



# FOCUS-EU

HEALTH

February 2021

Overview of EU and global policy developments

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## Horizon Europe

The [Horizon Europe](#) is now launched under the Portuguese presidency of the EU and its implementation under the Directorate-General for Research, DG RTD. It is the largest European programme so far with a budget of €95.5 billion for research and innovation activities between 2021-2027. The European Commission has reaffirmed its 3% target for public and private R&D investment in terms of gross domestic product by 2030 to achieve the green and digital switchover, and a resilient recovery through a renewed European Research Area (ERA). The [Horizon Europe Strategic Plan 2021-2024](#) defines the key priorities for its first four years with a focus on global challenges, European industrial competitiveness and the European Research Area. Horizon Europe has four pillars:

Pillar 1: 'Excellent Science', [European Research Council, [Marie Skłodowska-Curie Actions \(MSCA\)](#) and Research Infrastructures;

Pillar 2: 'Global Challenges and European Industrial Competitiveness' in six clusters: 1) Health; 2) Culture, Creativity and Inclusive Society; 3) Civil Security for Society; 4) Digital, Industry and Space; 5) Climate, Energy and Mobility; 6) Food, Bioeconomy, Natural Resources, Agriculture and Environment. It includes institutionalised partnerships in energy, transport, biodiversity, health, food and circular economy.

Pillar 3: 'Innovative Europe', supporting new market-building activities and SMEs, including support for [European Innovation Ecosystems](#), the [European Institute of Innovation and Technology](#) and the new European Innovation Council.

Pillar 4: 'Widening Participation and Strengthening the European Research Area', aimed at networking in terms of human resources and at the institutional level.

Source: <https://www.ani.pt/en/horizon-europe>

Work programmes: [Horizon 2021 Work Programme](#); [Research Missions Work Programme](#)

## European Parliament

### Expanded mandates ECDC and EMA

The European Parliament is to examine the set of proposals by the European Commission on the expanded legal mandate of European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

#### ECDC

A draft Regulation changes ECDC's current founding Regulation reinforcing the ECDC mandate so that the Centre may support Member States and the Commission in the following areas:

- real-time epidemiological surveillance;
- preparedness and response planning/reporting/auditing;
- provision of non-binding recommendations and options for risk management;
- capacity to mobilise and deploy EU Health Task Force to assist local response in Member States;
- build a network of EU reference laboratories and a network for substances of human origin.

A proposal for a new Regulation on serious cross-border threats aims at 'creating a more robust mandate for coordination by the Commission and EU agencies'. Its main new elements are:

- To strengthen preparedness: EU health crisis and pandemic preparedness plans and recommendations will be developed for adoption at national levels. The preparation of national plans would be supported by ECDC and other EU agencies.
- To reinforce surveillance: a strengthened, integrated surveillance system will be created at EU level, using artificial intelligence and other advanced technology.
- To improve data reporting: Member States will be required to step up their reporting of health systems

indicators (e.g. hospital beds availability, specialised treatment and intensive care capacity, number of medically trained staff etc.).

- The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis relevant products.

A reinforced mandate for the European Medicines Agency (EMA) aims to enhance its role in crisis preparedness and management so that it can facilitate a coordinated EU-level response to health crises by:

- monitoring and mitigating the risk of shortages of critical medicines and medical devices;
- identifying and providing scientific advice on crisis-relevant medicines and medical devices in a timely manner;
- coordinating studies to monitor the effectiveness and safety of vaccines;
- coordinating clinical trials.

The European Parliament will vote on the proposals in June 2021.

Sources: [https://ec.europa.eu/ECDC\\_mandate](https://ec.europa.eu/ECDC_mandate)  
[https://ec.europa.eu/EMA\\_mandate](https://ec.europa.eu/EMA_mandate)

## EU4Health

The European Parliament has voted for the EU4Health programme. EU4Health is the fourth EU health programme, which will run from 2021-2027 with a budget of €5.1 billion to address cross-border health threats, to ensure availability of affordable medicines, and to support resilience and digitalisation of health systems. It is a stand-alone programme with a budget ten times that of previous health programmes.

The programme is now awaiting adoption by the Council before it can enter into force. The programme will be implemented by a new executive agency, the Health and Digital Executive Agency.

Source: <https://ec.europa.eu/EU4Health>

## European Commission

### Structured dialogue Initiative

The structured dialogue initiative is a two-phase process steered by the European Commission to facilitate discussions with and between stakeholders in the pharmaceuticals manufacturing value chain, public authorities, research community, health professionals and patient organisations. The overall focus is on the resilience of pharmaceutical supply chains and the security of supply of affordable medicines.

Phase 1 is gathering evidence on the functioning and the vulnerabilities of the global pharmaceutical supply chains. Its four work streams are:

- **Robust supply chain** which will define a robust supply chain and analyse its key criteria.
- **Critical medicinal products** which will identify medicinal products that are considered to be critical to public health and discuss methodology to trace EU manufacturing capacity for those critical products.
- **Vulnerabilities** which will explore the causes and drivers of vulnerabilities, including dependencies considering at what stage in the supply chain they occur and if they differ for different types of medicines. This work stream will also assess the financial impact associated with addressing challenges and drivers.
- **Innovation** which will identify the innovation and prioritisation needs for resilient supply chains and will integrate considerations of green and digital transition requirements, as well as modernisation of manufacturing processes.

Phase 2 will focus on measures to address the identified issues and in compliance with EU competition and World Trade Organization rules. The initiative aims to deliver results by the end of 2021.

Source: [https://ec.europa.eu/structured\\_dialogue](https://ec.europa.eu/structured_dialogue)

## European Council

### Micro-credentials

The European Commission has published the *European Approach to Micro-credentials* report which analyses how micro-credentials will make education more inclusive and flexible and contribute to a sustainable post-pandemic recovery. Wider consultations on micro-credentials will cover all sectors of education and training to prepare a Council Recommendation on micro-credentials for lifelong learning and employability, by the end of 2021.

A European approach is needed because:

- European labour markets are transforming rapidly, especially influenced by the COVID-19 pandemic and the twin digital and environmental transitions;
- flexible, modular learning with agreed quality standards will facilitate recognition of these types of course across the EU.

The short courses can be provided by higher and vocational education and training institutions, and by different types of private entities, as a quick response to labour market needs for specific skills.

*A micro-credential is a proof of learning outcomes acquired following a short, transparently-assessed learning experience. They are awarded upon the completion of short stand-alone courses (or modules) done on-*

site/online/in a blended format. Micro-credentials are open to all types of learners and are particularly helpful for people who want to:

- build on their current knowledge instead of getting a full degree;
- bridge a gap between degrees or their initial formal education and emerging labour market skills;
- upskill or reskill.

Sources: [https://ec.europa.eu/exec\\_summary.pdf](https://ec.europa.eu/exec_summary.pdf)  
<https://ec.europa.eu/micro-credentials>  
<https://www.swisscore.org/microcredentials>

## Other

### Horizon IP Scan

The European Commission has launched Horizon IP Scan to help manage and valorise IP in research and innovation collaboration. The service is available to start-ups and SMEs that will sign a Horizon 2020/Horizon Europe Grant Agreement or already have signed one in the last six months. The Horizon IP Scan team assesses intangible assets of SMEs in order to present ways to protect existing IP while collaborating with multiple partners on R&I projects and to assist in shared strategy development for the management and exploitation of new IP that was jointly generated.

[Horizon IP Scan Guide for Applicants](#)

[Horizon IP Scan – Service Request Form](#)

### Decade of Healthy Ageing (2021-2030)

The United Nations Decade of Healthy Ageing (2021-2030) is a global collaboration, aligned with the last ten years of the Sustainable Development Goals. It brings together governments, civil society, international agencies, professionals, academia, the media, and the private sector to address four areas for action: age-friendly environments, ageism, integrated care and long-term care. A platform connects and convenes the stakeholders who promote the four action areas at country level and support those seeking to find and share knowledge on how to improve the lives of older people, their families and communities.

Source: <https://www.who.int/initiatives/decade-of-healthy-ageing>

### Assessment of health data governance under GDPR

A study on health data governance within the EU has highlighted the need to address legal and operational issues to optimise secondary use to improve performance of healthcare systems, and health research and innovation. The study distinguishes between using health data for primary purposes (for treatment of the patient) and secondary purposes (for research, registries and management of the healthcare system). Variations in

interpretation of the GDPR law have precipitated fragmentation and hindering cross-border cooperation for care provision, healthcare system administration or research.

A fully harmonised approach is needed to the rules on processing of data in healthcare provision and administration or research across the EU as patients do not always find it easy to exercise their rights granted by the GDPR. Operational governance based on the FAIR data principles and implementation of technical standards are needed to ensure data interoperability and to build trust in data governance amongst EU citizens.

There is support for the creation of an infrastructure to facilitate data access and sharing with a preference for a centralised operation of the infrastructure via an EU agency or EU committee, rather than via a voluntary network. Issues of technical nature such as technical and semantic interoperability, data quality, data acquisition and digital skills and capacity building in the Member States need attention together with significant support to empower patients as active agents in their own health and care and exercise their health data related rights. Future EU level actions should include stakeholder driven codes of conduct, and targeted and sector specific EU level legislation. It is important that any future action should be respectful of the principles of proportionality and subsidiarity.

Source: [https://ec.europa.eu/ms\\_rules\\_health-data\\_en.pdf](https://ec.europa.eu/ms_rules_health-data_en.pdf)

### Archiving EIP AHA & the future of European Partnerships

After 10 years of close and hands-on collaboration, the European Innovation Partnership in Active and Healthy Ageing (EIP on AHA) is closed in the light of the restructuring of the partnership landscape. Fewer European Partnerships are envisaged in only three distinct forms - co-funded, co-programmed and institutionalised. The latter will become the new form for public-private partnerships with industry, research groups, international organisations and Member States under Article 187 of the Treaty of the Functioning of the EU commonly known as Joint Undertakings (JUs). Several of the H2020 JUs will be reformed as institutionalised partnerships.

The archiving of the [EIP on AHA portal](#) has started in 2021. Information on its work will still be accessible at [the Library of Digital Strategy](#). [Ten EIP on AHA infographics](#) capturing the impressive work carried out over the years, are free for anyone to use in communications and distribution across social networks.

[Futurium](#), a platform dedicated to citizens discussing EU policies, is now housing the EIP AHA Action Groups reshaped as new communities around the umbrella of [Active and Healthy Living in the Digital World](#) with specific sub-groups on [Wellbeing and Health promotion](#), [Ecosystems and Deployment](#), [Silver Economy and HealthTech](#), [Age-Friendly Environments](#), [Digital Health Literacy](#), [International Cooperation](#).

Launched in 2011, the EIP AHA was the first EIP to be created aiming to foster innovation and digital transformation in the field of active and healthy ageing. The EIP on AHA had two main pillars (Action Groups and Reference Sites) and three crosscutting horizontal initiatives that fed into the EIP AHA (the Blueprint,

Innovation to Market (I2M) and the "Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing" (MAFEIP).

The 103 Reference Sites ecosystems continue the EIP AHA work in delivering and scaling up creative and workable solutions on improving the health of their communities.

*The concept of a European Innovation Partnership (an EIP) was based on voluntary collaboration of all the relevant actors at EU, national and regional levels across different policy areas. The stakeholders were organised around themes emerging from the interests of the participants (Action Groups) and involving all the innovation chain levels.*

**Action Groups.** Communities of partners committed to work on specific issues related to active and healthy ageing by sharing knowledge and expertise and identifying gaps that need to be addressed at European level.

**Reference Sites.** Regions, cities, integrated hospitals or care organisations and their quadruple helix partners from industry, civil society, academia and government authorities with a focus on a comprehensive, innovation-based approach to active and healthy ageing.

**Innovation 2 Market** targets the cross-border scale-up of digital health and care solutions as part of the Commission's strategy on [eHealth](#).

**Blueprint.** The common policy vision of the EIP on AHA partners with a "back-and-forth" mechanism between the EC and stakeholders (policy makers and other key opinion leaders) for its updating & implementation.

**MAFEIP.** The Monitoring and Assessment Framework is an impact assessment tool to support evidence-based decision-making process for all institutions and users in the health and care sector.

## Consultations & Events

[SBP Workshop Connecting researchers & biobanks: The Biolink experience What's "NEXT" ?](#)

April 20, 2021 from 1:00 to 5:30 pm

The following consultations are now open

[Blood, tissues and cells for medical treatments & therapies – revised EU rules](#)

Deadline: 15 April

[HERA - European Health Emergency Preparedness and Response Authority Public Consultation](#)

Deadline: 12 May

[Guidance on tackling disinformation](#)

Deadline: 29 April

[Drug resistance – criteria for identifying antimicrobial medicines reserved for treating humans](#)

Deadline: 23 April

[Evaluation and revision of the general pharmaceutical legislation](#)

Deadline: 27 April

## Calls

### A note to our readers

click on Call, Consultation & Event title to access details on submission of application or event registration.

[Call for expression of interest - Executive Agency for Small and Medium-sized Enterprises \(EASME/EISMEA\)](#)

Deadline: 12 April

[ERC Consolidator Grants](#)

Deadline: 20 April

[Open Call for COST Action proposals](#)

Next Collection Date: 29 October 2021

## EU on COVID-19

### Coronavirus variants

EU to invest €150 million for research to counter coronavirus variants

Source: [https://ec.europa.eu/EC\\_Invest\\_variants](https://ec.europa.eu/EC_Invest_variants)

### Temporary Reintroduction of Border Control

[Click here to access the notifications per country](#)

