocial factors.

The systematisation of large-scale statistical clinical trials at a European scale (including research institutes, hospitals and patients from the Member States) or the creation of cross-border clusters in sectors of the future (bioengineering etc.) would also help to promote research and innovation in the EU[97].

In the CESE'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.).

- ***Making the HERA a genuine European BARDA***

The EU's objective was to create a European BARDA (a US federal agency directly attached to the Department of Health), i.e. a body capable of pooling public and private funds for research and producing drugs, vaccines or other medical measures in times of crisis. While this decision was unanimously welcomed, what is the actual situation today?

The HERA's budget of €6bn over 2022-2027 is substantial, not counting additional funds that may come from other European instruments such as the Horizon Europe research funding programme. However, as Ms Colin-Oesterlé pointed out, the HERA's budget *"is half the size of the BARDA's in proportion to the number of inhabitants"*[98]. The French National Assembly[99] estimated that the total HERA and ECDC budget represented 0.0003% of the GDP of the 27 Member States, demonstrating that the EU's commitment to health could still go much further. However, the existence of the HERA will make it possible to mobilise new funds quickly in the event of a new major health crisis, which was much more complicated at the start of the Covid-19 crisis.

In terms of governance, the fact that the HERA was placed under the European Commission is criticised. In addition, it will be necessary to monitor the links that the HERA will develop with the pharmaceutical industry and its operation, which must be transparent so as to preserve its independence.

96 Paolo Vincis, Chair of Environmental Epidemiology, Imperial College London, quoted in Médiapart, 11 January 2022.
97 Report *For a Europe of Health*, Jacques Delors Institute, December 2021.
98 The BARDA has €1.4bn for 333 million inhabitants, compared to €1.45bn for 450 million Europeans.
99 French National Assembly report, already cited.

Lastly, other observers also point out that the tasks entrusted to the HERA could have been divided between the existing agencies, the ECDC and the EMA. Conversely, some advocate the creation of a single European health agency[100] with sufficient financial resources to conduct a common European health policy. Furthermore, the HERA agency should take into account the issue of supply distribution rather than production capacity.

The HERA, which is due to become fully operational in 2022, must therefore find its place in the European institutional landscape. The assessment of the HERA's work, which is scheduled for 2025[101], will therefore be a particularly important step.

Recommendation 8

Under the control of the Parliament and in association with civil society organisations, the assessment of the European Health Emergency Preparedness and Response Authority (HERA), planned for 2025, should be carried out in full transparency to verify whether the missions, budgets, synergies with other actors and the functional attachment of this agency to the European Commission are appropriate.

5. Industrial challenges

- ***The EU as a strategic market for health***

While the pandemic has served as a reminder of the vital and strategic nature of health for our societies and economies, it is also a sector with a particularly important economic weight in the EU. Healthcare accounts for 10% of the EU's GDP and employs 8% of its workforce, and with the expected ageing of the population this figure is expected to increase over the coming decades. In France, the healthcare sector as a whole represents 12.5% of economic activity and over 3 million jobs[102].

This makes the EU the world's second-largest pharmaceuticals market, behind the US (around 45% of the global market), and its total expenditure on pharmaceuticals amounted to €190bn in 2018. The pharmaceutical industry also accounts for 800,000 direct jobs in the EU and a trade surplus of nearly €110bn[103]. In recent years, the growth of the market has been stronger in the EU than in the rest of the world[104].

Lastly, the pharmaceutical industry is not very concentrated, with the top five players accounting for just 22% of the world market, and of the 10 major global players, each with a market share of between 3.5% and 5%, only Sanofi is European.

100 *For a single European health agency*, Jérôme Creel and Francesco Saraceno, OFCE, 20 May 2021.
101 https://ec.europa.eu/commission/presscorner/detail/fr/ip_21_4672.
102 European Investment Bank and Solutys Group figures.
103 European Commission figures.
104 Source: LEEM.

- ***Securing the supply of health products: a priority highlighted by the pandemic***

As mentioned earlier (see also I), the Covid-19 crisis highlighted the EU's supply problems, particularly in the early stages of the pandemic. Difficulties in obtaining masks and active ingredients demonstrated both a degree of unpreparedness on the part of the EU and all Member States to contend with the pandemic and a lack of cooperation between Member States in the distribution of available stocks.

Above all, the EU's dependence on third countries for the supply of health products was highlighted. Even so, this dependence and its most common manifestations (drug shortages and supply disruptions) are not new in the EU and have worsened since the early 2010s. According to figures quoted by the EMA, 80% of active pharmaceutical ingredients (APIs) and 40% of medicines sold in the EU come from India and China.

- ***Towards joint stock management to reduce shortages***

The causes of these shortages are complex. For example, the lack of manufacturing of certain products (e.g. masks) within the EU, the unilateral border closure measures taken at the beginning of the pandemic and the excessive stockpiling by some Member States also contributed to this. The lack of solidarity and cooperation between Member States on this issue is therefore a handicap.

Based on this observation, the European Commission proposed in its November 2020 health package that the EMA's mandate be extended[105] in order to be able, in the event of a public health emergency, to collect data more effectively and thereby have a clearer picture of the state of stocks in the Union. However, the CESE believes that this proposal is not ambitious enough. Firstly, as the MEP Nathalie Colin-Oesterlé pointed out at her hearing before the Commission, this is not strictly speaking a common database for real-time monitoring and management of stocks. Furthermore, the scheme only applies to health emergencies. However, drug shortages do not only occur during pandemics and the most common substances can be subject to supply difficulties.

In the CESE's view, it is necessary to go further than the European Commission's proposal to harmonise stocks within the EU: as a first step, identify medicines and medical devices that are likely to be subject to shortages; monitor tensions in supply chains; and develop a tool for the joint monitoring and management of medicines stocks at an EU level. The database must be secure and hosted in a solution with a guarantee of sovereignty.

105 Draft regulation.

Recommendation 9

The CESE recommends that a common database be set up at a European level, under the responsibility of the European Medicines Agency (EMA), in order to have an accurate real-time view of the state of stocks thanks to an early warning system in the event of insufficient stocks or tensions in the supply chains, based on a list of medicines of major therapeutic interest.

- ***Strengthening the European industrial landscape and supply chains for health goods***

The identification of vulnerabilities in the global supply chain of critical medicines, the necessary diversification of production areas and the introduction of stricter supply and transparency obligations, particularly in public procurement, are also among the avenues favoured by the European Commission in its November 2020 pharmaceutical strategy to combat drug shortages[106]. The CESE considers these avenues to be relevant and believes that it is essential to go further and restore greater autonomy to the EU in this strategic sector, to give it the means to be less dependent on third countries.

To this end, it is important to strengthen its clout in this sector by encouraging a partial relocation of production to European soil, including that of very small and medium-sized enterprises. Priority should be given to industrial sectors located in EU countries, relying on and supporting mid-market companies/SMEs/SMIs/micro-enterprises. For professionals in the sector, such as the LEEM, the idea here is indeed to *"reindustrialise or relocate without de-globalising"*. These relocations could focus on the production of a selection of medicines of major therapeutic interest that are regularly out of supply and of essential health protection materials. The CESE believes that the list should be drawn up and regularly updated in consultation with professionals in the sector and healthcare user associations. It is also important to ensure that costs remain under control.

In addition to the measures already envisaged by the Commission to promote research and innovation or to strengthen the compulsory nature of supplies, the CESE is in favour of a system of direct aid to relocate part of production or to bring about the emergence of one or more players of sufficient size to take on the risk associated with certain types of production[107]. This aid could, if necessary, form part of an Important Project of Common European Interest (IPCEI) on health that provides for significant funding compatible with the European state aid system. During the FPEU, France wants to advance its IPCEI project to support the development of health innovations. Its goal is to strengthen the EU's health sovereignty by relocating, for example, the production of certain

106 Commission Communication 761 of 25 November 2020 *Pharmaceutical Strategy for Europe.*

107 For Olivier Bogillot, President of the Fédération des Industries de Santé, the emergence of a large-scale player for production (notably of active ingredients) is useful, as its size enables it to spread the risk linked to production over several products.

strategic active ingredients, which are currently mainly produced in Asia. The CESE also considers relevant the proposal by the MEP Nathalie Colin-Oesterlé concerning the creation of *"European non-profit pharmaceutical establishments capable of producing medicines that are critical or no longer profitable for pharmaceutical companies"*.

Recommendation 10

Drawing in particular on Important Projects of Common European Interest (IPCEI), the CESE recommends fostering the relocation of the production of health protection equipment and certain medicines of major therapeutic interest to Europe. The list of these products must be regularly updated in consultation with the professionals and associations concerned and validated by the European Parliament.

6. The challenge of health data management and digital access

To build a Europe of Health, it is essential to develop a European Data Space. The healthcare systems of the 27 Member States are diverse and their interoperability faces many obstacles that restrict the free movement of patients and healthcare professionals. During the Covid-19 crisis, the lack of interoperability in the transmission of information and difficulties in sharing data at a European level complicated the monitoring and surveillance of the pandemic. Furthermore, the implementation of an interconnected system providing access to comparable and interoperable health data across the EU would be a real multiplier for research.

Significant efforts need to be continued in this area to improve the exchange, centralised access and cross-border analysis of health data in the EU.

The implementation of a data space is therefore one of the European Commission's priorities for the 2019 - 2025 period, particularly in the health sector. The aim is to improve the exchange of and access to health data, both for the provision of healthcare (primary use of data) and to support research and health policy development (secondary use of data). For Ms Isabelle Zablit-Schmitz from France's Ministry of Solidarity and Health, the drafting of texts relating to the European health area will be a major challenge for the French Presidency[108].

To develop e-health, the EU is drawing on three tools:

- **e-health action plans**, which aim to enable the EU to exploit the full potential of e-health systems and services within a European e-health space (full e-health interoperability by the end of 2015);

108 Hearing before the Committee on European and International Affairs of the Economic, Social and Environmental Council as part of the opinion *How to build a Europe of Health*, 7 December 2021.

- **the eHDSI** (operational since January 2019), which should enable EU citizens to use their health data in a cross-border environment. However, not all healthcare systems in Member States have yet accepted this practice, despite it being fundamental for the transfer of electronic patient records;
- **the exchange of electronic health records at a European level** (MyHealth@EU), a key objective supported by the Commission[109] that should allow for genuine movement of patients within the EU.

To implement its e-health policy, the Commission has also deployed substantial financial instruments:

Programmes (EUR)	2021 - 2027 budget
Connecting Europe Facility (CEF)	28,396,000
Digital Europe Programme	6,761,000
Horizon Europe	75,900,000
3rd Health Programme	1,670,000

However, in order to achieve these projects, the EU faces many challenges, particularly the challenge of ensuring strategic sovereignty in data hosting and management with regard to the digital giants. As already recommended by the CESE in its opinion on *Data economics and governance*[110], the European Union must speed up the investment needed for a sovereign European cloud, which is a prerequisite for its technological independence. The EU is currently working on the *Gaia-X*[111] European cloud project (a project involving 180 companies estimated at €400bn) to regulate data exchanges, foster the adoption of this technology and promote the data economy in Europe.

Concerning this European cloud, Ms Céline Ruiz[112], policy analyst at the European Commission's permanent representation in France, stressed the need to use servers hosted in Europe while ensuring a high level of data protection through the GDPR, as there has been a real awareness of the strategic dependence this implies, particularly with regard to non-European hosting providers.

Meanwhile, the President of Sanofi France, Olivier Bogillot, reiterated the importance of a European health data hub for scientific research purposes. To develop a new drug, it is essential to have a substantial database and significant computing capability, either autonomous or shared. The US has

109 Commission Recommendation 2019/243 of 6 February 2019 on a *"European format for the exchange of electronic health records"*.

110 Opinion of the Economic, Social and Environmental Council, *Data economics and governance*, Ms Soraya Duboc and Mr Daniel-Julien Noël, February 2021.

111 https://www.data-infrastructure.eu/GAIAX/Navigation/EN/Home/home.html.

112 Hearing before the Committee on European and International Affairs of the Economic, Social and Environmental Council as part of the opinion *How to build a Europe of Health*, 9 November 2021.

not yet succeeded in putting together such a project. However, to achieve this, the EU needs to implement regulation and harmonise the laws of Member States[113].

Lastly, it should be noted that the development of telemedicine has been accelerated due to the Covid-19 crisis. The database should not focus just on healthcare data but should be interoperable with other databases on people's living conditions (environmental data etc.). To ensure better access to healthcare, the Commission has encouraged this practice[114], which, among other things, helps to reduce inequalities in access to treatment. It has seen considerable development in the context of the coronavirus crisis to limit the risks of spreading the virus through the use of remote consultations. This is therefore a major additional challenge in terms of health data management and digital access.

For the Commission, digital transformation can also support the reform of health systems and their transition to new models of multidisciplinary care that are based on people's needs and enable a shift from hospital-centred systems to integrated, more community-based and patient-centred care structures[115]. This is therefore a global issue for healthcare systems in Europe.

Recommendation 11

The CESE believes that health data should be subject to the highest levels of security. They must be hosted in Europe and comply with EU data protection regulations.

In 2022, France must propose to its partners the launch of a project to harmonise the methods of analysis and epidemiological data collection, in order to have immediately comparable statistics, which will pave the way for the implementation of the Health Data Hub by ensuring that the hosting is secure and by ensuring interoperability with other scientific databases.

113 Private hearing with the rapporteurs of the Committee on European and International Affairs of the Economic, Social and Environmental Council in the context of the opinion *How to build a Europe of Health*, 20 January 2022.
114 Commission communication of 4 November 2008 (COM (2008) 689).
115 Commission communication of 25 April 2018.

B. Promoting an EU health model internally and internationally

1. Building a common European model for health based on EU values and commitments

The Europe of Health must develop around a common model, and in this respect, although the 27 Member States each have their own healthcare system, they share values and principles that can serve as a matrix.

Adherence 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.

- ***The right to health, a principle to be implemented***

Internally, in terms of the policies that the EU is able to implement with constant competences, the promotion of public health at a European level is guaranteed by the Charter of Fundamental Rights. Article 35 states that *"a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"*. The same article guarantees the right of everyone to *"access preventive health care and the right to benefit from medical care under the conditions established by national laws and practices"*.

Prevention, universal access to care, the promotion of public health and the integration of this transversal dimension into all European policies could therefore constitute the natural foundations for the implementation of a common model for the 27 Member States in the field of public health, regardless of their divergences concerning the deployment of care systems.

An EU of Health that should be inspired by the integrated and universal health vision of the Sustainable Development Goals (SDGs) and the One Health principle

The commitment of the EU and Member States to the 17 UN SDGs is another strong focus for developing this common health model. The interactions observed between health and other major current challenges such as the fight against inequalities and the eradication of extreme poverty, biodiversity loss, air and water quality, animal health and food all argue in favour of a holistic vision of health issues. Many of the representatives met by the CESE[116] defended a model that incorporates these possible health determinants and, conversely, the impact of human health on other sectors.

116 Including Sana de Courcelles, Counsellor at the Permanent Representation of France to the United Nations, and Professor Detlev Ganten, Founding President of the World Health Summit.

The sustainable development agenda itself promotes an integrated approach to global challenges that each party State must implement at its own level. While there is a separate SDG (SDG 3 "Good Health and Well-Being") dedicated to global public health, the agenda needs to be considered as a whole and the 17 goals implemented simultaneously, taking into account the interactions between them. The targets selected for SDG 3 are evocative in this respect: it contains the links between health and the environment (target 3.9) and the situation of the health workforce (target 3.c). Similarly, the targets of other SDGs are very directly relevant to health (e.g. SDG 1: Eradicate extreme poverty, SDG 5 "Gender equality" and goal 5.6 "Sexual and reproductive health"). It has been found that social, environmental and health inequalities are cumulative and exacerbate each other.

Furthermore, the type of model supported by the sustainable development agenda and the goals selected is again based on values of inclusion and solidarity, universal health coverage being one of the targets selected for SDG 3. For France, it would be all the more coherent to bring this model to the European level, as it worked before 2015 on adopting the agenda to ensure that this human rights approach structures the SDGs[117]. In any event, a conception of health as a common good must structure the construction of a Europe of Health.

Civil society also took up this integrated approach to health in the early 2000s. The "One Health" concept aims to highlight the relationships between human health, animal health and ecosystems and to link ecology with human and veterinary medicine. The "One Health" approach focuses primarily on infectious diseases, whether transmitted from animals to humans or vice versa, and their emergence in relation to global change, antimicrobial resistance and food safety[118].

If we want to create a Europe of Health that has a more all-encompassing vision than care, it is necessary to ensure its interconnection with other European policies. For example, exposure to many of the substances that cause the majority of diseases is a consequence of the way in which all human activities are developed. This means it is necessary to go beyond the silo approach of the different European policies.

This idea is supported today by many people, and Stéphanie Tchiombanio of the think tank Santé 2030[119] emphasised that it is a priority for our health systems to incorporate health into all areas (agriculture, transport, trade, etc.) and to lay the foundations at an EU level to establish a continuum between the health of humans, animals and the environment and to strengthen the links between health/environment/climate and animal health specialists[120].

117 See also *The French international cooperation policy in the context of the 2030 Agenda for Sustainable Development*, CESE opinion October 2016.
118 Contribution by the COVID-19 Scientific Council, *One Health* 8 February 2022.
119 Hearing at the CESE on 26 January 2022.
120 *Global health insights*, Santé mondiale 2030, January 2022.

This paradigm shift requires genuine transformations in practices, including for example the necessary implementation of mutual exchanges of information between specialists, concerted actions between public health managers and organisational changes (setting up of cross-functional departments etc.).

Recommendation 12

The CESE recommends constructing a common European health model based on the EU's values of solidarity and territorial cohesion, its international commitments (Sustainable Development Goals) and incorporating interactions with animal health and the environment (One Health integrated approach to foster global health).

2. Meeting society's expectations around health democracy

The construction of the EU of Health must take into account citizens' aspirations both in terms of the desired model and health democracy. It must be based more on the needs and expectations of populations, and increase the role of organised civil society in defining relevant policies and the governance of health institutions.

It is worth noting that as part of the Conference on the Future of Europe, French citizens clearly expressed their support for a common, solidarity-based and inclusive health model by 2035. Based, for example, on the principle of *"universal European social security"*, it is aligned with the vision of health as a common good described above. Moreover, regarding both health policy and all EU actions, citizens have called for a more democratic Europe that revisits its mode of governance to make it more transparent and more effectively involve civil society.

At present, the CESE has noted that health democracy is a weak aspect of EU health actions and there are still major gaps in this area.

As such, associations' role in managing the pandemic was not valued and taken into account at its proper level, at least in the early stages, even though they can lay claim to expertise and experience in the field gained over a long period of time, particularly in connection with the HIV epidemic. In particular, they have a key role to play in terms of prevention and, during pandemic periods, facilitate the population's adherence to the strategies deployed, as Mr Raymond noted[121]. They are also essential liaisons for ensuring that the measures taken are consistent with citizens' needs and the reality on the ground. Lastly, they are often the guarantors of the inclusive character of a policy. However, their role is still struggling to be recognised and although the European Medicines Agency (EMA) includes professional and patient associations on its board of directors, the same cannot be said

121 President of the National Union of Health System Associations (France Assos Santé), hearing at the CESE on 4 January 2022.

of the future European agency HERA, which does not provide for the formal participation of civil society organisations in its governance or for European Parliament scrutiny of its action.

A health democracy consists of taking into account civil society and citizens both in the development of health policies and in the governance of the structures concerned. In this respect, the French system, which is based on the law of 4 March 2002 on patients' rights and the quality of the healthcare system, can serve as a model in that it guarantees the provision of information to and the consultation and participation of healthcare users. Other initiatives taken by France in 2020 with the same concern for health democracy could be duplicated at a European level, such as the appointment of association representatives (as occurred for the Covid-19 Scientific Council) and the establishment of a citizens' liaison committee. Although the system remains imperfect, it is a step in the right direction and the CESE calls for similar governance systems to be put in place at an EU level.

A health democracy must also be based on the notions of control and transparency. Beyond citizen participation, democratic institutions' role in developing this EU of Health must be strengthened. Firstly, the European Parliament's role must be reasserted. The MEP Nathalie Colin-Oesterlé pointed out that it had not been very involved in the creation and implementation of the HERA and now sees itself as a mere observer of this agency, despite it being essential to the future EU of Health.

Given part of the population's mistrust of vaccination or the vaccine pass for example, involving users in the definition of health policies seems to have become essential. In this respect, it should be welcomed that the Commission has taken into account the views and priorities expressed by stakeholders and the general public in establishing its pharmaceutical strategy. The CESE believes that the health sector, which now accounts for 10% of global GDP, cannot do without control, checks and balances, and transparent procedures. Health must be seen as a common good and public health must take precedence over commercial and industrial interests.

Recommendation 13

To develop health democracy in the EU, the CESE recommends ensuring better representation of citizens and organised civil society in the governance system of European health agencies, based on the model of the French law of 4 March 2002 on patients' rights and the quality of the healthcare system.

Furthermore, it is necessary to develop a culture of partnership in healthcare for new therapeutic approaches that, in particular, allow patients to play a role in their care pathway. It must be possible for everyone to be a proactive participant in their own health and thereby improve the care and integration of people living with a chronic illness or disability. The Covid-19 pandemic has shown, among other things, that it is necessary to combine the experiential knowledge of patients and family carers with the academic and

clinical knowledge of healthcare professionals to achieve a care relationship based on co-leadership, co-construction and co-responsibility.

In order to be truly built, the Europe of Health needs the support of European civil society. Hundreds of organisations involved in global health issues took action in 2020 in the run-up to the Conference on the Future of Europe, producing a manifesto for a Europe of Health supported by the European Health Forum Gastein.

To mark the French Presidency of the Council of the European Union, the One Sustainable Health (OSH)[122], forum was able to launch a European professional civil society initiative for a Europe of Health in February 2022. The consolidated recommendations were submitted directly to the 27 European health ministers meeting on 10 February 2022 in Grenoble. This initiative will continue and be enriched during upcoming EU presidencies so that European professional organisations and their recognised experts can make their contribution to the construction of a Europe of Health.

3. Promoting an inclusive health model

Internally supporting a European model of health based on values of solidarity and social inclusion involves combating inequalities in access to healthcare and paying specific attention to the most vulnerable populations the furthest removed from it. However, the Covid-19 crisis has revealed persistent inequalities within the EU and, as the latest OECD report on the state of health in Europe (*Health at a Glance*: Europe 2020[123]) indicates: *"There is a clear social gradient in Covid-19-related deaths, and people who are poor and living in deprived areas have been disproportionately affected."* Therefore, taking action to achieve an inclusive health model also means acting on the social determinants of health, the gendered determinants and the root causes of inequalities through appropriate economic, environmental and social measures.

It is also important to talk about access to sexual and reproductive rights. Preventive care in sexual health and access to a variety of quality contraceptives remain blind spots in European health policy, despite successive calls from organised civil society, particularly the CESE[124] and in the European Parliament's 2021 resolution on this subject, while women's health rights have seen clear setbacks in recent years in the European Union. More generally, the gendered approach of the European Union's health policy, notably through the *EU4Health* strategy, remains insufficient.

The other central theme of this future EU of Health is to reduce the disparities between Member States. According to a Swedish study

122 In partnership with the World Health Summit in Berlin, the Network of European Foundations and many European academic associations such as the Karolinska Institute .

123 https://www.oecd-ilibrary.org/docserver/04ce39c5-fr.pdf?expires=1642002774&id=id&accname=guest&checksum=AA27D738B0600EB3CF7C71B0F268FAE6.

124 *Building a Europe with social rights (2016) and Sexual and reproductive rights in Europe: between threats and progress (2019).*

carried out in 2018 and published in 2019, the gap between member countries remains wide, especially between Northern European countries (Netherlands, Finland, Luxembourg) and Eastern European countries (Poland, Hungary and in particular Bulgaria and Romania)[125]. Moreover, the share of GDP spent on healthcare also varies widely across the EU, with Germany and France spending more than 11% and Romania and the Baltic States spending less than 7% (Eurostat, February 2020). The President of the Romanian ESC, Mr Bogdan Simion, stated[126] during his hearing the huge health challenges facing Romania: low public investment, little public support for vaccination policies and the departure of Romanian doctors to other EU countries.

This Europe of Health will also have to take into account the outermost regions, areas concerning several EU States. Often suffering from a lack of doctors, specific illnesses and higher medicine prices than in mainland France, the issues in these territories need to be integrated into the construction of an EU of Health. EU framework programmes (Horizon Europe) could therefore be mobilised to address these issues (e.g. research on vector-borne diseases).

These goals of social and territorial cohesion go beyond the strict framework of the measures planned for health, as part of the *EU4Health* programme in particular, and involve mobilising other existing European initiatives or policies.

On a constant treaty basis, it will therefore be possible for the EU to take action for more inclusive health by using the following tools:

- the European Pillar of Social Rights[127], which includes in chapter III Social Protection and Inclusion, *"healthcare"* (Article 16 on the right to access healthcare and Article 18 on the right to long-term care services). For the time being, this part of the Pillar has not yet been translated into concrete action;
- the European Semester and its Social dashboard. Inspired by the Pillar, it includes indicators related to healthcare;
- the rollout of Member States' National Recovery and Resilience Plans (NRRP). In its NRRP for 2021, France also listed investment in health as one of its priorities as part of the "Health Ségur" consultation;
- Horizon Europe, a key research and innovation funding programme for the EU with €95.5bn for the 2021 - 2027 period;
- The European structural funds intended to strengthen social and territorial cohesion within the EU, with the European Social Fund (ESF) and the European Regional Development Fund (ERDF) for example likely to be mobilised to finance projects with a strong impact on health (healthcare infrastructure, occupational health, etc.).

125 https://healthpowerhouse.com/media/EHCI-2018/EHCI-2018-report.pdf.
126 Hearing at the CESE on 8 December 2021.
127 See also *Building a Europe with a pillar of social rights*, CESE opinion, December 2016.

Citizens' aspirations for a more inclusive, egalitarian EU of Health were reinforced during the Covid-19 crisis[128]. Solidarity within the EU can exist. It worked during the crisis through bilateral actions (transfer of patients to cross-border hospitals, and therefore of vaccines), as well as at a Community level (arrival of vaccines at the same time in all EU countries).

On this point, it can be emphasised that the relaxation of the Stability Pact, at least until the end of 2022, should enable States to continue investing in their health systems (unlike the period of austerity plans following the 2008 financial crisis, which had a major impact on the health system in Greece for example[129]).

The CESE therefore proposes strengthening the health component of the European pillar of social rights. Indeed, this pillar, adopted in 2017, has enabled the EU to set a framework and objectives on social matters. Although it was a declaration of intent, this text has already inspired numerous initiatives such as the directive on work-life balance and the directive on the European minimum wage currently under discussion.

This health component could set a number of goals aimed at converging the health situations of EU Member States (level of healthcare expenditure to achieve, minimum ratio of medical staff to population, mobility of healthcare workers, etc.) and will have to establish objectives for monitoring its implementation (indicators, specific criteria, minimum expenditure threshold).

Recommendation 14

The CESE recommends strengthening the health component of the European pillar of social rights to make it an EU health roadmap, which can then be implemented through directives.

Recommendation 15

To ensure that health is more effectively taken into account in all public policies and that citizens are better informed, the CESE recommends strengthening the assessment of European policies to include:

- health impact assessments
- consideration of the social, environmental and economic trio
- an assessment of impact on the 20% of most vulnerable individuals
- healthy life expectancy as a leading indicator.

128 Regional Conference on the Future of Europe, 15 October 2021.

129 *The impact of the financial crisis and austerity measures on the health status of Greeks and the healthcare system in Greece*, Charalampos Economou, Revue française des affaires sociales, 2015.

4. Strengthening the EU's clout as a global healthcare actor and promoting a model of solidarity internationally

Enhancing the EU's visibility at an international level

The EU has no seat on the WHO. It is merely an observer, meaning that it is *"invited to participate with observer status in open meetings of the World Health Assembly, or one of its main committees, and the Council*[130]*"*. As such, the EU finds itself alongside the Holy See, Palestine and NGOs such as the Order of Malta.

Indeed, the EU does not represent a single voice at an international level, in the sense that it does not define the 27 members' policy in this field, although it maintains close partnerships with the WHO through the competent Commission services (Directorate-General of Health) and the specialised agencies (ECDC and EMA primarily). The EU is often even viewed as *"a 28th state alongside its 27 Member States"*[131]. It cannot be mandated to do so by the Commission, although this situation no longer seems appropriate in the current context.

Despite this institutional weakness, the EU can nevertheless claim clout on the international stage because of its donor policy: it is the third-largest contributor to the WHO ($373m in 2020-2021) and the sixth-largest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM – €550m in 2020-2022). It has also implemented numerous bilateral health programmes with countries such as Afghanistan, Burkina Faso and Niger. At an international level, it is worth noting that the EU has the capacity for financial action as the world's largest donor of official development assistance (including health aspects), with over €66 billion in 2020, i.e. 42% of the aid deployed.

The EU has the means to be heard at an international level and would therefore benefit from strengthening its positions when it sits on the WHO, although in order to do so it must start by developing its vision of health at an international level.

The CESE 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 project, the EU could use the *Council Conclusions on the EU role in global health*, which were drawn up in 2010, as a basis for its work[132]. This document was indeed an outline of the EU's international role.

The working groups set up in 2019 during the Finnish presidency of the EU should also be revitalised to relaunch the work on health and establish a clear roadmap towards a strategy.

130 WHO website, Executive Board, 27 December 2019.
131 Hearing with Ms Stéphanie Tchiombiano, coordinator of the think tank Santé mondiale 2030, at the CESE on 26 January 2022.
132 https://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/EN/foraff/114352.pdf.

However, it should be welcomed that in May 2021, at the G20 Summit, the President of the European Council Charles Michel spoke alongside several heads of State, including the President of the Republic Emmanuel Macron and the German Chancellor Angela Merkel, in favour of opening negotiations on an international treaty to combat pandemics. The CESE supports the efforts of the European Commission, which has been given a mandate to negotiate, on behalf of the EU, an international agreement with the WHO on *"Pandemic Prevention, Preparedness and Response"*. This EU position on a major international health issue is therefore important in the EU's strategy to assert itself on the international stage. As mentioned above, it is important for the EU and its member countries to be strongly involved in this ongoing negotiation, with the aim of achieving a precise and binding treaty, which is not a priori the view of all WHO member countries.

Recommendation 16

The CESE recommends defining a European health strategy that will strengthen Europe's voice on the international stage.

Leading a balanced view of international cooperation and solidarity in health

The EU and its Member States were early adopters of the need for a global response to the coronavirus, and while this response remains imperfect today, they are the most committed global players in this area. Similarly, they are among the largest financial contributors to global programmes such as GAVI, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID.

Since the outbreak of the pandemic, they have been actively involved in the Covax initiative to provide aid and vaccines to the least developed countries (Africa, Near and Middle East, Western Balkans). By December 2021, the EU had contributed €3bn and provided over 200 million vaccine doses. It has also pledged to provide 700 million doses by mid-2022 to reach the target of vaccinating 70% of the world's population.

In addition, the EU exported 1.7 billion doses as of January 2022[133].

Lastly, the actions carried out by the EU and the Team Europe[134] that it set up for this purpose also aim to provide these partner countries with their own vaccine production and testing capabilities, such as the Pasteur Institute of Dakar, Senegal, whose director, Dr Sall, was heard at the hearing[135], or to carry out projects aimed at mitigating the economic and social effects of the pandemic.

133 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_fr#exportations-de-vaccins.
134 Expression used by the European Commission.
135 CESE hearing of Dr Amadou Sall, Director of the Pasteur Institute of Dakar, 18 January 2022.

In any event, these actions are in line with European commitments to global health and sustainable development and need to be assessed, increased and sustained.

Beyond this positive appraisal, the EU must maintain this key position in the field of cooperation. As Dr Sall pointed out, the other powers, the US and China, are also very present in Africa. The EU must therefore reinforce its original vision of solidarity and above all implement strengthened partnerships with these States, rather than just having donation policies such as COVAX, the results of which are sometimes disputed. For example, GAVI, the Vaccine Alliance (an international organisation created in 2000) states that *"the global record on access to Covid-19 vaccines is unacceptable. Only 20% of people in low- and lower-middle income countries received a first dose of vaccine, compared to 80% in high and upper-middle income countries."*[136]

In this respect, operations such as the support for the Pasteur Institute of Dakar should be expanded. The Coalition for Epidemic Preparedness Innovations (CEPI) and the Pasteur Institut of Dakar have signed a memorandum of understanding to formalise the partnership between the two organisations. Its goal is to advance the project for a regional manufacturing centre for Covid-19 and other vaccines in Dakar, Senegal, and in its initial phase to manufacture up to 300 million doses of Covid-19 vaccine per year for use in Africa[137].

Recommendation 17

The CESE recommends developing a sustainable partnership with the least developed or middle-income countries through international cooperation policies that promote technology transfer and enable the development of local capacities in global health (training, research, production, distribution, etc.).

136 COVAX joint statement on supply forecasts for 2021 and early 2022, GAVI website.
137 Pasteur Institut of Dakar website https://www.pasteur.sn.

Appendices

NO.1: COMPOSITION OF THE PERMANENT COMMITTEE ON EUROPEAN AND INTERNATIONAL AFFAIRS AT THE TIME OF THE VOTE ON 15 MARCH 2022

Chair	Serge Cambou
Vice Chairs	Catherine Pajares y Sanchez Sabine Roux de Bézieux
Acting differently for social and environmental innovation	Sabine Roux de Bézieux
Agriculture	Catherine Lion Sébastien Windsor
Social and ecological alternatives	Serge Le Quéau
Crafts and Professions	Dominique Anract
Associations	Jean-Marc Boivin Lionel Deniau Benoît Miribel Françoise Sivignon
CFDT	Patricia Blancard Jean-Yves Lautridou Catherine Pajares y Sanchez
CFE-CGC	Fabrice Nicoud
CGT	Mohammed Oussedik
CGT-FO	Sébastien Busiris Serge Cambou
Cooperation	Olivier Mugnier
Businesses	François Asselin Jean-Lou Blachier Anne-Marie Couderc Didier Kling
Environment and nature	Lucien Chabason Nathalie van den Broeck
Families	Marie-Claude Picardat

Student Organisations and Youth Movements	Kenza Occansey
Overseas	Eric Leung Pierre Marie-Joseph
Health & Citizenship	Philippe Da Costa
UNSA	Saïd Darwane

NO.2: LIST OF INDIVIDUALS HEARD BY THE MEMBERS OF THE PERMANENT COMMITTEE AND MET BY THE RAPPORTEUR

For its information, the permanent committee heard the following persons:

✓ **Robert Barouki**

Research Director at INSERM and Coordinator of the Health Environment Research Agenda for Europe

✓ **Christine Berling**

Head of the International and European Affairs Mission at the Directorate-General for Health of the Ministry of Solidarity and Health

✓ **Patricia Blanc**

French member of the European Economic and Social Committee

✓ **Olivier Bogillot**

President of the French Federation of Health Industries (FEFIS)

✓ **Philippe Boutin**

Doctor and President of the European working group of practitioners and specialists in free practice

✓ **Nathalie Colin-Oesterlé**

Member of the European Parliament

✓ **Sana de Courcelles**

Health Counsellor at the Permanent Representation of France to the United Nations in Geneva

✓ **Joël Destom**

French member of the European Economic and Social Committee

✓ **Cyrille Duch**

Federal Secretary Europe - International at CFDT Santé Sociaux

✓ **Detlev Ganten**

Professor and Founding President of the World Health Summit

✓ **Amandine Gautier**

Researcher in sociology and political science at the École Nationale des Services Vétérinaires – France Vétérinaire International, VETAGRO SUP

✓ **Philippe Lamoureux**

General Manager of "Les Entreprises du Médicament (LEEM)"

✓ **Fabrice Meillier**

Head of Public Affairs Europe-International "Les Entreprises du Médicament (LEEM)"

✓ **Sylviane Ratte**

Director of the Vital Strategies Endowment Fund

✓ **Gérard Raymond**

President of France Assos santé

✓ **Benjamin Roche**

Director of Research at the Institute of Research for Development (IRD)

✓ **François Romaneix**

Deputy Director General for Administration and Finance at the Pasteur Institut

✓ **Céline Ruiz**

Policy Analyst at the Representation of the European Commission in France

✓ **Amadou Sall**

Doctor and Director of the Pasteur Institute of Dakar

✓ **Stéphanie Seydoux**

Ambassador for Global Health Issues and Inspector General for Social Affairs at the French Ministry of Europe and Foreign Affairs

✓ **Bogdan Simion**

Doctor and President of the ESC of Romania

✓ **Karin Sipido**

Professor and Head of the Department of Experimental Cardiology at KU LEUVEN

✓ **Stéphanie Tchiombiano**

Coordinator of the think tank "Santé Mondiale 2030"

Julien Vermignon

Co-leader and co-rapporteur of the Europe/International Commission and treasurer of the French Youth Forum (FFJ)

✓ **Jérôme Weinbach**

Deputy Delegate for European and International Affairs at the Delegation for European and International Affairs of the GeneralSecretariat of the French Ministry of Labour, Employment and Integration and the French Ministry of Solidarity and Health

✓ **Isabelle Zablit-Schmitz**

Project Director – Europe and International expert at the Ministerial Delegation for Digital Health of the French Ministry of Solidarity and Health

The President, the rapporteur and the members of the permanent committee would like to thank all of these individuals for their valuable contributions.

NO.3: TABLE OF ACRONYMS

TRIPS	Trade-Related Aspects of Intellectual Property Rights
ANEMF	*Association Nationale des Étudiants en Médecine de France* (National Association of Medical Students of France)
ANSES	*Agence nationale de sécurité sanitaire de l'alimentation de l'environnement et du travail* (National agency for health, food, environment and labour safety)
BARDA	*Biomedical Advanced Research and Development Authority*
CDC	Centre for Disease Prevention and Control
EC	European Council
EEC	European Economic Community
CEPI	*Coalition pour les Innovations en Préparation aux Épidémies* (Coalition for Epidemic Preparedness Innovations)
ECH	European Community of Health
CESE	*Conseil économique, social et environnemental* (Economic, Social and Environmental Council)
CIFDT	Confédération française démocratique du travail
CIFE-CGC	Confédération française de l'encadrement - Confédération générale
CGT	Confédération générale du travail
CGT-FO	Confédération générale du travail - Force ouvrière
CIR	*Crédit d'impôt recherche* (Research tax credit)
HSC	Health Security Committee
DDFE	*Délégation aux droits des Femmes et à l'égalité* (Delegation for Women's Rights and Equal Opportunity)
DG	Directorate-General
ECDC	European Centre for Disease Prevention and Control
EHDSI	eHealth Digital Service Infrastructure
EMA	European Medicines Agency
ERN	*European Reference Network*
ESI	Emergency Support Instrument
ISE	Intermediate Sized Enterprise
ERDF	European Regional Development Fund
FEFIS	*Fédération française des industries de santé* (French Federation of Health Industries)
FFJ	*Forum français de la jeunesse* (French Youth Forum)
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
ESF	European Social Fund
HaDEA	European Health and Digital Executive Agency
HCE	*Haut Conseil à l'égalité entre les femmes et les hommes* (High Council on gender equality)
HERA	Health Emergency Response Authority
HHS	*The United States Department of Health and Human Services*
INSERM	*Institut national de la santé et de la recherche médicale* (National Institute of Health and Medical Research)
API	Active pharmaceutical ingredients
IPCR	EU Integrated Political Crisis Response mechanism
IRD	*Institut de Recherche pour le Développement* (Research Institute for Development)
IRES	*Institut de recherches économiques et sociales* (Institute for Economic and Social Research)
JHU	Johns Hopkins University
LEEM	Les entreprises du médicament
CEF	Connecting Europe Facility
OECD	Organisation for Economic Cooperation and Development

SDG	Sustainable Development Goals
OFCE	*Observatoire français des conjonctures économiques* (French observatory of economic climates)
WHO	World Health Organisation
NGO	Non-governmental organisation
OSH	*One Sustainable Health*
FPEU	French Presidency of the European Union
GDP	Gross domestic product
IPCEI	Important Project of Common European Interest
SME	Small and Medium-sized Enterprises
SMI	Small or Medium-sized Industry
NRRP	National Recovery and Resilience Plan
R&D	Research and development
REACH	*Registration, Evaluation and Authorisation of Chemicals*
REMPART	*Réseau d'Expertise et Mobilisation PARTicipatif* (Participatory Expertise and Mobilisation Network)
GDPR	General Data Protection Regulation
OR	French outermost regions
TFEU	Treaty on the Functioning of the European Union
ME	Micro Enterprise
TUE	Treaty on European Union
EU	European Union
UNSA	*Union nationale des syndicats autonomes* (National Union of Autonomous Trade Unions)

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No. 41122-0006
ISSN 0767-4538 ISBN 978-2-11-155721-5