

## **A EUROPEAN HEALTH UNION - INCREASING EU COMPETENCE IN HEALTH - COPING WITH COVID19 AND LOOKING TO THE FUTURE**

The coronavirus has highlighted that the European Union does not have strong enough tools to deal with an emergency such as the spread of a novel infectious disease, which by its nature knows no borders. While the EU has significant competence in public health, healthcare systems remain the responsibility of Member States, with minimal cooperation at EU level.

Article 168 of the Treaty stipulates that ‘a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities’ and the European Court of Justice has ruled on numerous occasions that the EU can pursue public health objectives through internal market measures.<sup>1</sup>

Currently the EU regulates pharmaceuticals, medical devices, tobacco, alcohol, food and chemicals, amongst others. There are EU rules on clinical trials, and health research is financed through Horizon 2020, the upcoming Horizon Europe, the Health Programme and other EU funds. The European Medicines Agency, European Chemical Agency and European Food Safety Authority are all executive agencies with important public health functions. There is limited coordination of healthcare systems through voluntary measures, but also through the Cross Border Healthcare Directive, and the Health Technology Assessment Regulation, which is currently being negotiated, among others.

For emergency response there is the Union Civil Protection Mechanism, the Cross Border Health Threats Decision (including joint procurement), and the European Centre for Disease prevention and Control. All of these are being tested to their limits during the current crisis.

The right to physical and mental health is a fundamental human right. Every person, without discrimination, has the right to access modern and comprehensive healthcare. We have to safeguard citizens’ wellbeing not only during this current crisis but also in the aftermath. Never again can we allow doctors and nurses to be exposed to such high risk and be forced to make decisions on who can and cannot receive healthcare. Therefore, S&D calls for the urgent creation of a European Health Union, which would encompass:

- Stress-testing of EU healthcare systems
- A new Directive for Minimum Standards for Quality Healthcare
- A European Health Response Mechanism
- Strengthened Joint Procurement Mechanism under a regulation
- Revision of the Transparency Directive for pricing and reimbursement of medicines
- Full implementation of Cross Border Healthcare Directive and Clinical Trials Regulation
- Strengthened EU health agencies and strengthened civil protection capacities
- Legislative action on antimicrobial resistance and vaccination
- Robust Pharmaceutical Strategy and a European Resilience Strategy
- European Health Data Space
- A new approach to European health research
- New legislation on health and safety in the workplace

## **Stress Testing and Minimum Standards for Quality Healthcare**

Ensuring everyone can use the health services they need without experiencing financial hardship – universal health coverage – is a Sustainable Development Goal all countries have committed to reach by 2030.<sup>ii</sup> Health is an investment in human capital, social and economic development, which contributes significantly to the protection of human rights and dignity.

Health systems are facing the most serious global pandemic in a century. The current crisis exposes the difference in capacity between Member States' healthcare capacities, and shows that we are reliant on our neighbours having sufficiently resilient systems. Additionally some Member States suffer significantly from brain drain, with highly qualified healthcare professionals opting to work in Member States with better pay and conditions than their own.

In the face of different types of crises in recent years, the European Union has strengthened the systems that have proven to be too weak. For example, the EU has carried out stress tests in the energy sector and the banking system to assess the resilience of these sectors and their potential needs.

In order to be prepared for future pandemic scenarios, Member States should carry out stress tests on their healthcare systems to verify that they are prepared for the next health crisis. These tests should be carried out according to parameters established by the Commission and should help Member States detect the areas where their national healthcare systems need improvements and financing. Member States should commit to carrying out these tests as soon as possible.

Based on the findings of the stress tests the Commission should propose a Directive on minimum standards for quality healthcare. This would encompass a set of common criteria to be reported to the European Commission on a regular basis, using parameters such as hospital beds per head, critical care capacities, numbers of doctors and nurses per head, rate of health expenditure and access and affordability of healthcare for all, including for vulnerable populations. It should contain a minimum permitted level of health coverage. A European Healthcare Index summarising the relevant indicators would help track the progress of healthcare systems in the EU. While the management, organisation and funding of healthcare systems would remain Member State competences, European minimum standards for quality healthcare would guarantee patient safety, decent working and employment standards for healthcare workers and European resilience in the face of pandemics and other public health crises.

Alongside this, healthcare indicators must be integral to the European Semester, part of our agenda of reforming the Semester to reflect the SDGs.

S&D calls on the Member States to carry out stress testing of their healthcare systems, to assess their preparedness for epidemics and ability to meet the SDG targets. Based on the findings we call for an EU Directive for Minimum Standards for Quality Healthcare, which would set the EU on a clear path to providing exceptional healthcare in all regions of Europe.

## **European Health Response Mechanism**

COVID19 has affected Member States at different times and in varying severity. Some healthcare systems surpassed their capacities, while others still had critical care facilities available. Many healthcare professionals expressed an interest in helping the most affected areas. The Commission has produced guidelines to facilitate the treatment of patients, and temporary deployment of doctors, in other Member States. The Union Civil Protection Mechanism has also been used to mobilise doctors and nurses across Member States, and the mechanism includes capacities such as emergency medical teams. The rescEU capacity stockpiled key resources like masks, ventilators and laboratory equipment, to be deployed where most needed. The Commission has set up a panel of experts, which is being regularly consulted together with the ECDC and EMA on the COVID19 response.

While this work is to be commended, much of it came much too slowly, because the systems were not in place or had not been used before on this scale. The EU has the power to adopt measures to combat cross-border health threats under Article 168 paragraph 5.

S&D calls for these working methods to be formalised into a stronger legislative framework, building on measures in the Cross Border Healthcare Directive, which has been poorly implemented, and the Union Civil Protection Mechanism. This would allow patients and healthcare professionals to move more easily between Member States as needed, and give the Commission a greater role in identifying needs and surpluses. At its core would be a health crisis management unit, coordinated by the ECDC and led by the Commissioner for Health and the Commissioner for Crisis Management, together with the EMA and the expert panel. This unit will be prepared with a pandemic emergency plan, in order to have a coordinated response and the capacity to rapidly scale up the response to future health crises, based on standardised information. In its resolution on COVID19 the Parliament supported a general call for a European Health Response Mechanism.<sup>iii</sup>

As part of the response mechanism, the rescEU capacity should be reinforced, including the stockpiling and emergency medical team capacity. A recent instrument, rescEU does not yet have sufficient capacities and resources, and its functioning should be revised in light of the experience gathered from COVID-19.

S&D calls for a European Health Response Mechanism to ensure the EU is ready to respond immediately, with solidarity and unity, to a health threat. The Mechanism would be expert-led, have its own medical resources under a strengthened Union Civil Protection Mechanism, and facilitate the movement of patients and healthcare workers in the most efficient way.

## **Joint procurement and transparency**

In the face of a crisis, some countries have been tempted to engage in export restrictions to protect domestic supply of medicines and medical devices. We must avoid 'me first' behaviour when it comes to fighting a common enemy. For that reason we have the possibility at EU level to procure treatments and vaccines jointly. Particularly regarding COVID19, S&D will strongly advocate for rapid, fair, equal and affordable access to future vaccines and treatments once they are available.

More widely, there is a desperate need for new treatments for a number of conditions, particularly new antibiotics in the face of rising antimicrobial resistance. No innovative antibiotics have been developed in recent decades. Similarly, for other diseases only a small number of truly curative medicines have been developed in recent years, with many newly approved medicines designed to alleviate the symptoms of chronic diseases but not to cure them. Therefore, when the breakthrough medicines come they are often unaffordable for national healthcare systems, and EU Member States are competing against each other for quick access and the best deal.

EU joint procurement is an excellent tool that we have at our disposal to avoid competing against each other and secure equal access to important medicines and medical devices for Member States. This should be more routinely used with new treatments and vaccines. We should promote EU joint procurements for new innovative antibiotics, new vaccines and new curative medicines, for example for hepatitis C. It should also be used for treatments of rare diseases, which are not available in all Member States because of small patient populations or high prices. It should be more centralised, allowing the Commission to react more swiftly to needs. The Cross Border Health Threats Decision should be revised as a Regulation to address all of these concerns.

We also urgently call on the Commission and Member States to revisit the idea of transparency of net pricing and reimbursement of different treatments, to allow Member States equal footing when negotiating with pharmaceutical companies for treatments that are not jointly procured. This was blocked by the Council when it was last attempted nearly a decade ago. We also need to secure the transparency of clinical trial results through the swift implementation of the Clinical Trials Regulation, which has been heavily delayed.

S&D calls for the joint procurement procedure to be strengthened within a European regulation, to allow it to become the norm for procuring certain treatments. Transparency measures must also be improved. This will guarantee equal access to critical medicines and medical devices as fast as possible whilst avoiding price speculation between Member States.

### **Guaranteeing EU supply of pharmaceuticals and medical devices**

Many pharmaceutical supply chains are reliant on active pharmaceutical ingredients (APIs) or generics that are manufactured in China or India, sometimes by only one factory globally. The export bans put in place by India during the COVID19 crisis, and the fall in production caused by the crisis in China, highlight the very real dangers of relying on these supply chains for essential medicines. It has underlined the need to strengthen the European production of key products, building a strong EU health industry capable of producing equipment for our hospitals, including medical devices, active pharmaceutical ingredients and medicines.

We expect the Pharmaceutical Strategy, originally forecast for the end of this year, to address this issue. This strategy must include legislative measures, policies and incentives to encourage production of essential APIs and medicines here in Europe to guarantee supply at all times and to set up an EU system for the monitoring of medicines shortages. In this respect, mandatory national inventories of medicines and medical devices should be set up, with a

focus on the most critical ones, to be held in each Member State and communicated with the Commission and EMA to ensure any shortages can be foreseen and addressed.

Targeted guidelines for the pharmaceutical sector are needed in the Public Procurement Directive. These guidelines should clarify recommendations for Member States on what to consider specifically for the pharmaceutical sector whilst awarding bids. It should be based on the principle of the 'most economically advantageous tender' ('MEAT' criteria), which aims to ensure the best value for money rather than simply the cheapest product. Things to consider should include the contribution to the security of EU supply and sufficient manufacturing lead-time to guarantee the supply of medicines for patients.

S&D calls for the Commission to publish the Pharmaceutical Strategy as soon as possible to increase EU security of supply and encourage the production of essential APIs and medicines in Europe. We also call for the Commission to mandate national inventories of medicines and medical devices to be shared at a European level. Public procurement should also work towards these goals.

### **Strengthening EU agencies and guidance in health**

S&D calls for the two main EU health agencies, the ECDC and EMA, to have substantially strengthened competences, budget and staff to enable them to provide world-class public health protection at all times, including during epidemics. This call has also been supported in the Parliament resolution. Not only is their work invaluable at this current moment, but also to face ongoing threats in the EU such as HIV, tuberculosis and hepatitis, antimicrobial resistance, chronic diseases and future epidemics. The ECDC should have the capacity to run laboratory work and coordinate testing for infectious diseases. EMA should play a key role in the coordination of the design and approval of EU clinical trials during crises, including the use of companion diagnostics, to provide researchers with fast advice and access to clinical trial sites in the EU for the trials that are most needed.

The EU has no direct equivalent of the US Biomedical Advanced Research and Development Authority (BARDA), which is responsible for procurement and development of countermeasures against bioterrorism, chemical, nuclear and radiological threats as well as pandemic influenza and emerging diseases. The creation of an EU BARDA should be considered. The role of the European Agency for Safety and Health at Work (EU-OSHA) should also be strengthened to ensure healthcare workers are not put at risk.

The agencies and the Commission facilitate a lot of exchange of best practice and produce very relevant guidance and strategies. However, for the most part, following this guidance is voluntary. For example, EU Action Plans on antimicrobial resistance and vaccination should be reinforced with binding measures, including an EU vaccination card for citizens. Cancer screening guidelines could be made mandatory. In the COVID19 crisis we have seen that different Member States record deaths or recoveries related to COVID19 differently, which makes EU-wide comparison of data difficult. ECDC may develop guidance on this, but it will be up to Member States to follow it. Key guidance like this from the ECDC should be made mandatory, along with common protocols for hospitalisation and discharge of patients with infectious diseases. Standardisation, sharing of data and the adoption and promotion of

international health data standards, should also be addressed by the Commission in the creation of the European Health Data Space, while fully respecting European data protection framework, including the GDPR, and in full consultation with civil society.

New tech solutions and innovations may make a difference when facing pandemics and health crisis similar to COVID-19, and when exiting the current situation and restrictions. When new solutions emerge, EU should always aim for a common approach between MS enhancing cooperation and cross-border actions.

S&D calls for the budgets and competences of the ECDC and EMA to be increased, for the creation of an EU BARDA to be considered, and for the role of EU-OSHA to be strengthened. EU guidance and action plans should be made mandatory in some cases, and reinforced with legislative measures. Data needs to be shared more routinely, while ensuring quality and security standards, transparency about data access and control and fully respecting patients' privacy and the GDPR. In this regard, S&D calls for a proposal on the creation of the European Health Data Space.

### **One health**

COVID19 has demonstrated the inter-dependencies between human health and the health of our planet. The emergence of zoonosis, such as COVID19, that transfer from animals to humans is exacerbated by climate change and environmental degradation. More attention should be paid to the implications of unsustainable practices that lead to habitat and biodiversity loss and antimicrobial resistance.

We must clearly highlight the connections between human health, animal health and environmental protection, and explore ways to reinforce the application of 'One Health' approach in Europe, starting by taking action on the inappropriate and excessive use of antibiotics in humans, as we have already done for animals. The European References Networks (ERNs), which remotely join together European experts on specialist topics, should be expanded to include infectious diseases and zoonosis. Member States could build centres of excellence on these topics and other pressing health issues, which could join the ERNs.

The exacerbation of COVID19 by issues such as tobacco use, poor nutrition, air pollution and health inequalities shows the importance of continuing our work in those fields in a holistic approach.

S&D call for action on human, animal and environmental help to protect us against another emerging disease. Legislative action should be taken on antibiotic use in humans in the EU and an agreement should be reached at global level. S&D calls for the ERNs to be expanded to look at more issues including infectious diseases and zoonosis.

## **European Resilience**

The COVID19 crisis highlighted the lack of resilience of our underfunded healthcare systems, but also exposed weaknesses in our industries. S&D calls on the European Commission to develop a strategy for a “Resilient Europe”, consisting of a risk assessment map and intervention options to address, among other things, sound management and investments in healthcare systems and pandemic response at European level, including a plan for resilient supply chains in the EU. This is needed for the EU to regain its health sovereignty, as well as boosting the European medical and surgical manufacturing industry as a high-tech and high value-added sector. Health should be identified as a key Strategic Value Chain for the European Union.

Interventions should be focused on protecting and secure citizens, managing critical infrastructures and taking full advantage of digitalization and automation. Remote medical diagnostics and treatment will help to ease pressure on Europe's healthcare systems, providing specialised healthcare services over long distances, effectively eliminating the need for the physician and patient to always be present in the same place, reducing costs and limiting the possibility of transmitting infectious diseases between patients and healthcare professionals where appropriate. Needs and resources available at local and regional level could be assessed in order to provide information which would be very useful to the Commission in taking more centralised decisions in response to epidemics.

## **EU vision in Health Research**

COVID-19 is clearly showing us that we need a coordinated, collaborative and open approach in the field of research, especially research to help us prevent and recover from future pandemics. While in terms of research output Europe is a leader in terms of both quality and volume, better results will be achieved, including in the medical field, if this research is translated into products such as medicines, vaccines, equipment or devices meant to save or improve lives. The European Commission should be given a stronger role in coordinating research carried out at national level. Currently decisions relating to research are made primarily at the level of Member States. 'European research' is mainly considered to be research funded by the European Union rather than research undertaken within the entire European continent. While most scientific public health research publications (and abstracts) are now in English, public health research is mainly undertaken in national languages, which have to be translated for scientific reporting. Moreover, research projects through national funding agencies are often limited, by law or regulation, to researchers within the funding Member State, which means cross-border health research is still rare. The Health Programme is designed to encourage cross-border health research and projects, but has a very small budget. The European Commission, together with the Member States and the European Parliament, can contribute to overcoming barriers, avoiding duplication and supporting valid ideas in the best interests of patients and citizens. Open science will be crucial in this regard and as the EU has been a pioneer in this field, we should use this strength to push this leading position forward.

Horizon 2020 and Horizon Europe are meant to finance European collaborative projects in fields like environmental safety, health information, health determinants and health services, but Member States need to integrate these programmes and national programmes, which

will allow the European Union to better perform in health research and innovation and compete globally, avoiding the dependence from third countries. This will be key in the exit and recovery from the crisis. In order to help us achieve that, we need strong financial backing for research and innovation. When research is wholly or partially funded by European funding and other public funds, the results need to stay within the public domain and have clear affordability and accessibility conditions attached to them.

S&D calls for a new, more integrated approach to European research to ensure that it is fully coordinated and we can make the most of our world-class research capacities in the field of health. The budget of the Health Programme should be increased.

### **Health and Safety at Work**

Every worker has the right to a healthy and safe workplace, no matter the size of the employer, the contract or the place of employment. Safe workplaces are good for employees but also for businesses and the economy – fewer workplace accidents and diseases mean healthier and happier individuals, more work done in less time and more money saved for our healthcare systems. That is why we are expecting the European Commission to continue updating the Directive on the protection of workers from exposure to substances which cause cancer and mutations in DNA and extend it to include substances harmful to reproduction, as well as to cytotoxic substances.

The new Strategic Framework for Health and Safety has been long overdue and must reflect the COVID-19 crisis in terms of ensuring health and safety at the workplace. The pandemic has resulted in millions of employees working remotely, working under stressful conditions, overworking and putting their own health at risk. We urgently need a number of legislative measures to be put in place at the European level in this context.

S&D calls for legislation on the Right to Disconnect, a new Directive on Work-related musculoskeletal disorders such as back, neck or shoulder pain, and a new Directive on Mental Well-being at the Workplace aiming at recognising anxiety, depression and burn-out as occupational diseases, establishing mechanisms for prevention and reintegration of affected employees into the workforce, and protecting workers from mental illness in the workplace.

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<sup>i</sup> <https://www.europarl.europa.eu/factsheets/en/sheet/49/public-health>

<sup>ii</sup> <https://www.un.org/sustainabledevelopment/health/>

<sup>iii</sup> [https://www.europarl.europa.eu/doceo/document/RC-9-2020-0143\\_EN.html](https://www.europarl.europa.eu/doceo/document/RC-9-2020-0143_EN.html)