

White Paper

A New Political Cycle in the EU — What it Means for Health

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Introduction

The new political landscape in the European Union (EU) will have implications for EU health initiatives. This article analyses what the new European Parliament, Commission and Council agendas mean for health over this 5-year political cycle.

Key points

European citizens are as keen as ever for action to improve health but the EU's constrained remit in health policy, and the current political makeup, renders the EU's ambition limited to a few areas:

- Supporting medicine innovation, particularly in biotech, by funding Research & Development (R&D) and unlocking the finance sector to fuel its translation to the market, for example, by enabling the Capital Markets Union and Banking Union, and EU-wide venture capital.
- Strengthening the EU's manufacturing capacity, supply chains and alleviating shortages of medical products.
- New large-scale initiatives to advance the research, prevention and treatment of specific noncommunicable disease areas, particularly mental health, cardiovascular and degenerative diseases. These will be based on the Beating Cancer Plan, a 4-billion-euro initiative to improve the prevention, diagnosis and treatment across the EU, although likely with a lot less money in reality.
- Implementing initiatives from the previous cycle, which will encompass a large amount of Commission bandwidth, including the European Health Data Space; revision of the way the EU regulates pharmaceuticals; centralised route for Supplementary Protection Certificates, a key plank of Intellectual Property Rights protection; the Health Technology Assessment Regulation's pan-EU clinical assessments; Beating Cancer Plan; and meeting the deadline to disperse the Recovery and Resilience Funds.

In addition to these, new political imperatives, and unforeseen events, along with the size of the EU budget, will determine what will be undertaken in health.

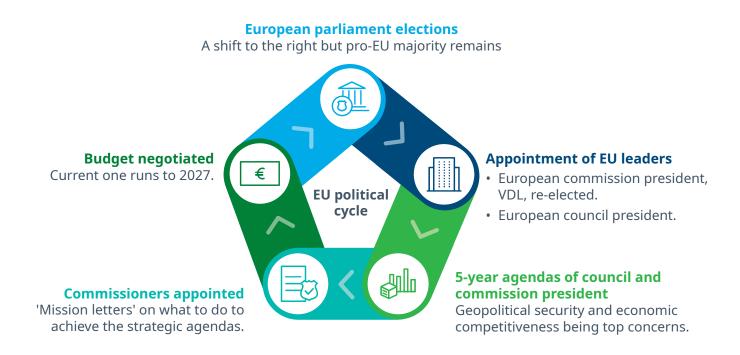


The previous European Union (EU) political cycle (2019-2024), saw an unprecedented surge of EU health initiatives, funding, and legislation, due to the COVID-19 pandemic; as has always been the case for the EU, crisis led to new action and new powers for the Union. This is particularly important for health where the foundation for new powers in the Union's underlying treaties are so weak, despite health being a top priority amongst the electorate¹. In response to this pandemic, the EU invested heavily in health initiatives, including 5.3 billion euros under EU4Health, upfront co-financing for vaccine procurement and disease surveillance, and poured tens of billions of euros into health systems via the under-recognised Recovery and Resilience Funds — summarised in our report². In tandem, new EU mandates in health were granted under the ambitiously named European Health Union³, and the EU's Data Strategy⁴ led to the major initiative to connect EU health data within a European Health Data Space⁵. It also drove forward legislation in a number of areas including a revision of the way the EU regulates pharmaceuticals; introducing a centralised route for Supplementary Protection Certificates, a key plank of Intellectual Property Rights protection; and passing the HTA Regulation, which will see joint health technology clinical assessments begin in 2025.

The current political cycle (2024-2029) will have several health challenges to contend with:

- Ageing populations, who will require more care, compounded by declining birth rates.
- Strengthening health systems who remain desperately hungover from COVID-19 and face budgetary constraints and staff shortages from a resigning, retiring and burnt-out staff base⁶.
- Improving the EU's innovation engine and affording those innovations, particularly medicines.
- Preventing shortages and ensuring the supply of medicinal products and devices.
- Preparing for the next pandemic and other health threats, particularly antimicrobial resistance (AMR).
- A growing environmental responsibility in preparing for and mitigating climate change and removing pollution.

Figure 1. A simplified schematic of the new EU political cycle



European Parliament

The European Parliament must approve the College of Commissioners (the EU equivalent to ministers) and therefore has power in shaping their agendas for the next 5-year term. During this term, the Parliament's primary role is to amend the legislative proposals that come out of the Commission, the EU's civil service. Whilst weak by national standards, the Parliament plays a key role in direction setting and the content of final legislation.

The political makeup of the Parliament has changed after the recent election. The difference between the former and current Parliament are displayed below by political groupings⁷ (Figure 2 and 3).

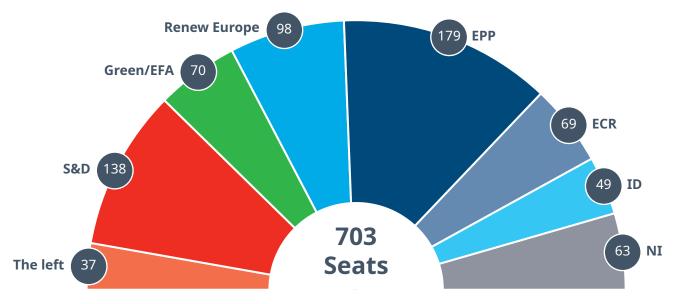
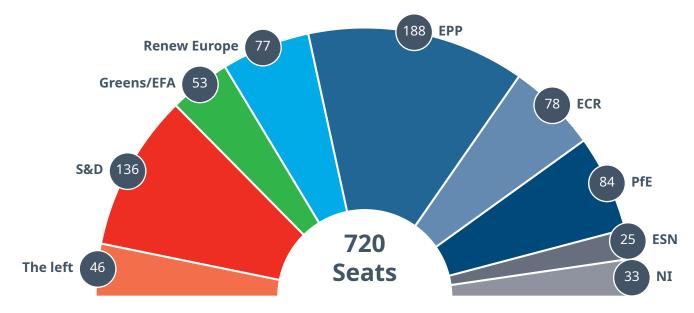


Figure 2. Composition of European Parliament 2019-2024.

The political leanings of the parties shown by their placement on the hemisphere.

Source: European Parliament⁸





The political leanings of the parties shown by their placement on the hemisphere.

Source: European Parliament⁹

What will this mean for health?

Politically, the shift to the right has not been as dramatic as expected. This will limit the consequences to the Parliament's health activities: influencing the Commission's agenda, staffing and priority setting of the committees, and voting. Although there has been a change in the makeup of the smaller political groups, this does not sway the pro-EU balance of power: the coalition of pro-EU groups, European People's Party (EPP), Socialist and Democrats (S&D), Renew (ALDE), and recently the Greens, remains viable. In previous parliaments, this coalition frequently acted to steer parliamentary decisions and block Eurosceptic initiatives, imposing a 'cordon sanitaire' to isolate and disempower the farright groups. In this Parliament, the EPP is showing new willingness to work with the right-wing, breaching this cordon and weakening the coalition. However, the pro-EU arithmetic remains dominant.

To understand the priorities of the Parliament this term, the manifestos the major political groups can be used as a proxy. Within these manifestos, health features sparingly even though it is so important for voters, because the EU has limited powers in health to deploy. The common priorities between the groups are mental health, included in the two largest parties' manifestos, and funding for health innovation, which may help mitigate health research from the anticipated cuts to the overall EU budget (Table 1). These groups incorporate the Members of the European Parliament (MEPs) from aligned national political parties and orchestrate the MEPs in a similar way. They also include leading national level politicians of these parties and Commissioners. They will seek to implement their manifesto areas via political pressure onto the Commission's agenda, as well as in amending legislation.

Given the limited electoral accountability at the EU level, due to a lower voter awareness and turnout than in national elections, the extent to which the groups stick to their manifesto priorities throughout the term varies. However, their political wrangling with the Commission President Elect, Ursula von der Leyen (EPP), has shown the difference between the frugal manifesto priorities and the expansive ask of what the groups demand in health in practice.

SUMMARY

Despite a growth in far-right parties, the pro-EU majority in the Parliament should see it retain a similar positivity towards EU action in health as in previous terms. However, any action undertaken by the EU will also be determined by the priorities of the other EU institutions and national leaders¹⁵.

EUROPEAN GREENS	PES SOCIALISTS & DEMOCRATS	ALDE PARTY	EPP european people's party	ECR GROUP
Health is somewhat absent, beyond measures to improve the indirect social, environmental, and dietary drivers of public health ¹⁰ . However, due to the interests of their MEPs, it can be expected that they remain active in parliament on health- related topics.	 Health is well represented, with the following priorities listed:¹¹ Pandemic preparedness and response. Creation of a new mental health strategy. Fair and transparent medicines pricing. Initiatives to support biomedical research. 	Health is notably absent in comparison to the other larger parties to its left and right ¹² . This will likely mean ALDE (Renew) continue to take a pragmatic approach to health legislation, as they are known for.	 Health is represented with the following priorities listed:¹³ A mental health action plan which focuses on Alzheimer's disease, Dementia, and Parkinson's. A cardiovascular Health Plan. An ambitious aim to double the EU's overall R&D funding. 	Health is absent from the European Conservatives and Reformists (ECR) manifesto ¹⁴ .

Table 1. The major European parties' manifesto mentions relating to health. With parties ordered by political persuasion from left to right.

The Council

The Parliament is only one centre of power. The Council, which consists of Member State (MS) national governments, is perhaps the most powerful institution. The political makeup of the Council affects its voting and its political priorities to a greater extent than in the Parliament as many of its decisions require larger 'qualified' majorities or unanimity, which enable smaller political blocs to stonewall initiatives. The makeup of the Council has been shifting to the right¹⁶ with national governments, or regressing to the mean, depending on what timeframe you pick (Figure 4). This rise in right-wing, Eurosceptic governments may make the Council less inclined for bold action at the EU level, particularly when it comes the budget¹⁷.

It should be noted that this does not take into consideration the population of the MS within each party. As population impacts voting weight within the Council, this is not a true representation of the change in power between the groups over time.

What will this mean for health?

The Council has put out two documents detailing its priorities, the first is from the heads of state: its strategic agenda 2024-2029. The second is from ministers in the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council: 'Future of the European Health Union: A Europe that cares, prepares and protects'²⁰.

COUNCIL STRATEGIC AGENDA 2024-2029

In June, the European Council agreed their Strategic Agenda 2024-2029²¹. This comprises the top-level wishes from the heads of MS to be implemented by the EU. Whilst non-binding as a document, it sets out the priorities that they expect the Commission to work on. Unsurprisingly, given current events and the Council's political makeup, and it was a geopolitically focussed list with security and economic competitiveness being the top concerns, supported by a firm push for EU enlargement.

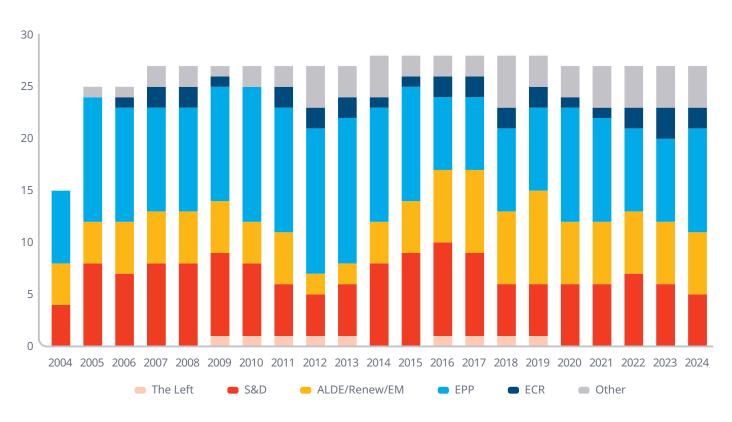


Figure 4. Political composition of the European Council over time by EU political affiliation of the Member States.

Source: LSE¹⁸ + European Parliament¹⁹

Health was mentioned in the document sparingly, with one reference to ensuring capacity in pharmaceuticals (which could mean reshoring manufacturing), another rather nebulous reference to access to medicines and one on pandemic preparedness. In other areas relating to health, the leaders call on the EU to complete the Capital Markets Union and Banking Union, which should enable²² pan-EU early stage funding such as venture capital, where the EU struggles:

"EU venture capital relative to GDP is still only a fifth of that of the United States." Luis de Guindos²³, Vice-President of the ECB.

THE FUTURE OF THE EUROPEAN HEALTH UNION

This document, approved by the national Ministers for Health, has a strong focus on public health promotion and disease prevention. What was notable was the relatively limited space for pharmaceutical or medical device innovation. Below are the key parts.

It begins by addressing the health workforce, suggesting the EU orchestrates national strategies, supporting them with existing funds.

The MS Ministers then invite the European Commission and national governments to "consider" a mechanism to determine the most pressing unmet health-related needs and prioritise them for research funding through the successor to Horizon Europe.

On non-communicable diseases, it gives a brief mention to mental health as a priority (in alignment with the Parliament) and calls to finish what was started and implement the outcomes of the EU's flagship initiative on cancer, its Beating Cancer plan.

On AMR, the MS reiterate their aim of curbing it but provide limited propulsion, requesting a voluntary pull incentive for existing and new antimicrobials but only using existing EU funds. These EU funds will likely be stretched thin for the next budget cycle and so are unlikely to provide sufficient fuel for an impactful incentive without the addition of MS money.

Pandemic preparedness is included as a clear priority. The MSs focus on improving the clinical trial landscape for the next pandemic, learning the lessons from COVID-19, where a flurry of small and underpowered trials did not generate useful evidence for treatment decisions. They propose an 'ever-warm'; network of clinical trial sites, ready to fire up and test medical countermeasures. Feeding this would be a mechanism to fund robust clinical trials, run with academia, when the next pandemic hits. Beyond clinical trials, the MS ask for simulations to prepare for the next pandemic, and a review into how the EU's bodies govern its pandemic response, with a spotlight on the relationship between the European Medicines Agency, European Centre for Disease Prevention and Control and the Health Emergency Preparedness and Response Authority (as well as DG SANTE).

The EU's clinical trial landscape is subject to several ideas to fertilise it, vis-à-vis other regions²⁴ including a public-private partnership to help recruit patients. Notably, the MS address the challenged implementation of the Clinical Trial Regulation — but only with a high-level request to enhance coordination of the regulatory and ethical reviews across MS, without any detail on how.

Another priority is to tackle the medicines supply issues that are plaguing the EU, and countries globally. They call for the Commission to build a better understanding of supply and shortages to inform stockpiling coordination across MS. On critical medicines, in addition to the planned work, they request a Critical Medicines Act to strengthen EU production and diversify supply chains of critical medicinal products and ingredients.

Regarding environmental concerns and pharmaceutical manufacturing, MS want to act, but seemingly softly, with no hard law beyond what they are already doing in the revision of the pharmaceutical framework and the Urban Wastewater Treatment Directive. They call for a roadmap to help stakeholders reduce environmental risks across the lifecycle. Somewhat belatedly, the MS also call for a holistic EU agenda on climate on health, including both adaptation and mitigation, but without additional money.

SUMMARY

In the minds of the heads of states and governments, health appears largely absent, as it has in previous strategic agendas. But down at the level of national Ministers of Health, there is more detail and a stronger focus on health promotion, although this is far from an ambitious agenda. Perhaps unsurprisingly, the priority topics are those which will have been causing national governments the most headaches: pandemic response and shortages of medicines and healthcare professionals. Less ambitious action is proposed in the other areas.

The Commission

The final major institution of the EU is the Commission, who plan, prepare, and propose new laws and initiatives. The Commission's priorities are shaped by those of the Council and Parliament, as these institutions decide the Commission President and Commissioners and thus require policy concessions for their support. The President-elect, Ursula von der Leyen, was re-elected by the Council in June after promising alignment with their priorities. She then secured the required votes in the Parliament, after an intense period of negotiation with the political groups to garner their votes in exchange for including their policy priorities — as in the manifestos above — in her work programme.

The President has now set out the results of those negotiations with the Council and Parliament in her 'Political Guidelines 2024-2029'²⁵. The Council then agreed with the President one Commissioner per MS, each of whom acts like a national government minister in charge of their part of the Commission, and who will be charged with delivering their section of these guidelines. Their broader priorities have been set out in 'mission letters'26 and the entire Commission is voted upon for approval by the Parliament.

Figure 5. Ursula von der Leyen, President of the European Commission



Source: European Union, 2022²⁷

What will this mean for health? POLITICAL GUIDELINES 2024-2029 AND MISSION LETTERS

For the most part, the Guidelines and Mission Letters run through measures to boost economic growth and ensure security, with defence seeing a raft if new actions including establishing a European Air Shield and a new Commissioner post. This is in alignment with the Council's Strategic Agenda. In health, this translates to a limited number of initiatives, focused on innovation. There are several large-scale initiatives that indirectly affect it, but few health-specific priorities. The documents are nonexhaustive, however, and explicitly leave the door open to more health initiatives for this 5-year term, likely to come from the institutions and the political priorities of the Commissioner for health. The areas where there is overlap between Parliament and Commission are in social, environmental, and biomedical research. Between the Council and the Commission, the EPSCO Council's focus public health overridden to favour innovation, but with overlap on strengthening critical medicines supply chains and EU manufacturing, and greening it, as well as the Capital Markets Union.

The initiatives directly affecting health are in noncommunicable diseases. Large scale initiatives like the existing 4 billion euro Beating Cancer Action Plan are signposted as preventative initiatives for mental health and cardiovascular, and degenerative diseases and autism where the focus is on R&D. These initiatives will likely include funds for the research, diagnosis, and treatment of the diseases on an impactful scale.

There are no new initiatives in communicable diseases, except for glancing mentions of pandemic preparedness as part of a Preparedness Union Strategy for chemical, biological, radiological, and nuclear threats. This Strategy will be based on a report coming out later this year by Finnish President Sauli Niinistö and may be followed by an EU Preparedness Law to align national preparedness.

Of the areas indirectly affecting health, biotech as a sector receives the most ambition, with a clear priority given to fertilising Europe's 'valley of death' — its difficult path from research to market for these biology-based innovations. A Competitiveness Fund will flow in large scale investment to the sector; a European Biotech Act, coming in 2025; and a broader Strategy for European Life Sciences. What these initiatives will mean in practice, however, will only be clear once more detail emerges.

Commitments to prevent medicines and device shortages are made. This will be done by improving the supply chain resilience of ingredients, increasing EU manufacturing (it is unclear how), the stockpiling of 'strategic reserves', and the joint procurement of medical countermeasures against public health threats, all as part of the planned Critical Medicines Act.

On the social determinants of health, implementation of the Action Plan on the European Pillar of Social Rights will continue. It will introduce the first-ever EU Anti-Poverty Strategy. As part of this, the Child Guarantee to education, healthcare and other essential public services will be strengthened.

There are several environmental initiatives featured within this document, many of which will impact healthcare. For greenhouse gas emissions, the target of a 90% reduction by 2040, relative to 1990, will be put into law, codifying the trajectory from the EU's 55% target for 2030 to its net zero by 2050. This will be coupled with an Industrial Decarbonisation Accelerator Act to support industries to transition. How and at what pace this will assist organisations in healthcare to meet these reduction targets is unclear.

On the pollution front, the EU's chemical regulatory framework, REACH, will be simplified and clarity will be provided on reducing Per- and polyfluoroalkyl substances (PFAS) "forever chemicals" — an existing promise but one of great importance for device and pharmaceutical manufacturers who currently rely on these chemicals.

In delivering the economic aims of the Commission, data is seen as a critical commodity, and a Data Union Strategy is proposed but without detail as to how it maps onto the existing EU Data Strategy²⁸ or of its content. In addition to this, a European action plan on the cybersecurity of hospitals and healthcare providers will be proposed in the first 100 days, and there will be an 'Apply AI Strategy" to improve the delivery of a variety of public services, such as healthcare, supported by facilitating supercomputer access for AI development.

Not forgetting finance, there is a commitment to enabling the free movement of capital across the EU (although such commitments have been made in the past with limited success). This includes yet another Union entitled initiative: the European Savings and Investments Union. This Union will attempt to redirect European savings and pension funds into the stocks and shares of innovative European companies, including those in healthcare. Another important financial initiative is in public procurement — which accounts for 14% of EU GDP. EU firms, particularly innovators, will get preferentially picked in certain strategic sectors. But it is not clear what these sectors would be and how this would operate were it to include healthcare.

Delivering many of these initiatives will require money. Counterintuitively, the budgetary cycle of the EU does not coincide with the EU policy cycle. The current budgetary cycle, called the Multi-annual Financial Framework, runs between 2021-2027 and the new one will run from 2028. With battles over the next EU budget soon to start, Ursula Von der Leyen proposes a budget which is more political: one which is more closely aligned with the policy priorities of the EU and where disbursements to MS and regions depend on their implementation of these priorities. Her Commission will put forward a budgetary proposal by 1 July 2025, which will be amended and agreed by unanimity at the Council, and by the Parliament. A major part of this budget affecting health is the allocation for research funding, and here, there is a pledge to increase spending. This would mainly be apportioned to the successor of Horizon Europe, the EU's major research programme and the world's largest at 82 billion euros. Within this apportion, priority will be given to the European Innovation Council, the EUs venture capital fund – benefitting EU health startups. However, this proposal is just that, a proposal, and budgetary decisions are mainly decided by the MS, as the ones who have to put their hands into their pockets. It is therefore unclear whether this increase will come about in reality and in 'real terms'.

Notable areas of omission from these Political Guidelines and mission letters include the sustainability of healthcare, including its finance and staffing, the affordability of medicines, improving the EU clinical trial landscape, combating AMR and more fundamentally, public health measures.

SUMMARY

The priorities of the Commission seem to benefit innovators and several non-communicable disease areas, with little attention given to improving health at a population level. In an area of little EU-power, this is somewhat predictable but traces a decline in health ambition from its pandemic peak to the lower priority it is sadly used to receiving.



Conclusion

European citizens are as keen as ever for action to improve health but the EU's limited remit in health policy, and the current political makeup, renders the EU's ambition limited to a few areas:

- Supporting medicine innovation, particularly in biotech, by funding Research & Development (R&D) and unlocking the finance sector to fuel its translation to the market, for example, by enabling the Capital Markets Union and Banking Union, and EU-wide venture capital.
- Strengthening the EU's manufacturing capacity, supply chains and alleviating shortages of medical products.
- New large-scale initiatives to advance the research, prevention and treatment of non-communicable disease areas, particularly mental health, cardiovascular and degenerative diseases. These will be based on the Beating Cancer Plan, a 4-billion-euro initiative to improve the prevention, diagnosis and treatment across the EU, although likely with a lot less money in reality.
- Implementing initiatives from the previous cycle, which will encompass a large amount of Commission bandwidth, including the European Health Data Space; revision of the way the EU regulates pharmaceuticals; centralised route for Supplementary Protection Certificates, a key plank of Intellectual Property Rights protection; the Health Technology Assessment Regulation's pan-EU clinical assessments; Beating Cancer Plan; and meeting the deadline to disperse the <u>Recovery and Resilience Funds</u>.

As always in the EU, where power and money must be relinquished from the national level, its action in health will be set as much by crises as by the more predictable political priories of its institutions and its politics.

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Philip analyses EU policy for its impact on healthcare

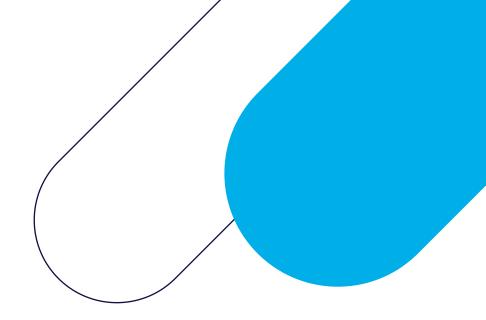
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