

Federal Ministry of Education and Research

Health research and innovation for the future of Europe This paper supplements the "German Discussion Paper for the Preparation of the 10th EU Framework Programme for Research and Innovation" of the Federal Government, which was published by the Federal Ministry of Education and Research (BMBF) in May 2024 and submitted to the European Commission. It is therefore part of a series of BMBF papers that go into more detail on individual aspects of the preliminary German position on the next EU Framework Programme for Research and Innovation.

In addition to the involvement of various ministries (Federal Ministry of Health, Federal Ministry of Labour and Social Affairs, Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection), a broad stakeholder survey was conducted and a group of experts was consulted for the preparation of this paper.

Political framework

In an increasingly mobile and interconnected world, European citizens expect their governments to be able to protect them from health threats and respond appropriately to cross-border crises. The Covid-19 pandemic has shown that global health has a direct impact on Europe and also how vulnerable European healthcare systems are. Increasing the **resilience** and **de-bureaucratisation of the European healthcare industry and global health** are therefore key concerns of the new European Commission.

It will also be important to preserve European values in a free and democratic Europe in the future. All members of the new European Commission have been called upon by the Commission President to implement the United Nations Sustainable Development Goals in their respective areas. This includes social fairness, which entails access to **high-quality healthcare for all**, but also the consideration of health aspects in other areas, e.g. in the workplace. **Mental health** in particular, including that of children, is mentioned in Commission President von der Leyen's priorities.

The healthcare sector also plays a crucial role in Europe's competitiveness. The Draghi report emphasises the pharmaceutical sector – one of the world's largest markets – as an important area for technological sovereignty and as one of the strategically important, innovative sectors.

Today's healthcare research sets the course for healthcare provision and the competitiveness of tomorrow's healthcare industry. Research and development are decisive factors in strengthening European sovereignty and competitiveness in the healthcare sector and in meeting the expectations of European citizens.

Health as a priority

Europe is confronted with numerous challenges:

- **Demographic change:** Falling birth rates and longer life expectancy mean that Europe's population is getting older and older. This comes along with an increase in the burden of disease and the growing incidence of chronic illnesses and co-morbidities, while the availability of healthcare professionals is decreasing.
- The triple planetary crisis¹: Climate change, environmental pollution and biodiversity loss are causing new health risks and placing new demands on healthcare, among others through new or reemerging (potentially pandemic) infectious diseases, significant health impacts due to environmental pollutants and burden caused by increasing heat and natural disasters. At the same time, they challenge the healthcare sector to become climate-neutral and sustainable. In order to successfully address this complex field in the long term, it is essential to take a holistic view of the close links between the human, domestic and wild animal, plant, and wider environmental sectors in line with the One Health approach. A healthy environment is of great importance for global health, as it enables a preventive approach aimed at avoiding diseases and health problems in the first place and thus protecting healthcare systems.

See also the focus paper "Accelerating the green transition – research for a competitive and resilient Europe within the Earth system boundaries. Priorities for the design of the 10th EU Framework Programme for Research and Innovation"

- Global health risks: In an increasingly mobile, interconnected world, health risks must be reflected on globally. Pandemics do not stop at national borders. The long-term consequences of infectious diseases must also be taken into account. The increase in antibiotic resistance is an increasingly urgent problem, for example for public health; but environmental influences, climate change, stress and unhealthy lifestyles also have a global impact on health. As a result, low- and middle-income countries are increasingly bearing a double burden of disease from infectious and non-communicable diseases. The triple planetary crisis and increasing mobility are exacerbating this trend. In addition, Europe must face up to its responsibility for countries with lower research and development capacities, as better healthcare is a prerequisite for social and economic development - especially in Africa, which, as a highly dynamic economic market in the future, is a privileged partner for Europe.
- Declining competitiveness and innovative strength of the healthcare industry and Europe as a centre of research: Europe's global market position in the pharmaceutical sector is declining due to comparatively lower investment in research and development as well as the sometimes highly complex regulatory framework compared to other regions of the world. This is particularly evident for modern pharmaceuticals such as biologicals and advanced therapy medicinal products (ATMPs), but also for innovative medical devices. New technologies and products must once again be developed and deployed to a larger extent in Europe in order to strengthen the competitiveness of Europe as a location for research, as well as of the European healthcare industry, and strengthen also Europe's resilience. Sustainable production processes can not only help to reduce the environmental impact of the sector, but also save costs at the same time. Attractive framework conditions also counteract the exodus of talent from Europe.
- Healthcare systems: European healthcare systems are faced with high expectations. They should be barrier-free, efficient, high-performance, crisisproof, inclusive, rehabilitative, digitally connected, needs-based and easily accessible for all, as well as taking sustainability aspects into account. The healthcare of the future should be increasingly

preventative, personalised, precise, participatory, and participation-oriented throughout the entire innovation process, and enable decision-making based on sound data. The shortage of personnel in the healthcare sector must also be countered by developing and utilising new care approaches and technologies.

Requirements for research, development and innovation

Addressing these challenges requires a **broad approach** to research, development and innovation that is holistic and sustainable and in which new technological developments and results from basic and clinical research as well as experience from patient- and population-centred care play a central role in generating new research questions and findings. The close link between research, development and application in healthcare is important for this in order to drive medical progress in a patient- and citizen-centred way and to integrate innovations into healthcare more quickly. Health research thereby focuses on numerous aspects: the promotion of physical and mental health, the influence of living conditions and health behaviour, the prevention of diseases, care in the event of illness, and the healthcare systems. A health-in-all-policies approach should support efforts in research and innovation and - in line with the One Health approach take account of the connections between human health, animals, plants and their shared environment to a greater degree.

The requirements for holistic health research can best be met by placing a specific focus on the topic of "health" in FP10 and providing an appropriate budget to address prioritised complex research and development issues within the framework of collaborative research performed by transnational interdisciplinary teams with the involvement of relevant stakeholders. Synergistic use of a thematic programme part with other programme parts of the Framework Programme for Research and Innovation is important here, e.g. by taking up the results of basic research in the health sector from the European Research Council (ERC) or the further development of medical devices in the European Innovation Council (EIC). It is also necessary for the programme to be closely coordinated with other EU programmes, such as the successor programmes of

"Digital Europe" and "EU4Health". These should complement the funding, e.g. by promoting innovations based on artificial intelligence (AI) and other digital technologies, as well as by transferring them to healthcare. Funding should be provided using the most appropriate instruments. Co-funded partnerships, for example, enable **coordination with Member States' activities** in priority fields of health research. Public-private partnerships, such as the Innovative Health Initiative, can provide a suitable framework for **cooperation with companies.** Smaller projects and the increased uptake of ideas from the academic sector could increase its added value.

Current developments such as increasing digitalisation and the rapid developments in the field of artificial intelligence² and in the personalisation of care services must be taken into account in research and development for all areas of disease and care. For the latter, in addition to the co-financed European Partnership for Personalised Medicine (EP PerMed), further targeted activities are necessary to support research and ensure the development of innovations and their implementation. In this context, it is also important to provide, link and promote the necessary infrastructures that have already been initiated at national and EU level (e.g. ESFRI infrastructures in the life sciences, the German Medical Informatics Initiative and University Medicine Network, also as a contribution to the future European Health Data Space - EHDS). The implementation of complex and resource-intensive projects, such the development of the EHDS, must therefore be supported appropriately by the EU through suitable programmes. This also applies in particular to investments for the coordinated provision of health data, including for care, research and development within the framework of the EHDS, utilising existing infrastructures and infrastructures currently being developed.

It is also crucial to address the **entire value chain**, whereby particular attention should be paid to the various "valleys of death". These funding gaps in the value chain (e.g. between preclinical and clinical research, between prototype and product, between placing on the market and widespread application) must be better bridged in order to ensure the translation of research results into practice.

2 See also the BMBF's focus paper "Key enabling technologies for the future of Europe".

The programme must allow for **addressing various indications** – both communicable and non-communicable diseases. In particular, health conditions with the greatest impact on the burden of disease should be considered, with a focus not only on **mortality** but also on the **morbidity load** (YLD – Years Lived with Disability). The actual affectedness of people (medical and care need), and thus also the challenges of global health, should be given appropriate consideration. In addition, there should be a focus on diseases that have been little researched to date and those in which there is no commercial interest. The **cancer mission** should be continued. After its expiry, the topic of cancer should be pursued in the long term – in close coordination with the European Cancer Plan.

Adequate involvement of patients, people in need of care, those affected, and health care providers, both in research projects and in strategic processes, is important for successful translation and research that is geared to actual needs

It is also crucial for competitive health research and innovation that the programme enables and promotes **international cooperation** with partners outside the EU, including with countries of the Global South. In particular, the newly created Global Health Joint Undertaking EDCTP3, in which European and African countries work together on an equal footing, creates a suitable framework for this, which can only be achieved at European level and which also effectively addresses the global policy priorities of the European Union.

In addition to efficient and effective funding for research and innovation, the **framework conditions in Europe**, including regulation and the transfer to healthcare, must be designed in such a way that Europe does not fall further behind in health research and innovation (new AI applications, animal testing, etc.). This can be supported by funding projects that generate the knowledge base for the development and design of rules and standards.

Overarching security interests must be taken into account. This also includes **research security.**³

³ See Position paper of the German Federal Ministry of Education and Research on research security in light of the Zeitenwende – BMBF

Topics for holistic European health research

In order to overcome these challenges, the following priorities should be set in European health research.

Health determinants

In order to maintain the health of European citizens, it is important to understand which factors influence the development of diseases. Individual factors as well as socio-economic and environmental influences must be considered. A better understanding of the interactions between these factors forms the basis for personalised medicine in the sense of an increasingly tailored treatment strategy or prevention for each individual. The influence of different lifestyle factors – such as diet and exercise – on health, illness and the need for care should also be more strongly the subject of research. The connections between environmental factors, society and health must - in terms of the One Health approach – be better understood and translated into forward-looking European health innovations, also with regard to future health crises such as advancing climate change or pandemics.

Research across all age groups that sheds light on the transitions between life phases and factors that promote early ageing can contribute to maintaining the health of the European population. In this context, child health must be given greater attention. The foundations for a healthy life are laid in childhood. Research can help to ensure that care is tailored to needs and requirements. This also includes **reducing unjustified inequalities and discrimination** in healthcare provision and promotion, particularly in relation to gender and other determinants such as socio-economic status, age or migration background. One approach to this could be, for example, public health and the socially compensatory impact of the public health service.

There is also a need for research into how (digital) **health literacy** and thus health behaviour and the ability to navigate the healthcare system can be sustainably improved. According to recent studies, more than half of the population has insufficient health literacy. One focus should be on how to reach people with (particularly) low health literacy.

Prevention

Many diseases that lead to a high burden of disease or premature mortality are preventable. In a society of longer life, targeted health promotion and prevention at every age are of crucial importance in order to minimise risks and prevent diseases or contain their consequences. For prevention to succeed, it must address two different levels: the behaviour of individuals and their living conditions. In order to be financially viable in the long term, the healthcare system of the future must also place a stronger focus on prevention. This concerns both the avoidance of pandemics and infectious diseases, e.g. through the use of suitable cross-sector surveillance and monitoring systems, as well as the reduction of non-communicable diseases such as cancer, cardiovascular diseases, dementia, obesity and diabetes. Mental health, including that of children, should also be a priority. Here, a holistic focus should be placed on the cross-sectoral One Health approach with comprehensive implementation as part of the Health in All Policies approach. It is important to investigate which **biomarkers** allow **early detection of** diseases and which health promotion and prevention measures are suitable for avoiding possible diseases, bringing about sustainable behavioural changes and improving health-related living, working and environmental conditions. This also includes new technologies that allow risk-adapted screening for early detection, approaches to personalised precision prevention, vector control measures and measures in the workplace - also against the backdrop of longer working lives.

Understanding diseases

Understanding diseases is an important prerequisite for the development of preventive measures, diagnostics and treatment methods. **Basic research** in this area must also be possible within the framework of thematically centered collaborative research. Subsequently, the transfer into practice for **prevention, diagnosis, treatment and care** is central. Obtaining evidence for gender-sensitive diagnosis and treatment is also playing an increasingly important role here. The aim here is to reduce existing data gaps in medical research ("gender data gap") and thus strengthen the knowledge base for gender-sensitive medicine and care.

Combating diseases

The development of new diagnostic procedures and **new therapeutic approaches** should be promoted as a priority by the framework programme. On the one hand, priorities should be set where there is little interest from the private sector and a high added value of cooperation at European level, e.g. in poverty-related, neglected diseases, rare diseases, in the development of new antibiotics or in relation to non-pharmacological psychosocial or commercially unattractive interventions. On the other hand, diseases that affect a large group of people, such as cancer, dementia or cardiovascular diseases, should be addressed. Transnational clinical studies for diagnostics and therapy are central to translation. Supporting university medical networks could be a sensible approach to increase the attractiveness of conducting innovative clinical trials in Europe and thus compensate for the strategic disadvantage of European hospitals compared to large researchstrong hospitals in the USA or China. Innovative approaches such as the use of virtual control groups and cohorts in clinical trials should also be considered. The transition from preclinical research to the first human trials also deserves special attention.

Healthcare systems

European healthcare systems are facing major challenges, including due to an ageing population with specific needs, due to the development of new, expensive healthcare services, the increasing demand for healthcare professionals, and care in rural areas. At the same time, European healthcare systems need to reduce their energy consumption, greenhouse gas emissions, water consumption and waste generation in the face of increasing demands. Research into measures to secure skilled labour, such as increasing the resilience and health of healthcare workers and fair, ethical and sustainable methods of recruitment from third countries, must therefore be given greater focus. In addition, technical support systems must be developed and their use researched, and measures to increase environmental compatibility must be explored.

Implementation research to identify the most suitable interventions as well as health technology assessment, the **development of new (digital) forms of care** and **equal access to care services** and equity should be addressed by the framework programme, and the findings – possibly supported by the EU4Health successor programme – should be transferred into care.

- New technologies and methods for research, development and supply
 The development and use of new technologies are important for the areas of health research and innovation listed above. They can make a fundamental contribution to addressing the above-mentioned challenges. In order to be internationally competitive, a common European approach makes sense, for example in the following areas:
 - Biotechnology including synthetic biology, genetics and cell biology as the basis for new diagnostics, e.g. therapy-accompanying diagnostics (so-called CDx), and therapy,
 - use of bio(techno)logical procedures in healthcare,
 e.g. genome medicine, gene and cell therapies,
 especially for use in the field of personalised
 medicine,
 - Medical technology, e.g. in imaging techniques, additive manufacturing, robotics and automation, theranostics, smart medical devices, closwed-loop systems and in-vitro diagnostics,
 - Supporting independence at old age through assistance systems, including age-appropriate working methods,
 - the improvement of high-quality care through telemedicine and secure, data protection-compliant access, exchange and corresponding use of health data, including across national borders, and
 - Compensating the shortage of skilled labour through digital methods and applications as well as the use of technical aids (robotics), for example in care, but also in information/consultation.

In addition to the development, the **continuation** of promising technologies towards innovative products should also be promoted. A low-threshold continuation of funding for promising technologies/approaches would be welcome. This requires funding that enables technologies to be brought to the point where they are industrially viable as well as suitable instruments to bring new technologies to the market more quickly - possibly also outside of the health programme part. Appropriate framework conditions could incentivise industry to further develop new technologies in Europe. In this context, research into the ethical, legal and social aspects (ELSA) of modern life sciences should be addressed by the framework programme as an integral part of research into new technologies and methods. ELSA research contributes to increasing awareness and understanding of new technologies, including their opportunities and risks, in society, and to developing suitable options for action on an interdisciplinary basis in order to utilise scientific progress responsibly for the benefit of mankind.

Digitalisation and AI

The European Health Data Space (EHDS) creates a legal framework for the cross-border use of health data for healthcare and research. On this basis, data-based health research with innovative "in silico" approaches must be expanded. Findability, accessibility, interoperability and reusability (FAIR principles) as well as the representativeness and storage of data in compliance with data protection and data security are important here. Existing infrastructures play an important role here by contributing to the success of the development of the EHDS and enabling access to linked research and healthcare data. When further developing existing infrastructures or setting up new ones, such as in university networks, the creation of duplicate structures must be prevented and the interoperability of data must be ensured. This in turn facilitates the use of data, for example to train AI systems.

Data linkage is an important future topic also within prevention research. The great potential of health promotion and prevention in relation to the health risks associated with advancing climate change can only be realised by analysing different data sources from a wide range of areas. The generation and use of "big data", e.g. to train AI, and better **analysis tools using AI** offer great opportunities for personalised medicine and addressing numerous health challenges. The use of generative AI and other AI applications in healthcare processes – including care – should be addressed. Multimodal and open source AI models and the explainability of AI are also of particular interest for research in the healthcare sector, also against the background of the EU's AI Regulation.

