

Briefing

Is EU4Health fit for future crises?

Is the budget for the EU's most ambitious health programme up to the challenge of the Covid-19 health crisis and beyond?





Introduction

The outbreak of the Covid-19 health crisis in the year 2020 particularly affected the European continent. Faced with shortages of masks and tests and many deaths, certain actions by European states could suggest a lack of coordination and solidarity between members of the European Union. Aware of these shortcomings and this bad image, the European Commission has taken action. In order to respond to the strains placed on European health systems by the COVID-19 pandemic, the EU institutions instituted an envigored fourth EU programme on health. Named "EU4Health", this programme is the largest in the EU's history in terms of health spending, totalling ξ 5.1 Billion, and is dedicated to providing funding to EU countries, health organisations and NGOs. The intended goals of EU4Health are:

- To boost the EU's preparedness for major cross border health threats by creating:
 - reserves of medical supplies for crises
 - \circ a reserve of healthcare staff and experts that can be mobilised to respond to crises across the EU
 - increased surveillance of health threats
- To strengthen health systems so that they can face epidemics as well as long-term challenges by stimulating:
 - o disease prevention and <u>health promotion</u> in an ageing population
 - o <u>digital transformation</u> of health systems
 - o <u>access to health care</u> for vulnerable groups
- To make <u>medicines</u> and <u>medical devices</u> available and affordable, advocate the prudent and efficient use of <u>antimicrobials</u> as well as promote medical and pharmaceutical innovation and greener manufacturing.

In this briefing, all four geographies of the Dods Monitoring team (the EU, Germany, France and the UK) take a deeper look into the new EU4Health programme.





The EU

Public health is an area which falls within the competence of Member States and therefore in which the European Union can only complement their action. However, this limited room for manoeuvre has begun to widen in the face of global health challenges, especially the Covid-19 pandemic. EU competence in this area is based on Article 168 of the Treaty on the Functioning of the European Union, which provides a broad enough basis for action in the following areas: improving public health; health information and education; prevention of diseases and causes of danger to physical and mental health; combating, transmitting and preventing major health scourges; monitoring, warning and combating serious cross-border threats to health; and reducing the harmful effects of drugs. In concrete terms, this enables the European institutions to adopt binding texts, for example on tobacco.

There has been an increase in the European budgets dedicated to health, rising from ≤ 321.5 million between 2008 and 2013 to ≤ 449.4 million over the period 2014-2020. In the same logic, the EU4Health programme succeeds the Horizon 2020 programme with a record budget proposal by the European Commission: 9.4 billion for the years 2021-2027.

A hard-negotiated budget

Since the European Commission announced its creation, the budget of the EU4Health programme has undergone several changes. Following the European Commission's health budget proposal of \notin 9.4 billion for this period, the European Council agreed on a much lower amount of \notin 1.7 billion. The worsening health situation in Europe and the persistence of the Covid-19 epidemic have nonetheless prompted the European institutions, notably at the instigation of the European Parliament, to review their position.

On December 15, the <u>Parliament</u> and <u>Council</u> announced they had reached an agreement on the budget.

Parliament's rapporteur Cristian-Silviu Busoi <u>stated</u>: "The COVID-19 crisis has exposed the need for well-defined and adequately-financed health instruments. We also need to boost innovation and invest more in health in general. It was crucial to increase funding for the EU4Health Programme from \notin 1.7 billion to \notin 5.1 billion in order to be able to deal with future pandemics and health threats, and to make our health systems more resilient. I am also happy that this deal will contribute to the establishment of a reserve of health crisis relevant products, such as essential medicines, vaccines and medical devices."

Jens Spahn, German Federal Minister of Health, representing the German Council Presidency, <u>said</u>: "This agreement shows the EU's determination to protect the health of its citizens. This programme, with its budget and scope, gives our Union the tools and capacity to better prepare for and cope with future health crises. At the same time, it allows a strong focus on long-term health issues, such as cancer and mental health. I expect that EU4Health will have a clear EU valued added in complementing member states health policies."

These announcements were welcomed by the Commission. Vice-President for Promoting the European Way of Life, Margaritis Schinas, said: "The provisional agreement is yet another proof that the European Health Union is becoming a tangible reality. It is our dedicated answer to Europeans who want Europe central, and not an accessory to health policies. We are taking concrete action for more cooperation, more coordination and definitely more EU overall in health." Stella Kyriakides, Commissioner for Health and Food Safety said: "I warmly welcome the swift provisional agreement of the European Parliament and the Council on the most ambitious funding programme for health ever. With €5.1 billion, EU4Health will help strengthen our crisis preparedness and management of cross-border health threats as well as reinforcing the EU's healthcare systems overall. EU4Health opens up a new chapter for EU health policy and sends a clear signal to



people in Europe that public health is our priority and that we have listened to their concerns."

In January 2021, speaking at an EPP event on the subject of health, **Commissioner Kyriakides** <u>remarked</u>: "A key issue here is money and funding. That is why an essential pillar for the European Health Union is the new EU4Health Programme. With EUR 5.1 billion thanks to the European Parliament, it is over ten times larger than any previous Health Programme. It will enable us to deliver important priorities that improve public health and support more resilient health systems across the EU. The European Health Union will also be the umbrella for many critical priorities in the area of health, such as the Pharmaceutical Strategy and Europe's Beating Cancer Plan."

A programme consisting of several concrete actions

An example of how EU4Health is already being planned for in member states was <u>highlighted</u> by the EFPIA and the Innovative Medicines Initiative in mid-January.

Earlier in November 2020, the Commission also put forward a number of <u>proposals</u> intended to build a stronger <u>European Health Union</u>, with the aim of: better protecting the health of EU citizens, equipping the EU and its Member States to better prevent and address future pandemics, and improving resilience of Europe's health systems. In particular, the proposals include a Regulation on serious <u>cross-border threats</u> to health, and expanded roles for the <u>EMA</u> and <u>ECDC</u>. During an <u>exchange</u> with the European Parliament, Commissioner Kyriakides noted that the crisis has shown the need to give the EU's key health agencies more competences to better tackle cross-border threats.

In February 2021, DG SANTE published a statement text in which it <u>described</u> the goals of the European Health Union, noting that EU4Health will be crucial in financing these efforts.







Germany

Germany took over the presidency of the Council of the EU in July 2020 for the rest of the year. Its six-month presidency was dominated by the European response to the COVID-19 pandemic and it coined its campaign under the slogan "**Together for Europe's recovery**". Consequently, in preparation of the EU4Health programme, Germany occupied the role of a "*neutral mediator*" trying to forge a common position of the European member states.

A balance between European and national competences

On the national level, responding to <u>parliamentary enquiries</u> from the opposition, the government clarified where it sees the main competency of the supranational institutions. It emphasizes on levelling up cross-border surveillance capabilities, the abilities to detect epidemic outbreaks and to trigger protective measures consistently and on time. The German Government backs enlarged competencies for the <u>European Centre for Disease Prevention and Control</u> (ECDC) to *supplement* the necessary steps on the national level. A point affirmed by **Chancellor Merkel** during a <u>recent</u> <u>questioning</u> in the Bundestag. Same accounts for the improvement of resilience in terms of medical equipment, vaccines, protective equipment, pharmaceuticals etc, by building up the capacities of rescEU while building a new established "National Health Reserve". However, the opposition FDP has warned against Brussel's "*competency pretensions*" in the health sector. They demand that financial authority must remain with the national parliaments.



Indeed, according to the government's interpretation, the main tasks to improve the quality and coherence of the European health systems shall be done by member states. Specifically, the objectives of the program aim to progress the digital transformation of European health systems, improve the access of vulnerable groups to health services, strengthen the resilience of the medical workforce, accelerate the fight against non-communicable diseases (NCDs), and build the foundations of what shall become a European health data infrastructure. To support these developments, Germany has already invested in the improvement of its legal framework with the goal to make its health system ready for a new decade of digitalization. Most recently, the German Government presented its national <u>Data Strategy</u> which hopes to *"significantly increase data provision and data utilisation in Germany and Europe"*.

While not specifically aimed at the health sector alone, this data strategy includes many potential points of contact with future initiatives and objectives under the EU4Health plan. For example, the strategy articulates the will to establish a code of conduct that shall make the cross-border utilisation of health data legally watertight in accordance with high standards of data protection.

Health data

The strategy emphasises strongly on concerns of ethical data usage and data protection. A national characteristic of the debate about digitalisation in general. Though these concerns have blocked digital transformation in the German health sector in the past, the Ministry of Health under the guidance of **Minister Jens Spahn** has pushed for what could be called a campaign for digitalisation during the current legislative term. In the past weeks a third "digital health law" has passed the cabinet and shall pass parliament before elections in September. Without a quick and successful implementation of these reforms, connecting Germany to a "Digital Europe" might become a lasting challenge. While the need for these reforms is widely acknowledged, it is also met with some concerns over the rapidity with which they are introduced. It is yet to be seen how the country will live up to its ambitious goals, considered that in the past, it has struggled to keep up with the pace of digitalization compared to other EU countries. The European Fonds for Regional Developments could provide crucial incentives to stakeholders to meet these goals.

It will also be interesting to see how the comprehensive scope of the EU4Health programme will be coordinated and if the German federalist structure will allow for all *Bundesländer* to profit equally. The current pandemic has shown that not only do large differences exist in their ability to cope with crisis management, but that it is hard to implement top-down solutions in the areas of digitalisation, prevention, and education of medical professionals. The latest example of this is the implementation of a new <u>Surveillance Outbreak Response Management and Analysis System</u> (SORMAS). Some public health boards refuse to implement the software and the federal government has no legal capability to enforce it. Given the intertwined and complementary structure of the EU financing programmes, a risk persists that federal states that struggle to keep up with current reform processes might fall further behind, while the existing champions of the German healthcare sector profit.

An advocate for EU4Health rather than a beneficiary

Compared to the comprehensive scope, the financing framework with €5,1 Billion, is still rather moderate. For the modernisation of its public health boards alone, Germany plans a €4 Billion investment. Considering the large sums the





country plans to invests in its effort to catch up with digitalisation processes and the rather low attention EU4Health has received inside the country, there might be some awareness that a lot of the structural improvements must be undertaken on the national level. While the European approach for better cooperation, coordination and resilience is widely supported, Germany appears to be more of an advocate for EU4Health, rather than a main profiter of its financial resources.







France

During the health crisis, France has tried to defend greater solidarity and cohesion within the European Union. As President **Emmanuel Macron** has, on many occasions, defended the idea of "European sovereignty", it is therefore quite natural that the country has positioned itself in favour of the EU4Health programme, by supporting the initiatives of its German neighbour.

A reluctant opposition to this European programme

Several criticisms have arisen from the national opposition. For example, **Joelle Melin**, MEP Rassemblement National, strongly <u>criticised</u> the commission's proposal. According to her, the European Union acts as "*a Trojan horse to encroach as much as possible on the prerogatives of the Member States in the area of health, instead of confining itself to simple public health measures.*" Within her party, the vision of a Europe of health would rather be that of "*close and responsible coordination and collaboration between Member States in the field of public health*", but in a different form.

France Insoumise, for its part, <u>pointed</u> out the gap between the promises of the speeches and the budgetary reality. Indeed, in a press release from 17th September 2020, the left-wing party criticised the President of the Commission **Ursula von der Leyen** who seems to "forget that the European health budget has gone from 9.3 billion to 1.67 billion euros following the negotiations on the recovery plan." and the "63 times that the European Commission has asked Member States to reduce public health spending."

The desire for a more cohesive Europe





In the face of these criticisms, the French Government sought to defend the relevance of this new European programme. On 18 June 2020, **Olivier Véran**, Minister of Solidarity and Health, and **Agnès Pannier-Runacher**, Secretary of State to the Minister of the Economy and Finance, <u>brought</u> together the Strategic Sector Committee (CSF) for "Health Industries and Technologies". On this occasion, they called for the establishment of enhanced European coordination to support the European Union's capacity to deal with health crises.

Thus, the CSF welcomed the plan proposed by the European Commission which "*places health at the centre of European recovery*" with this new dedicated budgetary programme and the strengthening of the research and innovation programme "Horizon Europe" on the same theme. The creation of a "*European industrial ecosystem for health*" announced by the Internal Market Commissioner, **Thierry Breton**, should, according to the CSF, allow "*structuring all European actions towards shared objectives*", and in particular a reinforcement of European strategic autonomy for health.

In the same vein, on the occasion of a topical question in the Senate on "Cross-border health cooperation", during the <u>public session</u> of 16th December 2020, the minister for solidarity and health, **Olivier Véran**, explained the French position on the EU4Health programme. According to him, the coronavirus-related health crisis has shown "*the limits of the organisation of crisis management and the lack of cooperation between Member States*". Expressing his desire for a "*robust, effective and mutually supportive Europe of health*", he defended the principle of extending the mandate of the European Centre for Disease Prevention and Control and of revising the decision on serious cross-border health threats. Making health a priority of the French presidency of the European Union in January 2022, he also supported a strengthening of the Union's capacity to prevent and manage health threats and the creation of a biomedical research and development agency on the model of the Barda (Biomedical Advanced Research and Development Authority).

The EU4Health programme corresponds to some of the government's priorities in the field of health and particularly on prevention. Thus, it seems that there are complementarities between this programme and the "Ma Santé 2022" bill adopted by the French parliament in July 2019, such as: prevention of risky behaviour such as tobacco or alcohol consumption, or the development of digital technology with the deployment of digital health services and the creation of a health data hub.

Health: a major challenge for the 2022 presidential elections

In the long term, it will be interesting to see how the implementation of the EU4Health programme will be coordinated with the urgent needs of the French health system. The health crisis linked to Covid-19 has revealed, among other things, an urgent need for resources for public hospitals as well as for an increase in the salaries of health professionals. These costly needs are above all linked to national decisions and will be fiercely debated during the campaign for the 2022 presidential elections, which risks making the implementation of the EU4Health programme even more invisible.







The UK

Whilst the UK is no longer a member of the European Union, the EU4Health Programme did allow third party countries, such as the UK to participate. In an <u>Explanatory Memorandum</u>, UK Health Minister, **Ed Argar**, explained that:

"Careful consideration was given to the benefits of participation in the EU's future Health Programme's to the UK and the EU, including the value of participation to the UK taxpayer, and based on this assessment Ministers decided not to pursue future participation in the EU Health Programme."

The Government decided that all the areas included in the EU4Health Programme fell under UK competence and the Government, therefore, did not consider participating in the programme. Argar explained in his memorandum that the UK would not be offering a domestic alternative for the programme, because there was domestic funding available from UKRI and NIHR. The UK Government explained that the terms of the Withdrawal Agreement meant that for the current EU Health Programme (2014-20), UK organisations would continue to receive funding for the lifetime of their projects and could continue to bid for funding during 2020. This has now expired.



The EU4Health Programme is set to address a number of challenges, including: the development of new medicines; procurement; supply of medicines, Personal Protective Equipment; health security; and other health issues. Over the last year, the UK Government has addressed these same issues in its own way.

Development of new Medicines

Whilst the EU Programme has an aim of speeding up clinical trials and developing innovative medicines, the UK's NHS Health Research Authority this month <u>announced</u> the launch of a new service with the same goal.

The new service for pharmaceutical companies and research organisations will offer a swift review of global trials and first-in-human studies, developing medicines in key areas of patient need such as heart disease and diabetes.

Procurement

The UK's procurement process during the pandemic has been surrounded in much controversy, with Opposition claims of <u>cronyism</u> for expensive Government contracts. The health service has not been immune to the reports, with the operation of <u>Track and Trace</u> a particular sticking point.

In December last year the Government issued a consultative <u>Green Paper</u> "Transforming public procurement," which reinforced the Government's post-Brexit goal to "speed up and simplify our procurement processes, place value for money at their heart, and unleash opportunities for small businesses, charities and social enterprises to innovate in public service delivery."

Supply of Medicines

The recent border and trade threats between the UK and the EU has caused concern amongst stakeholders in the UK around the supply of medicines. Threats to restrict the UK's access to vaccines produced in Europe has reignited theories of vaccine nationalism.

It has prompted the CEO of NHS England, Sir Simon Stevens, to <u>tell</u> a recent session of the Health and Social Care Committee that he hoped that pharmaceuticals would build up more resilient domestic supply chains which could ensure the smooth production and distribution of new and innovative medicines. The UK Government's recent deal with CureVac to manufacture is a signal of its intent to secure its supply of, in the short-term, vaccines and in the long-term medicines.

Personal Protective Equipment

A huge concern in the UK during the early months of the pandemic was the supply of PPE. A Public Accounts Committee <u>report</u> this week criticised the Government's stockpile and pandemic plan for leaving frontline workers "risking their own and their families' lives to provide treatment and care."

The UK Government responded by awarding over 8,000 contracts in its Covid response, which it has reassured stakeholders will be enough to cover the course of the pandemic. Domestic production has increased significantly, though there is little assurance that the products will be fit for the future.





Public Health

On the 18th August last year, the UK Government announced the creation of a new public health body, that would bring together the work and capabilities of Public Health England (PHE), NHS Test and Trace, and the Joint Biosecurity Centre.

The National Institute for Health Protection (NIHP) began work immediately and would be in formal operation from Spring 2021. Its primary responsibilities would be focusing on the coronavirus pandemic, and ensuring the country was better equipped to respond to future health protection crisis.

The new body is expected to be designed on Germany's Robert Koch institute, though the publication timelines for the consultations on the new system are already running behind <u>schedule</u>.





Conclusion

Faced with the most serious health crisis in its history, the European Union has undeniably had difficulty in reacting. The first few weeks were marked by a lack of solidarity and cohesion between Member States. However, and not for the first time, the EU managed, through discussions and negotiations, to create new tools to fight effectively against a new threat. This has resulted in the creation of EU4Health, the largest health programme in the EU's history, with a budget of €5.1 billion, ten times more than the previous one.

Having to do without the United Kingdom now, Germany and France have strongly supported this new programme although they are not the first beneficiaries, a sign of a desire for greater solidarity within the EU.

However, despite this record budget, this programme does not represent enough money to meet the health challenges of tomorrow. <u>Compared</u> to Germany's €360 billion of health spending in 2017, or France's €260 billion for the same year, a budget of €5.1 billion seems rather low. Despite this, the programme is also symbolic. While it may seem insufficient in the short term, it is important to look at the starting point of its negotiation. To conclude, the EU4Health programme, as the starting point for a possible "Health Europe", can be defined as imperfect but also ambitious in a longer-term perspective.





MONITORING

Essential information and connections

London 11th Floor | The Shard | 32 London Bridge Street | London SE1 9SG Brussels 7th Floor | Rue du Trône 60 | Brussels 1050 | Belgium Edinburgh 32 Calton Road | Edinburgh | EH8 8DP Tour Voltaire | 1 place des Degrés | CS 80235 Puteaux | 92059 Paris La Défense cedex +44 20 7593 5500 +44 20 7593 5501 customer.service@dodsgroup.com www.dodsgroup.com

Registered in England number: 04267888 © Dods Group plc 2017