

Horizon EUROPE - Specific Programme

proposal for a Decision of the Council [ST_8550/19_INIT]

PILLAR II - Global Challenges and European Industrial Competitiveness

CLUSTER I - Health

The EU is confronted by many challenges, some of which are also global challenges. The scale and complexity of the problems are vast, need to be tackled jointly and matched by adequate, properly trained and skilled human resources, by the appropriate amount of financial resources and a proportionate effort in order to find solutions. These are precisely the areas where the EU must work together; smart, flexible and joined-up for the benefit and well-being of all our citizens.

Greater impact can be obtained through aligning actions with other nations and regions of the world within international cooperation along the lines indicated by the United Nations 2030 Agenda for Sustainable Development and the Sustainable Development Goals and the Paris climate agreement. Based on mutual benefit, partners from across the world will be invited to join EU efforts as an integral part of research and innovation for sustainable development.

Research and innovation are key drivers of sustainable and inclusive growth and technological and industrial competitiveness. They will contribute to finding solutions to today's problems, and the problems of tomorrow, in order to reverse as quickly as possible, the negative and dangerous trend that currently links economic development with the growing use of natural resources and growing social challenges. This will turn the challenges into new business opportunities and into rapid benefits for society.

The EU will benefit as user and producer of knowledge, technologies and industries showcasing how modern industrialised, sustainable, inclusive, creative, resilient, open and democratic society and economy can function and develop. The growing economic-environmental-social examples of the sustainable economy of the future will be fostered and boosted, be they for: health and well-being for all; or resilient, creative and inclusive societies; or societies strengthened by civil security; or available clean energy and mobility; or a digitised economy and society; or a transdisciplinary and creative industry; or space-related, marine or land-based solutions; or a well-functioning bioeconomy, including food and nutrition solutions; sustainable use of natural resources, protection of the environment, climate change mitigation and adaptation, all generating wealth in Europe and offering higher quality jobs. Industrial transformation will be crucial, as well as developing EU innovative industrial value chains.

New technologies affect virtually all policy areas. For each separate technology there is often a combination of social and economic opportunities, opportunities for efficiency and quality and improvement of the government, consequences for employment and education, but also possible risks for safety, privacy and ethics. Technology policy therefore necessarily requires an integral weighing of interests, and cross-sectoral cooperation and strategy formulation.

Research and innovation under this pillar of Horizon Europe is grouped into integrated, non-siloed broad clusters of activities. Rather than addressing sectors, the investments aim at systemic changes for our society and economy along a sustainability vector. These will only be achieved if all actors, both private and public, engage in co-designing and co-creating research and innovation; bringing together end-users, scientists, technologists, producers, innovators, businesses, educators, policy-makers, citizens and civil society organisations. Therefore, none of the clusters is intended for only one set of actors and all activities will be implemented primarily by collaborative research and innovation projects selected on the basis of competitive calls for proposals.

In addition to addressing global challenges, activities in the clusters will also develop and apply, key enabling and emerging technologies (either or not digital-based) as part of a common strategy to promote the EU's industrial and social leadership. Where appropriate this will use EU space-enabled data and services. All TRL levels up to 8 will be covered in this pillar of Horizon Europe without prejudice to Union competition law.

Actions will generate new knowledge and develop technological and non-technological solutions, bring technology from lab to market and to develop applications including pilot lines and demonstrators, and include measures to stimulate market uptake and to boost private sector commitment and incentives to standardisation activities within the Union. Technologies require critical mass of European researchers and industry to establish world leading eco-systems, that include state of the art technology infrastructures e.g. for testing. Synergies with other parts of Horizon Europe and the EIT, as well as other programmes will be maximised.

The clusters will boost the quick introduction of first-of-its-kind innovation in the EU through a broad range of embedded activities, including communication, dissemination and exploitation, standardisation as well as support to non-technological innovation and innovative delivery mechanisms, helping create innovation friendly societal, regulatory and market conditions such as the innovation deals. Pipelines of innovative solutions originating from research and innovation actions will be established and targeted to public and private investors as well as other relevant EU and national or regional programmes. Synergies will be developed with the third pillar of Horizon Europe in that perspective.

Gender equality is a crucial factor in order to obtain sustainable economic growth. It is therefore important to integrate a gender perspective in all global challenges.

Cluster 1: 'Health'

1.1 Rationale

The EU Pillar of Social Rights asserts that everyone has the right to timely access to affordable, preventive and curative health care that is safe and of good quality. This underlines the EU's commitment to the UN's Sustainable Development Goals calling for universal health coverage for all and at all ages by 2030, leaving no one behind, and ending preventable deaths.

A healthy population is vital for a stable, sustainable and inclusive society, and improvements in health are crucial in reducing poverty, in dealing with an ageing European society, in fostering social progress and prosperity, and in increasing economic growth. According to the OECD a 10% improvement in life expectancy is associated with a rise in economic growth of 0.3-0.4% a year. Life expectancy in the EU increased by 12 years since its establishment as a result of tremendous improvements achieved in the quality of life, environment, education, health and care of its people. In 2015, overall life expectancy at birth was 80.6 years in the EU compared to 71.4 years globally. In the past years, it increased in the EU on average by 3 months annually. Besides these improvements social and gender-specific differences in life expectancy can be observed between specific groups and across European countries.

Health research and innovation have played a significant part in this achievement but also in improving productivity and quality in the health and care industry. However, the EU continues to face novel, newly emerging or persisting challenges that are threatening citizens and public health, the sustainability of its health care and social protection systems, as well as the competitiveness of its health and care industry. Major health challenges in the EU include: accessibility and affordability of health and care; the lack of effective health promotion and disease prevention; the rise of non-communicable diseases; the increased cases of cancer; the increase of mental illness; the spread of antimicrobial drug resistance and the emergence of infectious epidemics; increased environmental pollution; the persistence of health inequalities among and within countries disproportionately affecting people that are disadvantaged or in vulnerable stages of life; the detection, understanding, control, prevention and mitigation of health risks, including poverty-related aspects, in a rapidly changing social, urban, rural and natural environment; demographic change, including ageing-related issues, and the increasing costs for European health care systems; and the increasing pressure on the European health and care industry to remain competitive in and by developing health innovation vis-a-vis emerging global players. In addition, vaccine hesitancy may decrease immunisation coverage among certain population groups.

These health challenges are complex, interlinked and global in nature and require multidisciplinary, technical and non-technical, cross-sectorial and transnational collaborations. Research and innovation activities will build close linkages between discovery, clinical, translational epidemiological, ethical, environmental and socio-economic research as well as with regulatory sciences. They will address areas of unmet clinical needs such as for example rare or hard to treat diseases (cancers, such as paediatric and lung cancer). They will harness the combined skills of academia, practitioners, regulatory bodies and industry and foster their collaboration with health services, social services, patients, policy-makers and citizens in order to leverage on public funding and ensure the uptake of results in clinical practice as well as in health care systems taking into account the competencies of

Member States regarding the organisation and financing of their health systems. Full advantage will be taken of genomic and other multiomics frontier research, as well as the progressive introduction of personalised medicine approaches, relevant for addressing a variety of non-communicable diseases and the digitalisation in health and care.

Research and innovation will foster strategic collaboration at EU and international level in order to pool the expertise, capacities and resources needed to create scope, speed and economies of scale, as well as to exploit synergies, avoid duplication of effort and share the expected benefits and financial risks involved. Synergies in health research and innovation in Horizon Europe shall be promoted, in particular with the Health Strand within the European Social Fund Plus.

Digital health solutions have created many opportunities to solve the problems of care services and to address other emerging issues of ageing society. Full advantage should be taken of the opportunities that digitalisation in health and care can provide without jeopardising the right to privacy and data protection. Digital devices and software have been developed to diagnose, treat and facilitate patients' self-management of illness, including chronic diseases. Digital technologies are also increasingly used in medical training and education and for patients and other healthcare consumers to access, share and create health information.

The research and innovation activities of this global challenge will develop the knowledge base, exploit existing knowledge and technologies, consolidate and create the research and innovation capacity and develop the solutions needed for a more effective promotion of health and the integrated prevention, diagnosis, monitoring, treatment, rehabilitation and cure of diseases and (long-term and palliative) care. Results of research will be translated as recommendations for action and communicated with the relevant stakeholders. Improving health outcomes will in turn result in increased well-being and life expectancy, healthy active lives, improved quality of life and productivity, more healthy life years and sustainability of health and care systems. In line with articles 14 and 15 of the Regulation and the Charter for Human Rights and Fundamental Principles, ethics, protection of human dignity, gender and ethnic aspects and the needs of disadvantaged and vulnerable people will receive special attention.

Addressing major health challenges will support the EU's commitment to the United Nation's 2030 Agenda for Sustainable Development and those in the context of other UN organisations and international initiatives, including the global strategies and plans of action of the World Health Organization (WHO). It will contribute to the EU's policy goals and strategies, notably to the EU Pillar of Social Rights, the EU Digital Single Market, the EU Directive on cross-border healthcare, and the European One Health Action Plan against antimicrobial resistance (AMR), and to the implementation of the relevant EU regulatory frameworks.

Activities will contribute directly to the following Sustainable Development Goal (SDGs) in particular: **SDG3** – Good Health and Well-Being for People; **SDG13** – Climate Action.

1.2 Areas of Intervention

1.2.1 Health throughout the Life Course

People in vulnerable stages of life (perinatal, birth, infancy, childhood, adolescence, pregnancy, mature and late adulthood), including people with disabilities or injuries, have specific health needs that require better understanding and tailored solutions, taking gender and ethical aspects into consideration. This will allow reducing related health inequalities and improving health outcomes to the benefit of active and healthy ageing throughout the life course, including through a healthy start of life and diet reducing the risk of mental and physical diseases later in life. Prevention and communication will consider characteristics of specific audiences:

BROAD LINES:

- Understanding the early development and the aging process throughout the life course;
- pre- and neo-natal, maternal, paternal, infant and child health as well as the role of parents, family and educators;
- Health needs of adolescents, including factors influencing mental health;
- Health consequences of disabilities and injuries;
- Research on measures to plan, implement and monitor rehabilitation throughout the life course and especially early individual rehabilitation programme (EIRP) for children affected by disabling pathologies
- Healthy ageing, independent and active life, including social participation for the elderly and/or disabled people;
- Health education and health literacy, including digital.

1.2.2 Environmental and Social Health Determinants

Improved understanding of health drivers and risk factors determined by the social, culture, economic and physical environment in people's everyday life and at the workplace, including the health impact of digitalisation, human mobility (such as migration and travel), pollution, nutrition, climate change and other environmental issues, will contribute to identify, prevent and mitigate health risks and threats; to reducing death and illness from exposure to chemicals and environmental pollution; to supporting safe, environmental-friendly, healthy, resilient and sustainable living and working environments; to promoting healthy lifestyles and consumption behaviour; and to developing an equitable, inclusive and trusted society. This will also be based on population based cohorts, human biomonitoring and epidemiological studies.

BROAD LINES:

- Technologies and methodologies for assessing hazards, exposures and health impact of chemicals, indoor and outdoor pollutants and other stressors related to climate change, workplace, lifestyle or the environment and combined effects of several stressors;
- Environmental, occupational, socioeconomic, cultural, genetic and behavioural factors impacting physical and mental health and well-being of people and their interaction, with special attention to vulnerable and disadvantaged people, age-specific and gender-specific issues where relevant, and including the impact on health of the design of buildings, products and services;

- Risk assessment, management and communication, supported by transdisciplinary approaches, where relevant, and improved tools for evidence-based decision-making, including replacement of and alternatives to animal testing;
- Capacity and infrastructures to securely collect, share, use, re-use and combine data on all health determinants, including human exposure, and ensure their connection with databases on environmental parameters, lifestyles, health status and diseases, at EU and international level;
- Health promotion and primary prevention interventions, including occupational aspects

1.2.3 Non-Communicable and Rare Diseases

Non-communicable diseases (NCDs), including cancer, rare diseases, pose a major health and societal challenge and call for improved understanding and taxonomy, as well as more effective approaches, including personalised medicine (also called "precision medicine") approaches, in prevention, diagnosis, monitoring, treatment, rehabilitation and cure as well as understanding of multimorbidities.

BROAD LINES:

- Understanding the mechanisms underlying the development of non-communicable diseases, including Cardiovascular diseases;
- Longitudinal population studies to support understanding health and disease parameters and help stratifying populations in support of the development of preventive medicine;
- Diagnostic tools and techniques for earlier and more accurate diagnosis and for timely patient-adapted treatment, enabling delay and/or reversal of the progression of disease;
- Prevention and screening programmes, in line with or going beyond WHO, UN and EU recommendations;
- Integrated solutions for self-monitoring, health promotion, disease prevention, and management of chronic conditions and multi-morbidities, including neurodegenerative and cardiovascular diseases;
- Treatments, cures or other therapeutic interventions, including both pharmacological and nonpharmacological treatments;
- Palliative care;
- Areas of high unmet clinical need, such as rare diseases, including paediatric cancers
- Assessment of comparative effectiveness of interventions and solutions, including based on Real World Data (RWD);
- Implementation research to scale up health interventions and support their uptake in health policies and systems;
- Development of research and improvement of information, care and treatment, including personalised medicine, for rare diseases.

1.2.4 Infectious Diseases, including poverty-related and neglected diseases

Protecting people against cross-border health threats is a major challenge for public and global health, calling for effective international cooperation at EU and global level. This will involve understanding and prevention of, preparedness for, early detection of and research response to outbreaks, treatment

and cure of infectious diseases, including poverty-related and neglected diseases, and also tackling antimicrobial resistance (AMR) following a 'One Health approach'.

BROAD LINES:

- Understanding infection-related mechanisms;
- Drivers for the emergence or re-emergence of infectious diseases and their spread, including transmission from animals to humans (zoonosis), or from other parts of the environment (water, soil, plants, food) to humans, as well as impact of climate change and ecosystems evolutions on the dynamics of infectious diseases;
- Prediction, early and rapid detection, control and surveillance of infectious diseases, healthcare-associated infections and environmental related factors;
- Combatting antimicrobial resistance, including epidemiology, prevention, diagnosis, as well as the development of new antimicrobials and vaccines;
- Vaccines, including vaccine platform technologies, diagnostics, treatments and cures for infectious diseases, including co-morbidities and co-infections
- Addressing low vaccine uptake, understanding vaccine hesitancy and building vaccine confidence;
- Effective health emergency preparedness, response and recovery measures and strategies, involving communities, and their coordination at regional, national and EU level;
- Barriers to the implementation and uptake of medical interventions in clinical practice as well as in the healthcare system;
- Trans-border aspects of infectious diseases and specific challenges in low- and middle-income countries (LMICs), such as AIDS, tuberculosis and tropical diseases, including malaria, also in relation to migratory flows and, in general, to increased human mobility.

1.2.5 Tools, Technologies and Digital Solutions for Health and Care, including personalised medicine

Health technologies and tools are vital for public health and contributed to a large extent to the important improvements achieved in the quality of life, health and care of people, in the EU. It is thus a key strategic challenge to design, develop, deliver, implement and evaluate suitable, trustable, safe, user-friendly and cost-effective tools and technologies for health and care, taking due account of the needs of people with disabilities and the aging society. These include key enabling technologies from new biomaterials to biotechnology as well as single cell methods, multiomics and systems medicine approaches, artificial intelligence and other digital technologies, offering significant improvements over existing ones, as well as stimulating a competitive and sustainable health-related industry that creates high-value jobs. The European health-related industry is one of the critical economic sectors in the EU, accounting for 3% of GDP and 1.5 million employees. Relevant stakeholders need to be involved as early as possible, and the non technological dimension will be taken into account, in order to ensure acceptability of new technologies, methodologies and tools. This includes citizens, health care providers and professionals.

BROAD LINES:

- Tools and technologies for applications across the health spectrum and any relevant medical indication, including functional impairment;

- Integrated tools, technologies, medical devices, medical imaging, biotechnology, nanomedicine and advanced therapies (including cellular and gene therapy), and digital solutions for human health and care, including artificial intelligence, mobile solutions and telehealth, while addressing, when relevant, cost-efficiency production aspects at an early stage (in order to optimize the industrialisation stage and the potential of innovation to become an affordable medicinal product);
- Piloting, large-scale deployment, optimisation, and innovation procurement of health and care technologies and tools in real-life settings including clinical trials, implementation research including diagnostics based on personalised medicine;
- Innovative processes and services for the development, manufacturing and rapid delivery of tools and technologies for health and care;
- The safety, efficacy, cost-effectiveness, interoperability and quality of tools and technologies for health and care as well as their ethical, legal and social impact, including social acceptance issues;
- Regulatory science and standards for health and care technologies and tools;
- Health data management, including data interoperability, integration, analytical and visualisation methods, decision making processes, building on artificial intelligence, data mining, big data technologies, bioinformatics and high performance computing technologies to foster personalised medicine including prevention, and to optimise the health journey.

1.2.6 Health Care Systems

Health systems are a key asset of the EU social systems, accounting for 24 million employees in the health and social work sector in 2017. It is a main priority of Member States to render health systems safe and secure, accessible for all, integrated, cost-effective, resilient, sustainable and trusted with timely and relevant services, as well as to reduce inequalities, including by unleashing the potential of data-driven and digital innovation for better health and person-centred care building on open and safe European data infrastructures. New opportunities such as 5G deployment, the concept of 'digital twins' and the Internet of Things will advance the digital transformation of health and care.

BROAD LINES:

- Supporting the knowledge base for reforms in health systems and policies in Europe and beyond;
- New models and approaches for health and care, including personalised medicine approaches, management and organisational aspects, and their transferability or adaptation from one country/region to another;
- Improving health technology assessment;
- Evolution of health inequality and effective policy response;
- Future health workforce and its needs, including digital skills;
- Improving timely, reliable, safe and trustworthy health information and use/reuse of health data, including electronic health records, with due attention to data protection, including the misuse of personal life style and health information, security, accessibility, interoperability, standards, comparability and integrity;
- Health systems resilience in absorbing the impact of crises and to accommodate disruptive innovation;
- Solutions for citizen and patient empowerment, self-monitoring, and interaction with health and social care professionals, for more integrated care and a user-centred approach, while considering equal access;

- Data, information, knowledge and best practice from health systems research at EU-level and globally building on existing knowledge and databases.