

**QUESTIONNAIRE TO THE COMMISSIONER-DESIGNATE****Olivér VÁRHELYI****Health and Animal Welfare****1. General competence, European commitment and personal independence**

*What aspects of your personal qualifications and experience are particularly relevant for becoming Commissioner and promoting the European general interest, particularly in the area you would be responsible for? How will you contribute to implementing the political guidelines of the Commission? How will you implement gender mainstreaming and integrate a gender perspective into all policy areas of your portfolio? How will you implement youth mainstreaming?*

*What guarantees of independence are you able to give Parliament, and how would you make sure that any past, current or future activities you carry out could not cast doubt on the performance of your duties within the Commission?*

*What aspects of your personal qualifications and experience are particularly relevant for becoming Commissioner and promoting the European general interest, particularly in the area you would be responsible for?*

I have dedicated my entire career to strengthening the European Union – through working on deepening its internal integration but also on advancing relations with the EU’s direct neighbourhood and supporting candidate/potential candidate countries on their EU path.

Before joining the European Commission as Commissioner for Neighbourhood and Enlargement in 2019, I have spent my entire professional career as a civil servant working for advancing European integration. During this period, I have acquired a deep understanding and knowledge of the EU decision-making processes and the different EU sectoral policies, including health policy and rules on animal welfare.

I have also proven my skills to promote the general interest of the European Union, serving as Head of Unit at the European Commission when the European unitary patent was created in the framework of the second enhanced cooperation in the EU. During this period, I was responsible for developing and safeguarding the intellectual property rights of different sectors, including the pharmaceutical one, strengthening EU’s competitive edge and assuring level playing field vis-a-vis our international partners.

My career in the Hungarian public administration - be it as the Head of the Legal Service at the EU mission of Hungary or as the Deputy Permanent Representative at the Permanent Representation of Hungary to the EU - has offered numerous opportunities to work on politically, economically and financially sensitive dossiers related to health and to food sector, inter alia the general pharmaceutical legislation and its 2003 review, the Regulation on medical devices, the Tobacco Products Directive or the Directive on the possibility for the Member States to restrict or prohibit the cultivation of GMOs (“GMO Directive”) in their territory.

After having joined the European Commission in 2019, I had the honour to serve the EU as the European Commissioner for Neighbourhood and Enlargement. During this time, I was actively taking forward the EU response to many unforeseen challenges that reshaped the geopolitical landscape in Europe and in the world. An important part of my work has been to ensure support to the Western Balkans and to the EU’s neighbourhood in the wake of the COVID-19 pandemic. To this end, we have swiftly repurposed existing assistance to provide the most urgent needs, including by the delivery of vaccines, therapeutics, and protection equipment. We have also put a stronger emphasis on developing more resilient health systems and aligning the relevant legislation with EU rules. Altogether, in across my portfolio regions we have mobilised in these critical moments over EUR 8.1 billion.

For example, regarding Ukraine, in February 2022, the European Commission provided EUR 120 million grant as budget support to assist the government in strengthening civilian crisis preparedness and management at central and local levels. This contributed to the continued delivery of basic services including the medical assistance to the most vulnerable citizens. Moreover, the Commission has provided EUR 12 million in support for related actions to support the design and implementation of childcare reform and strengthen access to trauma-informed care for children. We have expanded partnership with United Nations Development Programme through the EU4Recovery programme (EUR 35 million), which focuses on provision of quality public services including healthcare in frontline and adjacent communities. Investments to improve Ukraine's public healthcare system have been embedded into the Ukraine Facility - which will continue to support Ukraine in the coming years.

It is my firm belief that the EU is much stronger when its neighbours are stronger. Therefore, since the beginning of my mandate, as a Member of the College, I have taken action to support the socio-economic development of the countries under my portfolio. With this in mind, we have launched the Economic and Investment Plans for the Western Balkans, for the Eastern Neighbourhood and for the Southern Neighbourhood. I am proud to say that out of the €77 billion target of mobilised investments by 2027, at the end of my term we are ahead of the schedule at €54.68 billion, which is over 70% of the target for 2027. This already bodes well with the ambition of the Political Guidelines of the President-elect to make the 2024-29 Commission an Investment Commission. Moreover, within these programmes, we have mainstreamed healthcare as a key sector of development in all three regions, bringing the share of support for healthcare related actions from EUR 579 million in the last three years of previous multiannual financial framework (2018-2020) to over EUR 696 million (2021-2023), representing an increase of 17%. The financing covered a wide number of actions, ranging from support of primary health care centres access and immunization of vulnerable population in such countries like Lebanon, or enabling more responsive healthcare system in the Western Balkans, where it was possible for the first time to provide EU support for basic and middle level healthcare infrastructure, like for example the new Paediatric Hospital in Belgrade, a leading and high quality facility in the Western Balkan. We also combated multidimensional poverty in unprivileged rural areas of Egypt enhancing manufacturing capacities and access to medicines, including vaccines, and other health technologies. We supported, as well, healthcare quality and access for refugees in Türkiye, providing as well immediate post-earthquake support for health and education infrastructure.

*How will you contribute to implementing the political guidelines of the Commission?*

I fully support the vision of the President-elect set out in the Political Guidelines: a vision for a stronger Europe that delivers sustainable prosperity and competitiveness, that protects people and our quality of life, that defends democracy and delivers on social fairness.

If confirmed, as Commissioner for Health and Animal Welfare I intend to put all the necessary efforts into completing the European Health Union, fostering the resilience, security, quality and sustainability of health systems to protect the health of our citizens from health threats and promoting preventive health and healthy lifestyles.

The connection between people, animals, plants and the environment will guide my work under a One Health approach.

I will focus on making the EU an innovation powerhouse that provides innovative and affordable medicines and treatments to its citizens, and that upholds our high standards for food safety and animal welfare. I will ensure that the Political Guidelines of the President-elect are duly implemented in all the areas of responsibilities I have been assigned.

Recent ransomware attacks against hospitals and healthcare systems are unacceptable. I will work with digital health stakeholders to identify means to detect, prevent and respond to cybersecurity threats. In collaboration with the Executive Vice-President for Tech Sovereignty, Security and Democracy we will prepare a European plan on the cybersecurity of hospitals and healthcare providers in the first 100 days of the mandate.

I am acutely aware of the need to boost our competitiveness, building on our unique socio-economic model. We need to focus on key strategic sectors where Europe can build a competitive edge such as biotechnology (and work on a new European Biotech Act) and health data, including by implementing the European Health Data Space. I will pursue the completion of the Pharmaceutical Reform by supporting co-legislators in achieving the right balance between the much-needed innovation boost and the accessibility, availability, and affordability of medicines that our citizens expect. I will step up the implementation of the current framework regarding medical devices and assess the need for potential legislative changes.

Through a Critical Medicines Act, I will tackle the endemic risks of shortages of critical medicines and medical devices, and reduce dependencies. Building on the experiences of the COVID-19 pandemic, I will further strengthen our health security architecture and ensure Europe is prepared for and well equipped to respond to future health threats.

As entrusted in my mission letter by President-elect von der Leyen, I will step up our work on preventive health, to ensure a comprehensive approach to health promotion and disease prevention across the life course. Investing in effective prevention can offer the right tools to face such challenges, reduce the burden of non-communicable diseases, supporting healthy longevity and easing the load on healthcare systems.

As part of the health prevention work and as announced by the President elect, I will propose a revision of the Tobacco Product Directive, after the ongoing evaluation is completed. The use of emerging tobacco products should be a key focus of the revision of the directive.

Mental health is in the Commission's agenda, with 20 flagship initiatives presented in 2023. I will continue implementing these initiatives with Member States and stakeholders. I will pay special attention to mental health in children and youngsters. I will collaborate with the Executive Vice-President for Tech Sovereignty, Security and Democracy and other Members of College on an enquiry on the impacts of social media on children and young people's wellbeing.

I will spare no efforts in tackling the huge risks of anti-microbial resistance, building on and further developing our work with Member States to reach the 2030 targets through the One Health approach.

Our food safety and animal welfare standards are the highest in the world: I will continue gradually modernising our legislation based on the latest science, balancing sustainability, ethical, and the economic reality while safeguarding the competitiveness of our farmers and citizens' expectations. I will work with Member States to level the playing field in the internal market and internationally in line with trade rules.

Last but not least, I will make sure that my policies will leave no one behind, creating conditions for truly inclusive health and animal welfare systems catered fairly to the needs of people and animals.

*How will you implement gender mainstreaming and integrate a gender perspective into all policy areas of your portfolio?*

Equality between women and men is indeed a fundamental EU value enshrined in the Treaties. In my current mandate, I have been strongly committed to strengthening gender equality and women's and girls' empowerment in the Neighbourhood and Enlargement regions, in line with the Gender Equality Strategy and EU Gender Action Plan III. In particular, the aim has been that all financial assistance under my portfolio - across all sectors - should integrate a gender perspective and support gender equality.

I would proudly use the opportunity to continue serving under the first female President of the European Commission to advance gender mainstreaming and integrating a gender perspective into the area of health and animal welfare.

Moreover, I have also made significant efforts and achieved tangible results in strengthening gender equality within the European Commission, including in the services under my responsibility, as I have committed myself in my previous written response to the European Parliament back in 2019: on 1 December 2019, the share of female senior managers in the Directorate-General for Neighbourhood and Enlargement Negotiations (DG NEAR) was 33% and among middle managers 39% both below the European Commission average. By 2024, the situation has significantly improved whereby the percentage of female senior managers has risen to 56% and among middle managers to 54%, both above the European Commission average.

Building upon this experience, I intend to continue promoting gender equality also in the future – in line with the Political Guidelines for the 2024-2029 European Commission.

*How will you implement youth mainstreaming?*

Over the last 5 years I have made sure that supporting young people in their endeavours becomes a cross-cutting element of our relations with and assistance to partner countries.

In the framework of the European Year of Youth 2022, we participated in the development and implementation of the first ever policy framework for a strategic partnership with young people around the world, entitled the Youth Action Plan (YAP) in European Union external action for 2022-2027. In this context, we have strengthened 'The Young Mediterranean Voices', supporting cooperation between young people on both sides of the Mediterranean in public affairs and in local and regional transformative initiatives; the Erasmus+ programme which supports capacity-building in the field of youth in the Western Balkans and the Southern Mediterranean; the EU4Youth programme, fostering youth participation and leadership in policy-making in the Eastern Partnership, especially in Ukraine, and the network of Young European Ambassadors in the Western Balkans and Eastern Partnership and the Goodwill Ambassadors in the Southern Neighbourhood.

When it comes to health, mental health and well-being of the youth: we agreed to strengthen health systems (tackle inequalities and advance towards universal health coverage) and support comprehensive, safe, inclusive and child and youth-friendly health services, including mental health and digital health services in our partner countries. Besides the many regional events, during the Year of the Youth we hosted more than 150 students Brussels visit from the three regions to celebrate the European Year of Youth.

During my mandate in years 2021-2023, over EUR 966 million were committed for youth related actions, which is over 60% higher compared with the previous three years (EUR 594 million for 2018-2020). Those include for instance improvement of education infrastructure in Montenegro, empowering Kosovar youth by 'learning through experience' programme, increasing quality education for vulnerable children and youth in Jordan and Lebanon, or supporting green and digitally fit schools in Tunisia, supporting youth entrepreneurship through Erasmus for Young Entrepreneurs Programme or the EU4Youth Employment and Entrepreneurship mechanism. We supported as well, youth employment programmes in Bosnia and Herzegovina, and through the 'EU4Schools' Programme we have already completed 57 education facilities and improved education conditions for about 25 000 students, children and teachers in Albania, following the devastating earthquake in 2019. In Ukraine we support the reconstruction and rehabilitation of schooling across Ukraine (EUR100 million).

Moreover, I consider it paramount importance to actively seek and take into account the views of the young people not just in the EU but also in partner countries in designing our policies. My doors have been always open to the young generation. During the mandate, I had the chance to meet many groups of young people and students from the EU enlargement and neighbourhood regions - whether visiting youth labs, IT infrastructure facilities, schools, hospitals etc or hosting them in the Berlaymont.

If confirmed, as the Commissioner for Health and Animal Welfare I will continue the same approach – so as to ensure that that the decisions we make are long-lasting and future-proof. As a start, I will hold the first annual Youth Policy Dialogue within the first 100 days in line with my mission letter. I will also focus on the impact of social media and excessive screen time on people with special focus on young people and their wellbeing and mental health, also in line with my mission letter. I consider of utmost importance to put focus on the preventive part of the health policy for the youth as a long-term investment into their future.

*What guarantees of independence are you able to give the European Parliament, and how would you make sure that any past, current or future activities you carry out could not cast doubt on the performance of your duties within the Commission?*

My obligation will be to continue to comply with the highest ethical standards and the obligations set out in Articles 17(3) of the Treaty on European Union (TEU) and Articles 245 and 339 of the Treaty on the Functioning of the European Union (TFEU) and the Code of Conduct for Commissioners.

My declaration of interest is complete and accessible to the public and I will amend it should there ever be changes. I will also avoid any situation where my impartiality and independence could be put in question and I will inform the President of the Commission of any situation, which might involve a conflict of interest.

I will comply with transparency obligations on matters relating to EU policy making and implementation, as set out in the Code of Conduct, as regards meeting only with those professional organisations/ interest representatives or self-employed individuals which are registered in the Transparency Register.

As I have done over the last five years, I will continue to publish information on my travel expenses, together with detailing their aim and objective through photo/video coverage and media/social media appearances.

To support direct transparency and scrutiny of the public, all my meetings will continue to be duly published on the official calendar sites of the European Commission. On my official homepage all my public speeches and statements will continue to be published on the day of its presentation.

I will obey to the highest ethical obligations. This includes accepting gifts, hospitality, decorations, prizes and awards. This includes external activities during the term of office as well as post-term activities. I will use the Commission financial and other resources with utmost care.

## **2. Management of the portfolio and cooperation with the European Parliament**

*Can you commit to duly informing Parliament about your actions and those of your departments? In what respect do you consider yourself accountable to Parliament?*

*What specific commitments are you prepared to make in terms of your engagement with and presence in Parliament, both in committee and in plenary, transparency, cooperation and effective follow-up to Parliament's positions and requests for legislative initiatives? In relation to planned initiatives or ongoing procedures, are you ready to provide Parliament with timely information and documents on an equal footing with the Council?*

### *Role and co-operation with the European Parliament and its committees*

As it has been the case for the past five years, engagement with the European Parliament is of paramount importance to me. I have represented the European Commission in altogether 43 plenary meetings. As the Commissioner responsible for Neighbourhood and Enlargement, I participated in 31 meetings organised at Committee level. This included items such as formal dialogues in the remit of the financial instruments under my portfolio (7 on the Neighbourhood, Development and International Cooperation Instrument and 6 on the Instrument for Pre-accession Assistance). In this context, I have also considered it important to present all key proposals and reports (such as the 4 yearly enlargement packages) promptly to the Parliament, already on the day of their adoption in the relevant Committee (AFET). I have worked with the European Parliament and its relevant committees at all stages of both the policy-making process and the political dialogue.

Looking ahead, I intend to establish a very close working relationship, based on mutual trust and constructive dialogue with the Members of the European Parliament in the area of health and animal welfare. I firmly believe this is fundamental to ensure citizens' trust and oversight of our policies and institutions and to help fight disinformation.

Effective interinstitutional cooperation is essential for the EU's institutional system to work, and for the efficiency and legitimacy of EU decision-making system. It relies on certain guiding principles that I am fully committed to follow and I will make sure that services under my responsibility follow the same approach. These principles include openness, mutual trust, efficiency, and regular exchange of information. President-elect von der Leyen's Political Guidelines fully reflect these principles and stress the intention to reinforce the special relationship between the European Parliament and the Commission. If confirmed as Commissioner, I will work towards this objective, and in doing so I will fully respect the provisions of the 2010 Framework Agreement and the 2016 Interinstitutional Agreement on Better Law-Making.

In line with the Political Guidelines, I will make myself fully available to take part in meetings in the European Parliament such as plenary debates, committee meetings, trilogue discussions as well as bilateral meetings with Members of the European Parliament. I will ensure that the European Parliament is informed of any major developments under my responsibility and I am fully aware of the importance of equal treatment of the Parliament and the Council as regards access to meetings and the provision of contributions or other information.

### *Transparency*

President-elect von der Leyen's Political Guidelines stress that in order to regain citizens' faith in the Union, our institutions should be open and beyond reproach on transparency issues. This requires that citizens know the positions defended in the legislative process, including those of the Commission. Strengthening interinstitutional cooperation by promoting legitimacy and accountability will boost the EU's efficiency and good governance.

I am therefore fully committed to implementing the wide-ranging provisions on transparency and the flow of information in the Framework Agreement on relations between the European Parliament and the Commission and the Interinstitutional Agreement on Transparency and on Better Law-Making. In particular, I will ensure that these provisions are respected in my structured dialogues and other contacts with the Parliament's committees.

I will also actively contribute to the Commission's efforts to inform citizens on its role in the EU's institutional set-up. In addition, policy proposals under my responsibility will be based on proper consultations of experts and the public, in line with Better Regulation principles.

#### *Follow-up to Parliament's positions and requests for legislative initiatives*

President-elect von der Leyen has made a clear commitment to give the Parliament a stronger role in initiating and shaping legislation. Under the current Treaty provisions, she has stressed that her Commission will follow up on Parliamentary resolutions adopted by a majority of members with a legislative act, in full respect of proportionality, subsidiarity and better law-making principles.

I fully subscribe to this objective and will ensure the Commission acts accordingly in areas under my competence. As part of the commitment to a deepened partnership with the European Parliament, I will work hand in hand with Parliament on resolutions under Article 225 TFEU. I strongly believe that this will improve dialogue, foster confidence and a sense of working together towards a common goal.

I will also ensure the questions from Members of the European Parliament to the Commission that come under my responsibility are responded to swiftly and accurately. I will appear before the European Parliament's plenary and committees whenever called to answer a question or provide any particular response.

#### *Provision of information and documents*

I am fully aware that the provision of information and documents is an essential aspect of deepening the partnership between the European Parliament and the Commission. I therefore commit to fully implement the relevant provisions of the Framework Agreement between the two institutions, and of the Interinstitutional Agreement on Better Law-Making. The Lisbon Treaty sets out the equality of Parliament and Council as co-legislators, and I will ensure that this is respected in terms of how information is shared in areas under my responsibility.

#### Questions from the Committee on Environment, Public Health and Food Safety

*3. How will you work on strengthening the resilience of healthcare systems, ensuring access to and affordability of care and medical products in the EU and stimulating EU research and competitiveness in the pharmaceutical sector? Despite the efforts, the EU remains divided in terms of the access to healthcare and the availability of medicines, which affects both the quality of life of patients in the EU and their chance of curing diseases. How will you as Commissioner for health, including in cooperation with EU Member States, reduce these health inequalities, combat shortages of medicinal products, address shortage of healthcare professionals and ensure that all Europeans receive the best treatments regardless of where they live in the Union? Do you see a revision of the cross-border care Directive as a solution? What can you already say about the Critical Medicines Act in this context? How will the Act enhance the capability to respond to health crises, reduce the dependency from third countries for imports of critical medicines and ingredients and address critical needs in healthcare, while also improving access and affordability? How will you ensure that the EU fosters research and development of new medicines or treatments, in particular for rare diseases, and increase its competitiveness, innovation and strategic autonomy, while ensuring access to patients? How do you see the link to the European Biotech Act? How do you see the role of the EU4Health in this context, especially taking into account the recent budget cuts proposed?*

Over recent years, a growing array of challenges has tested the resilience of health systems in the EU. These have shown that health systems need to strengthen their capacity to foresee and adapt to shocks and structural changes. By reducing the vulnerabilities of health systems, they will be able to continue deliver top quality healthcare for EU citizens and will also help Member states ensure their sustainability, while generating better health outcomes. The health policy has also developed a much stronger European dimension. The European Semester and the country specific recommendations, as well as OECD work and the European Observatory on Health Systems and Policies on the State of Health in the EU, are valuable resources to support this work. If confirmed, I intend to pursue this work on strengthening the health systems within the limits of EU competences.

Given the dependence of our health systems on digital technology, one key aspect of resilience is their cybersecurity: if confirmed one of my first actions would be to deliver the action plan on the cybersecurity of hospitals and healthcare providers set out in the Political Guidelines, working closely with the Executive Vice-President for Tech Sovereignty, Security and Democracy.

Access to effective, high quality and safe medical products is essential for well-functioning healthcare systems. We need a regulatory framework suited to the rapid pace of technological change in the healthcare sector. That is the goal of the overhaul of the EU pharmaceutical legislation proposed in April 2023. This would put in place a modern, simplified and supportive regulatory framework that makes it more attractive for companies to invest in research and development for innovative medicines in the EU, including specific incentives for medicines for rare diseases. I consider that this reform is a cornerstone for the future and if confirmed, I will do everything I can to support the co-legislators in concluding this reform.

As the European Parliament has itself highlighted, innovative medicines authorised in the EU are not reaching patients quickly enough and are not equally accessible. Patients in some western and larger Member States have access to 90% of newly approved medicines, while in some southern and central European Member States and smaller Member States this can be less than 20%. The proposed reform promotes faster patient access across all Member States and the earlier entry to market of generic and biosimilar medicines. In addition to support access to medicines, and of course depending on the outcome of the negotiations on the pharmaceutical reform, I would also look into further non-legislative actions which could complement the reform. I would continue supporting voluntary cooperation across competent authorities on the cost-effectiveness and affordability of medicines.

There is a particular challenge with shortages in the health workforce, seen across Member States and affecting many parts of the profession. An uneven distribution of health professionals is a challenge in at least half of Member States, resulting in the so-called ‘medical deserts’. This problem will only exacerbate with the expected rise in demand for healthcare. If confirmed, I will also support the work of the future Executive Vice-President for People, Skills and Preparedness and help to build a coherent framework for addressing long-term care workforce challenges.

Medicine shortages are also a long-standing problem in the EU, with serious impact on the quality of life of patients across Europe. In line with the European Parliament’s Resolution, the Commission extended the mandate of the EMA to the coordinated and collaborative management of critical shortages at EU level in times of crisis. There are also strong regulatory measures in the pharmaceutical reform which seek to prevent and mitigate shortages, and to strengthen supply chains. Additional non-legislative measures are in place, with the new Critical Medicines Alliance proving a valuable forum to explore progress.

If I am confirmed, I will work towards complementing the measures proposed in the pharmaceutical reform with a proposal for a Critical Medicines Act. The act would offer a coordinated approach to tackling severe shortages of critical medicines. It would aim to strengthen the resilience of and diversify our supply chains, and reducing dependencies on non-EU countries for critical medicines and their ingredients, while helping to keep medicines affordable. I would ensure that the Commission’s impact assessment explores all potential policy options. The options that could be considered include procurement measures to help to make demand more predictable, measures to maintain and strengthen Europe’s manufacturing capacity, developing strategic partnerships to diversify supply chains.

To improve our global competitiveness, we should do more to keep innovation at the heart of our economy, not just as drivers of new medical breakthroughs, but also to attract global talent and investment to the EU’s health sector. Biotechnology, artificial intelligence and data from the European Health Data Space (EHDS) are of strategic importance for the EU’s long-term competitiveness. They can help in the development of novel therapies, manufacturing processes and innovative products, including for rare diseases, by securely making health data available for research, in addition to allowing patients to share their data with healthcare providers and avoid unnecessary tests.

If I am confirmed, one of my top priorities will be to bring forward a Biotech Act to reposition the EU biotechnology sector as a global leader and supporting the sector where needed. Part of a broader Strategy for European Life Sciences, the Act will aim to make the EU regulatory environment simpler and more conducive to innovation, attract innovators and investors to conduct research and make it easier to bring biotechnologies from the laboratory to the factory and onto the market, in line with the work set out in the Political Guidelines on encouraging start-ups and scale-ups. At the same time, we also need to boost the R&D and biotech skills of our scientists, entrepreneurs and workforce.

The Cross-border Healthcare Directive is a great achievement for EU citizens' access to medical treatment. Nevertheless, its implementation needs continued attention. The 2022 evaluation confirmed that the Directive adds value for EU citizens, though it is also true that most cross-border healthcare is still managed effectively through social security coordination. One important success of the Directive is that some of its key elements (such as the eHealth European Reference Networks for rare diseases and health technology assessment) have resulted in dedicated initiatives and legislation. The next evaluation will be carried out in 2027, and we will need to look carefully at implementation in practice and whether this could be enhanced.

The EU4Health Programme has made a major contribution to health initiatives in the EU in very challenging circumstances. I will work closely with Member States to use the programme to foster more equitable healthcare access and outcomes across the Union. If confirmed, I would continue to leverage partnerships and innovative funding solutions to keep driving improvements in health systems, research capabilities and digital health. Currently, in terms of public financial support and investment, the first priority should be ensuring the use of the resources available via NextGenerationEU and the current budget. Looking ahead, the next Multiannual Financial Framework is an opportunity to make our spending more focused, simpler and more impactful.

We must continue to strengthen our prevention, resilience and competitiveness through our health policies and focused investment. Europe needs a strong, competitive and innovative pharmaceutical sector and to make the most of the biotech revolution. The Political Guidelines made clear that we need to invest in the innovation and technologies that will shape our economy and drive our transitions: this must be our priority.

*4. What are your concrete plans to fight against AMR at national, EU and international level, in line with the One Health approach, with regard to environmental, human and animal health? In particular, what additional measures do you envisage in addition to those already proposed in the revision of the pharmaceutical legislation, both in human and veterinary fields? How do you plan to address shortages and ensure access to antimicrobials and diagnostic tools, while ensuring prudent use and stewardship? Will you present an update of the list of antibiotics reserved for human use? Since research and innovation are a crucial component of the fight against AMR, how do you plan to incentivise both public and private research and innovation in this field? Do you envisage looking into untapped medical counter measures such as bacteriophages?*

Antimicrobial Resistance (AMR) is a serious global health threat. We cannot ignore the UN estimates that without serious action, by 2050 we could see 10 million people dying each year at global level and 390 000 in Europe alone. This is without counting the economic cost, which amounts to an estimated €11.7bn every year for Europe, due to increased healthcare costs and productivity losses.

It is therefore crucial to step up actions to combat AMR. Last year's Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach was an important milestone, particularly in terms of the concrete, measurable recommended targets to be reached by 2030. It includes recommendations on surveillance, infection prevention and control, stewardship, prudent use of antimicrobials and raising awareness. The Commission supports Member States' actions in this field.

Tracking progress could be an important theme for work on implementation in this area, with annual monitoring of progress towards these targets. In 2027, the Commission will decide on the next steps, based on the implementation report of the Council Recommendation planned for the same year.

We also intend to develop new guidelines on infection prevention and control to support interventions in Member States, especially for hospitals, which carry some of the heaviest burden of AMR. The European Centre for Disease Prevention and Control can be a major support here.

For veterinary medicines, Member States report data on the sales and use of antimicrobials every year. From this we can see that over half the expected reduction in antimicrobial sales for animals set in our Farm to Fork Strategy has already been achieved. Once trends in sales and use become discernible over time, we will be able to assess the need for additional targeted measures.

If I am confirmed, in this area too, my focus will be on the application and enforcement in all Member States, including by means of audits, of the obligations related to AMR and veterinary medicine (including those stemming from the Veterinary Medicinal Products Regulation and the Medicated Feed Regulation). This also applies to non-EU countries wishing to export animals and animal products to the Union, which are obliged to respect our rules not to use antimicrobials for growth promotion or antimicrobials reserved to treat human



infections in the EU. New information as regards a potential revision of the list of antimicrobials reserved for humans, as defined in the Veterinary Medicinal Products Regulation, should be swiftly followed up.

We all agree that the development of new antimicrobials is urgent. However, curbing the use of antimicrobials has an impact on the volume of sales and consequently return on investment for marketing authorisation holders. This is a major reason for underinvestment in this area and why additional incentives for developing innovative antimicrobials and securing access to antimicrobials are needed.

Overcoming this market failure is why the proposed pharmaceutical reform included an innovative data exclusivity voucher, to create a special incentive to develop new break-through antimicrobials effective against AMR. It also included measures to foster prudent use of antimicrobials, monitor resistance to them and prevent shortages and to strengthen the evaluation of the potential impact of medicines on the environment. I therefore very much welcome that the Parliament put particular emphasis on AMR measures in its first reading position, and if I am confirmed as Commissioner, I will do everything to support the Parliament and Council in the negotiations to ensure a successful outcome, in particular on this critical problem.

Complementing the measures set out in the proposed pharmaceutical reform, the planned proposal of a Critical Medicines Act set out in the Political Guidelines would have an important impact on the supply of antimicrobials. Many antimicrobials are considered to be critical medicines, so they would benefit from actions to address shortages of critical medicines, including by remedying the supply chain vulnerabilities that contribute to such shortages.

At global level, if I am confirmed as Commissioner, I will work with Member States and our partners to implement the recently adopted United Nations Political Declaration on AMR. This declaration acknowledges the need to foster a One Health approach, sets concrete objectives and calls on the Quadripartite to establish an “independent panel for evidence for action against AMR” in 2025 to guide UN Member States in their national actions.

I would also advocate for increasing the number of contributors to the AMR Multi-Partner Trust Fund, which is a crucial source of funding dedicated to AMR. This fund plays an essential role in supporting the implementation of national action plans in low- and middle-income countries.

In conclusion, if I am confirmed, I will commit to strengthening our efforts to curb AMR at all levels and across all relevant sectors in a One Health approach. I will work with you, the Members of the European Parliament, with the Council, stakeholders, and our international partners to achieve this goal.

*5. What are your proposals to improve mandatory food information to consumers, in particular regarding nutrient content (for healthier choices, without oversimplification), sustainability aspects (CO2 footprint) and animal welfare labelling (AWL), while avoiding administrative burden and ensuring safe and affordable food? Will you commit to presenting the measure announced in the Farm to Fork Strategy in 2020 regarding the introduction of an EU-wide front of pack labelling scheme? Similarly, do you plan to present the delayed legislative proposal on sustainable food systems, which was also announced as part of the Farm to Fork Strategy? What is your vision on this initiative? Regarding pesticide use, what are your proposals to support the farmers to reduce the use and risks of chemical pesticides, and how will you accelerate the availability of alternatives, such as biocontrol products or low-risk substances? Lastly, what are your concrete plans to increase food safety controls on imported products?*

Mandatory food information, including nutrient content, and front-of-pack nutrition labelling can help consumers to make healthier food choices. If confirmed, I will work with Member States and stakeholders on a comprehensive approach to promote healthier food choices, addressing issues including food information, food reformulation and the marketing of unhealthy food. This has a link with the cross-cutting approach to lifelong prevention, which I will work on, building on existing actions on health promotion and disease prevention. As national information campaigns can better target consumers, I will support national efforts to improve awareness around food information.

Work should continue on food labelling, with particular attention on minimising any related burdens and finding balanced, pragmatic solutions which facilitate the functioning of the internal market. As regards animal welfare labelling, I would focus on gathering robust evidence, particularly on the impact of a voluntary animal welfare labelling scheme on farmers, food business operators, consumer behaviour and the internal market.

President-elect von der Leyen announced in the Political Guidelines that the new Commission will present a Vision for Agriculture and Food in its first 100 days. This will look at how to ensure the long-term competitiveness and

sustainability of the EU farming and food sector within the boundaries of our planet. If confirmed, I will work closely with my colleagues in the College to help develop the Vision in a way that ensures a resilient, competitive and sustainable EU food system, with food safety as one of its cornerstones. The Vision will build on the report of the Strategic Dialogue on the future of agriculture in the EU, where all stakeholders recognised that a systems-based approach and sustainability remain key. The transition to sustainable food systems requires various policy tools, including investment, incentives and regulation, all contributing to an enabling policy framework that provides clarity to all stakeholders. If I am confirmed, I will work closely with the Commissioner for Agriculture and Food on developing a new benchmarking system for agriculture and food systems, aimed at harmonising methodologies including for on-farm sustainability.

I will also pursue our efforts to reduce the risks of pesticide use and promote non-chemical alternatives, which are core objectives of the current Directive on the Sustainable Use of Pesticides. If confirmed, I will look at ways to further improve the implementation of the Directive or assess new legislative initiatives, in dialogue with the Member States and other stakeholders, and based on the recommendation of the Strategic Dialogue that the European Commission would enable a robust legislative framework for biocontrol products and approaches.

Technical innovation through digital tools and precision application techniques also has significant potential to reduce risks from pesticide use, by reducing the quantity of pesticides needed for crop protection. If confirmed, I will work towards integrating these technologies in the risk assessment process so that they are fully considered before decisions on pesticide approvals are made. Alongside boosting innovation and modernising equipment used to apply pesticides, this will allow farmers to achieve ‘more with less’. I intend to work with the Commissioner for Agriculture and Food to support farmers in this shift towards digital and precision techniques.

I am committed to increasing the availability of alternatives to chemical pesticides, such as biopesticides, by fostering their access to the market. During the last mandate, the Commission simplified data requirements and assessment methods for pesticides based on micro-organisms and developed specific guidance for other biopesticides such as plant extracts and pheromones. If confirmed, I intend to take additional steps so that applications for biopesticide authorisation are evaluated with high priority and that these pesticides can have faster access to the market to expand the toolbox of farmers protecting their crops. This would support innovation, cater for the evolving needs of plant protection and address emerging phytosanitary problems.

The EU has one of the strictest and most rigorous food safety control systems in the world, as one of the biggest global food importers. It is obviously of critical importance to our citizens that these rules are properly implemented. One of the main principles of this system is that food placed on the EU market has to be safe whether its origin is inside or outside the EU. This means that if non-EU countries or their establishments that produce food of animal origin want to export to the EU, products need to demonstrate compliance with our rules, and we grant access to the EU market only when the third country and the establishment are listed for the respective product. This is supported by audits that the Commission carries out in non-EU countries to verify compliance with EU requirements. If necessary, the Commission can then take emergency action to prevent import of unsafe foodstuffs.

Better targeting food safety controls for imports requires constant effort: it involves analysing data from Member States and considering scientific evidence in relation to possible risks, statistical data on trade, and evidence on the control systems of exporting non-EU countries, some of which comes from Commission audits. On this basis, controls are continuously prioritised based on the nature of the risks and the potential exposure to these risks of consumers and businesses in the EU.

Member States need to have the necessary tools to perform controls in an efficient and coordinated manner. Improved options for data analysis and traceability, using artificial intelligence, could contribute to the easier and faster detection of anomalies and to the better handling of any incidents with the help of existing IT systems managed by the Commission. Other important elements are EU reference laboratories and reference centres funded by the Commission, the review of control resources in Member States by Commission auditors and training for national officials implementing EU food chain legislation. If confirmed, I will continue to work to make these tools more efficient, improving the guarantees for EU consumers that all imported food is safe.

#### Questions from the Committee on Agriculture and Rural Development

*6. Animal welfare is increasingly considered a priority for citizens. As Commissioner-designate, how would you react to growing demand for higher animal welfare standards while addressing sustainability, economic considerations and farmer positions? How do you intend to modernise the existing regulations on animal welfare? Which new elements would you like to assess and address? Which legislative proposals on animal welfare are you*

*planning to make? In addition, how do you intend to examine and address the varying levels of compliance and enforcement of the current legislation in EU Member States and ensure that new regulatory proposals as well as improved enforcement secure a level playing field and do not compromise the competitiveness of EU farmers?*

As set out in my Mission Letter, if confirmed, I will modernise the rules on animal welfare standards building on our existing legislation. I will do this in line with the latest science, taking account of sustainability, ethical, scientific and economic considerations, as well as concerns around the competitiveness of European farmers and citizens' expectations. I firmly believe that the competitiveness of EU farming needs to be maintained. Our future legislation must reflect this objective.

The approach to the welfare of on-farm animals must be balanced, take socio-economic criteria and competitiveness into account and based on robust evidence. In the follow-up to the European citizens' initiative 'End the Cage Age', phasing out animal cages with appropriate species-specific transition periods will require a targeted legislative approach and accompanying measures that support stakeholders in making this transition in a sustainable and economically viable way, safeguarding the competitiveness of Europe's farmers.

To provide a level playing field, it is important to ensure that EU animal welfare standards are implemented and enforced in a consistent manner across the European Union and that we step up our action globally. To this end, if confirmed I will draw on work under way, with audits of Member States' and non-EU countries' official control systems, the work of the EU Reference Centres for Animal Welfare, and the development of detailed rules, recently for example on livestock vessels. I would continue to work closely with Member States and all stakeholders through a variety of instruments and forums. Where systemic and significant implementation problems are identified, I would strengthen dialogue with the relevant Member States to bring swift results, always with the possibility to take infringement measures if necessary.

At global level, I would continue to promote high international standards both in multilateral forums (in particular the international animal welfare standards of the World Organisation for Animal Health), with candidate countries for accession to the EU and through bilateral cooperation (for example an animal welfare chapter in trade agreements). This is important to ensure that imports into the EU of live animals comply with EU rules or equivalent standards, thereby fighting the race to the bottom in animal welfare standards globally, which will be contrary to our citizens' expectations. The two most recent animal welfare legislative proposals (on the transport of animals and on the welfare of dogs and cats) both contain requirements for equivalent standards for imports into the EU of live animals from non-EU countries.

*7. As Commissioner-designate, how would you ensure that the increasing risks from animal disease outbreaks and antimicrobial resistance are granted a more prominent role in EU policy? What type of actions would you propose to ensure the improvement of animal health and eradication of animal diseases across the EU, particularly in terms of disease prevention, surveillance and biosecurity? In addition, how do you envisage addressing the growing threats posed by cross-border diseases and coordination between EU Member States? How would you guarantee that the future Commission ensures adequate funding and resources to enhance research on the development of affordable vaccines to combat diseases such as African swine fever and on the prevention of the spread of diseases such as bluetongue?*

I am fully committed to strengthening our efforts to preventing, controlling and eradicating animal diseases and in the fight against antimicrobial resistance.

Transmissible animal diseases do not stop at borders. They have a major impact on farming and they threaten food security in the Union. Some can also be transmitted to humans. Preventing and controlling animal diseases is and will remain a priority, also for the safe functioning of the single market. To this end, if confirmed I will ensure that our robust system to prevent, control and eradicate animal diseases is implemented properly across the EU. With the support of the European Food Safety Authority, we will develop and implement science-based measures to prevent and control animal disease outbreaks. Working together with the European Food Safety Authority and the European Centre for Disease Prevention and Control, we will also focus on zoonotic diseases such as avian influenza. I would pay particular attention to vector-borne diseases, which pose a growing risk due to climate change, the increased movement of goods and people across borders, and closer contact between humans and wildlife. Working closely with Member States, I would continue deploying all tools at our disposal to deal with animal disease outbreaks, including EU Veterinary Emergency Teams. Together with the Commissioner for Agriculture and Food, I will work to ensure that the Common Agriculture Policy includes a comprehensive set of tools to help farmers prevent and mitigate the economic impact of animal diseases and reinforce biosecurity on farms.

If confirmed, I would not confine my attention to animal diseases. Antimicrobial resistance is a major concern for human, animal and plant health, food safety and security, and the environment. In the veterinary sector, the EU has progressed in reducing the use of antimicrobials. Member States report data on the sales and use of veterinary antimicrobials every year. Here, EU policy is already yielding results - over half the expected reduction in antimicrobial sales for animals set in our Farm to Fork Strategy has already been achieved. Once trends in sales and use become discernible over time, we will be able to assess the need for additional targeted measures.

In line with the policy on prudent use, non-EU countries wishing to export animals and animal products to the Union must respect our rules not to use antimicrobials for growth promotion or antimicrobials reserved in the EU to treat human infections. It will be essential to continue monitoring antimicrobial resistance in the main species of food-producing animals bred within the EU (poultry, pigs and bovines). We should also step up work with Member States on targeted surveillance programmes (e.g. in aquaculture animals) and encourage Member States to establish integrated surveillance of antimicrobial resistance and antimicrobial consumption, using a One Health approach. I will also look into the rules of imports of wild animals.

At EU level, harmonised measures exist for early detection of animal diseases through a well-developed animal disease notification and reporting system and established surveillance across Member States. We should continue to improve notification and reporting through new features of the Animal Disease Information System. It is also important to minimise duplication of work and ensure consistent data across platforms via the interoperability of our information system with the notification system of the World Organization for Animal Health. The network of Union animal health laboratories ensures quality and harmonised diagnosis for early detection and effective surveillance of animal diseases. Through close cooperation with and the scientific support of the European Food Safety Authority, I would target robust and science-informed measures. A well-trained workforce is essential to implement EU measures correctly in Member States, so it is important to continue to increase capacity at Member State level by training officials on surveillance, disease control, biosecurity and compliance with EU animal health rules. Our animal health audits should continue to inform the implementation of EU rules, by identifying bottlenecks, challenges, and good practices, with effective audits crucial to ensure evidence-based policymaking and informed decision-making.

Only through close cooperation and coordination between Member States can we prevent the spread of animal diseases across the EU. The Standing Committee on Plants, Animals, Food, and Feed and the network of Chief Veterinary Officers play a key role in this process. If I am confirmed, I will also seek close coordination with key international standard setting bodies such as the World Organisation for Animal Health. I would reinforce a broader global and regional approach to fight animal diseases, working hand in hand with neighbouring countries through the Global Framework for Transboundary Animal diseases and our regional capacity-building projects in the Western Balkans. On food safety, I would continue to ensure the full implementation of the EU legal framework for preventing and managing foodborne incidents, building on experience from past emergencies.

The availability of safe and effective vaccines is a key tool for preventing and controlling outbreaks of major animal diseases. In the past few years, the Commission has dedicated more than EUR 20 million to fund African swine fever vaccine research. I would make sure that the Commission continues to make necessary vaccines available to Member States and countries outside the EU through the Union animal vaccine banks, a critical tool for management and response. When deciding to vaccinate poultry, Member States have to follow the measures in place at EU level and in line with international standards, to ensure the most effective use of vaccines in preventing and controlling the disease. If confirmed, I would support Member States vaccinating against avian influenza, so that they do not lose access to markets.

*8. The availability of effective and economically viable alternatives is the main factor in reducing the use of chemical plant protection products. How would you improve biological control authorisation and implementation of integrated pest management? As Commissioner-designate, how would you spur the development of bio-pesticides, monitor their effectiveness and encourage their use? Do you think biological control agents should be subject to fast-track authorisation procedures? In a general way, do you think it is necessary to speed up the authorisation procedures for active substances used in the manufacture of plant protection products? How do you intend to counter the risk that Europe will run out of effective products to fight off plant diseases - especially since new pests are emerging in certain regions in the context of climate change? How would you ensure that the Union remains attractive for investment in this area? What are your views on the EU zonal authorisation procedure for plant protection products?*

Increasing the availability of biological and other low-risk pesticides is vital to reduce the use of chemical pesticides. The existing EU legislation on the placing on the market of pesticides is fit for the purpose of protecting

the health of EU consumers through its strict safety standards, as shown in the REFIT evaluation of 2020. This provides concrete reassurance for our citizens, whose concerns focus mainly on the impact of the use of pesticides on the safety of the foods they consume.

I consider that, objectively, EU requirements remain among the strictest in the world and allow approvals of active substances and authorisations of plant protection products in line with the latest science. Many active substances that were on the market in the early nineties – when the first EU legislation on pesticides was enacted – are prohibited today because they do not satisfy our demanding safety requirements for the protection of health and the environment. At the same time, there has been a steady stream of newly developed active substances with improved properties coming to the market. This shows that the EU remains an attractive place for innovation and development in plant protection and provides reassurance that companies will continue to bring new products to the EU market.

More specifically, under the existing legislation, the availability of biological control and low risk substances has increased by 125% over the last decade. About half the applications for approval of new active substances are for biopesticides. Recent steps have simplified data requirements and assessment methods for pesticides based on micro-organisms, complemented by specific guidance for other biocontrol substances such as plant extracts and pheromones to make it easier for applicants to compile their dossiers and for risk assessors to review them.

I am aware that delays in approval procedures hinder access to market for innovative biopesticides. This is partly due to the fact that expertise on risk assessment for biopesticides in some Member States and EFSA is still being built up. If confirmed, I am committed to continuing efforts to increase Member States' expertise and resources, and to encourage national authorities to prioritise the risk assessment of biopesticides. Potential applicants are entitled to advice prior to submission of application dossiers - I will call on Member States to be attentive to the particular needs of SMEs for preparing application dossiers and increase the involvement of EFSA in pre-submission meetings with applicants, which can have a positive impact on the quality of dossiers, facilitate the subsequent risk assessment by Member States and reduce difficulties during the peer review of the Member States' risk assessment overseen by EFSA.

A fast-track authorisation procedure for low-risk plant protection products, such as biopesticides, is already laid out in the current Plant Protection Products Regulation, but it is underused. Similarly, Member States do not make enough use of mutual recognition of product authorisations and of zonal authorisations as provided for in the Regulation. It was a conscious choice of the European Parliament and the Council, when adopting the Regulation, to leave responsibility for the authorisation of plant protection products to Member States, while only the approval of active substances is carried out at EU level. Reflecting the principle of subsidiarity, this approach allows Member States to consider authorisation of individual pesticides based on the variable agroecological situations in their own territories. Nevertheless, if confirmed, I would of course continue and step up efforts by the Commission to help Member States around product authorisation, mutual recognition and zonal cooperation.

Digital tools and precision application techniques also have significant potential to mitigate the risks from pesticide use by reducing the quantities needed for crop protection. If confirmed, I would work towards including these technologies in the risk assessment process so that they are fully considered before decisions on approving pesticides are made. In addition to boosting innovation and modernising equipment to apply pesticides, this will allow farmers to achieve 'more with less' and to save money. I intend to work with the Commissioner for Agriculture and Food to support efforts to help farmers in this shift towards digital and precision techniques. I am acutely aware that pesticides are an essential part of the toolbox of farmers protecting their crops and, where appropriate, I intend to consider very carefully the availability of alternatives in the context of the decision-making process on the renewal of approval of pesticides.

In addition, it is important to reinforce practices for crop protection that reduce the need for chemical pesticides, such as Integrated Pest Management. A good candidate for one of the planned implementation dialogues under this portfolio would be to bring together Member States and other stakeholders to look at how to improve the implementation of the Directive on the Sustainable Use of Pesticides. In addition to dialogue with stakeholders, controls on Member States will be carried out from next year to verify how the Directive is being implemented on the ground. My intention is to pursue dialogue with stakeholders and to review the results of the planned controls before deciding on the best way forward.

## Question from the Committee on Industry, Research and Energy

*9. What concrete measures do you envisage to further diversify supply chains and boost the competitiveness of the health sector? How do you plan to address the severe shortages of medicines and medical devices in the context of the Critical Medicines Act? What further actions will you propose to ensure the availability and competitiveness of medical devices? What measures do you think should be included in the new European Biotech Act and the action plan on cybersecurity of hospitals and healthcare providers? How do you aim to complete the European Health Data Space?*

A strong and competitive health industry is crucial for our healthcare systems and for responding to patients' needs. The EU pharmaceutical sector relies on a strong manufacturing base, employing 937,000 people directly and developing scientific and research expertise. If I am confirmed, I will work to strengthen the competitiveness of the EU pharmaceutical sector, notably by working with the co-legislators to complete an ambitious pharmaceutical reform which includes shorter and simplified procedures for authorisation, regulatory support for companies developing new medicines – especially SMEs and start-ups – and support to new approaches such as regulatory sandboxes.

Shortages of critical medicines are a serious concern, recognised by the European Parliament since 2020. If confirmed, I would take forward the approach set out in the Commission's 2023 Communication "Addressing Medicine Shortages in the EU". My top priority in this respect will be to support the co-legislators in the adoption of the reform of the pharmaceutical legislation. It proposes shortage prevention plans by companies, earlier warning for shortages and withdrawals and stronger EU coordination, as well as setting how to identify medicines to be deemed critical in the EU. I will update the Union list of critical medicines and look at ways how public procurement can address this issue.

As mentioned in detail under question 3, if confirmed, I will complement the measures in the pharmaceutical reform by taking forward the preparations for a Critical Medicines Act, to provide a coordinated and secure approach to tackling severe shortages of critical medicines, taking into account the recommendations of the Critical Medicines Alliance.

The medical device sector is one of the most diverse and innovative EU sectors, with more than 37,000 medical technology companies – 95% of which are SMEs – employing more than 695,000 people. The transition to the new EU regulatory framework adopted in 2017 proved more challenging than anticipated. If I am confirmed, my priority will be to conclude the ongoing targeted evaluation of the current regulations and build evidence on the need for potential legislative changes, taking into account last year's European Parliament resolution. My aim would be to support innovation and safeguard the availability of devices to ensure high-quality patient care, including orphan devices aimed at small patient populations. I would focus on improving predictability and look at the need to reduce costs and administrative burdens, especially for SMEs.

As also explained in my reply under question 3, if confirmed, one of my top priorities will be to bring forward an ambitious Biotech Act, linked to a broader Strategy for European Life Sciences to position again the EU biotechnology sector as a global leader, also building on the recommendations outlined by Professor Draghi. The future Biotech Act would boost research and innovation by stimulating investment into strategic areas, such as clinical development and new production technologies, including for biological medicines. It could look at how to help bio-innovative companies in general, but also to look at further simplifying regulatory procedures in particular sectors, including of course health. Another area to explore would be access to AI and big data, as well as the development of skills. We should pay particular attention to SMEs, start-ups and spin-offs, who are key drivers of innovation in biotech, but often struggle to scale up and bring research to the marketing stage in Europe.

I will work with the Executive Vice-President for Tech Sovereignty, Security and Democracy on a European action plan on the cybersecurity of hospitals and healthcare providers as a matter of priority within the first 100 days of the mandate, to protect our healthcare sector, where a cyber-attack can be a matter of life or death. Health systems are increasingly the target of cybercriminals and ransomware gangs. One in twelve cyber-attacks target hospitals and healthcare providers, with 54% of incidents involving ransomware and 30% targeting patient data. The impact of an attack on health systems is extremely serious – such attacks can disrupt the capacity of hospitals to provide care and compromise sensitive personal health data. The action plan will build on the existing cybersecurity framework to foster cyber-resilience in hospitals and healthcare facilities. Authorities at all levels and industry will need to work together to improve threat detection, preparedness, deterrence and crisis response.

Finally, the work of the Parliament to ensure a successful conclusion of negotiations on the European Health Data Space (EHDS) Regulation earlier this year provides an excellent springboard for future work. The EHDS is an essential part of the European Health Union that will facilitate the use of advanced technologies, including Artificial Intelligence, to benefit patients, healthcare professionals, universities and industry, while ensuring the highest protection of patients' data privacy. Now it is time for its full implementation on the ground. If confirmed, I will focus on rolling out the actions within the Commission's remit based on the timeline in the Regulation, including the necessary standards and guidelines, and ensuring the development of secure and robust EU digital infrastructures to facilitate cross-border access to health data and secure use of health data for research and policy making. I would pay particular attention to driving this key initiative forward to delivery.

#### Question from the Subcommittee on Public Health

*10. How will you commit to work on preventive health as one of the key areas, ensuring a comprehensive approach to health promotion and disease prevention across the life course? In this regard, many proposals under the beating cancer plan were promised in the previous mandate but were not delivered by the previous Commission. Do you commit to delivering on the missing actions and goals under this plan including, inter alia, a review of the relevant legislation on tobacco (including to tackle novel products such as vapes), proposals for labelling and health warnings on alcohol beverage products? Concerning other non-communicable diseases, can you provide us with the main elements that you will put forward regarding a common approach in these areas? Will you continue to focus on boosting immunisation and vaccination as key components of this effort? In addition to the measures mentioned in your mission letter, can you elaborate on further actions you will take regarding prevention with respect to mental health and the implementation of the Mental health strategy? Do you commit to deliver the revision of the Medical Devices Regulation and how will you ensure affordability, availability, safety and the prevention of shortages?*

Non-communicable diseases currently account for almost 80% of the disease burden in the EU and are the major cause of mortality in the EU. These deeply concerning figures are projected to increase, due to the demographic patterns in the EU, with a fast-ageing population. These diseases reduce people's quality of life, affect life expectancy, exacerbate social and economic inequalities, and have a heavy impact on Member States' healthcare systems and economies, accounting for the biggest share of healthcare costs in OECD countries.

The European Parliament has given particular attention to this issue. I would fully agree that prevention is the most effective way to curb the incidence of non-communicable diseases and to ensure long-term sustainability of our health systems. Many of the health determinants (for example physical activity or nutrition) and risk factors (for example use of tobacco or the harmful use of alcohol) are the same in different cases. If I am confirmed, I will therefore tackle the specific challenges of these diseases with a cross-cutting approach to lifelong prevention, building on existing actions on health promotion and disease prevention. This cross-cutting approach will be the most effective way to promote public health action that is efficient and sustainable.

Addressing cardiovascular diseases should be a major component of this cross-cutting approach. Cardiovascular diseases are the leading cause of mortality and the principal factor for ill-health and disability in the EU: cardiovascular diseases and cancer together cause more than half of premature deaths in Europe. If confirmed, I will look to build on existing collaborative action with Member States, such as the joint actions on cardiovascular diseases and diabetes and look further into the connections with health determinants, risk factors and chronic conditions such as obesity. A particular focus might be improving the prevention and early detection of cardiovascular diseases. To do so, fully harnessing digital health solutions including AI would help to allow EU patients to benefit from the latest technology in terms of precision diagnostics and treatment.

Within this framework, if confirmed, I will drive forward the implementation of Europe's Beating Cancer Plan. Combatting cancer continues to be one of the greatest challenges of our time, as again highlighted by the European Parliament in its resolution of 2022. To date, more than 90% of actions in the Cancer Plan have been implemented or are ongoing. But work must continue, together with you, with Member States and stakeholders on implementing the plan and its very ambitious actions. The 5th edition of the European Code Against Cancer should be completed next year, empowering people to reduce their individual cancer risk, and another step will be the EU Network of Comprehensive Cancer Centres, which by 2028 will link 100 multidisciplinary structures that manage all aspects of cancer care, research and specialised medical training. Moreover, between 2026 and 2028, guidelines and quality assurance schemes for lung, prostate and gastric cancer care are envisaged to be released to support Member States in implementing new screening methods, enabling earlier detection that can save lives.

If confirmed, part of my work to advance a comprehensive approach to health promotion and disease prevention would be a revision of the tobacco control legislation, on the basis of the ongoing evaluation, and as supported by the European Parliament in 2022. One of the points of focus for the ongoing evaluation is around the use of emerging tobacco and related products, such as electronic cigarettes, and nicotine addiction. This is essential to better protect children, young people and citizens in general from the negative effects of these products. I would also intend to support the implementation of the proposed Recommendation on Smoke and Aerosol-free Environments, once adopted by the Council. More generally, I believe that we need to reflect on how to change the narrative on risk factors, including alcohol, and the economic determinants of health. Social attitudes can be a key driver for change.

Vaccination is one of the most effective and cost-efficient prevention measures. If confirmed, within the limit of the Union's competences, I will take measures to combat misinformation and vaccine hesitancy, monitor vaccination coverage in Member States, support vaccination campaigns and help Member States control possible disease outbreaks. I will look at ways to help Member States to address structural barriers to vaccination, from reducing costs and increasing access to vaccines, to addressing administrative hurdles and promoting the use of electronic registries. For example, the recently adopted Council Recommendation on vaccine-preventable cancers will help Member States boost the uptake of vaccines against human papillomaviruses among girls and boys and Hepatitis B virus among affected population groups. Implementation of the Recommendation would make a real difference.

If confirmed, I would also continue the work on mental health, an area which is very important to our citizens. Already before the COVID-19 pandemic, mental health problems affected around one in six people in the EU at a cost of EUR 600 billion, or more than 4% of our GDP. The European Parliament has recognised that better mental health is both a social and an economic imperative, and I would intend to take forward the measures set out in the 2023 Communication on a comprehensive approach to mental health. The implementation of the 20 flagships set out is either in progress or already completed, but we need to continue working with Member States and stakeholders. The comprehensive approach to mental health already has a strong focus on children and young people, who are increasingly affected by mental health disorders: in 2021, one in five adolescents had a mental health condition. While the digital transition obviously brings huge benefits, we cannot be blind to its downsides: we need a safer and healthier digital space for children that addresses the risks of excessive online presence and social media use, access to illegal or unsuitable content and cyberbullying. The Political Guidelines included a particular focus on this area. I will work with the Executive Vice-President for Tech Sovereignty, Security and Democracy, the Commissioner for Equality and the Commissioner for Intergenerational Fairness, Youth, Culture and Sport and lead an EU-wide inquiry on the broader impact of social media on people's well-being, with a special focus on children and young people. We need a strong evidence base on which a debate can be founded: work has also started on a prevention toolkit for children that will help map and address the impact of screen time and social media.

As detailed in my replies to questions 9 and 3, if confirmed, I will prioritise the ongoing evaluation of the regulatory framework on medical devices and consider potential legislative changes to ensure that the framework supports innovation and the availability of devices to safeguard high-quality patient care, including for children. In this context, I would look at the need to reduce costs and administrative burdens, especially for SMEs.