



FOCUS-EU

HEALTH

March 2021

Overview of EU and global policy developments

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HaDEA: a new Agency for Health

The new European Health and Digital Agency ([HaDEA](#)) has taken up its role in managing European programmes and initiatives in close collaboration with its parent Directorate-Generals, namely CNECT, DEFIS, GROW, RTD and SANTE, the latter is in the lead.

HaDEA is located in Brussels and is governed by a Steering Committee composed of DG SANTE as the lead parent DG and DGs Research & Innovation (RTD), Communications Networks, Content and Technology CNECT, Internal Market, Industry, Entrepreneurship and SMEs (GROW) and Defence Industry and Space (DEFIS). It will start with around 280 staff, a figure which is expected to grow to more than 500 by 2027.

The HaDEA will implement the following programmes:

- EU4Health programme: €5,1 billion;
- Horizon Europe: Pillar II, Cluster 1: Health: €5,4 billion;
- Single Market Programme: Food safety: €1,3 billion;
- Digital Europe Programme: €0,8 billion;
- Connecting Europe Facility: Digital: €1,7 billion;
- Horizon Europe: Pillar II, cluster 4: Digital, Industry and Space: €5,5 billion.

The expected total budget managed by the HaDEA will amount to over €20 billion over the 7 years period of the 2021-2027 Multi-annual Financial Framework (MFF).

Source: https://hadea.ec.europa.eu/about-hadea_en

[Overview of Horizon Europe](#)

Access a reader-friendly outline of Horizon Europe at the Euresearch site, a Swiss information and guidance service on cooperation and funding opportunities in Europe.

European Parliament

The European Parliament's Industry and Research committee (ITRE) have voted in support of the Commission's proposal to create the first ever Digital Europe programme by investing €8.2 billion under the EU budget 2021-2027. The programme is complementary to Horizon Europe and to the EU's new pandemic recovery fund, which mandates EU member states to allocate at least 20% of the money to projects that help countries digitise their economies. The ITRE has also voted to:

- Increase the Horizon Europe research programme budget for 2021-2027 to €120 billion in 2018 prices (instead of €83.5 billion, as proposed by Commission).
- Increase support for small and medium-sized enterprises (SMEs) by reintroducing the possibility of grants for incremental innovation, with a ring-fenced budget of €2.5 billion.
- Introduce innovative measures, such as widening fellowships to strengthen European Research Areas, and reduce the scientific and technological divide.
- Give priority to programmes that include women, SMEs or participants from lower-performing EU countries when deciding on two equally strong applications.

The ITRE has also voted to allocate €11.5 billion to the [European Defence Fund](#) and raise the Commission's proposed budget to the [EU Space Programme](#), to €14.82 billion for 2021-2027 to finance cross-border collaboration in defence research, development projects, address cyber threats and support space diplomacy.

Source: https://www.europarl.europa.eu/Research_2021-2027

European Commission

The European Commission (EC) has launched their own Open Access Publishing Platform 'Open Research Europe' in cooperation with [F1000 Research](#), an open access publishing platform supporting data deposition and sharing. The platform will offer fast publication and open peer review for research stemming from Horizon 2020 funding across all subject areas. The platform may also extend to research of the Horizon Europe programme.

The platform enables researchers to publish any research they wish to share, supporting reproducibility, transparency and impact. It uses an open research-publishing model, which will see publication within only days of submission, followed by open invited peer review. Expert reviewers will be selected and invited, and their reviews and names will be published alongside the article, together with the authors' responses and comments from registered users. To facilitate reuse, reanalysis and replication of results, articles published on the platform will include citations to all supporting data and materials. All Horizon 2020 grantees are eligible to publish at no cost to them.

Sources: <https://open-research-europe.ec.europa.eu>

European Innovation Council is launched

The European Innovation Council (EIC) is a new key element of Horizon Europe with a budget of €10 billion for 2021-2027. The EIC has a mission to identify, develop and scale-up breakthrough technologies and disruptive innovations. The EIC will support startups, SMEs and research teams developing high-risk, high-impact breakthrough innovation, with a particular focus on scaling up game-changing solutions that contribute to the objectives of the European Green Deal and the Recovery Plan for Europe. The EIC combines research on emerging technologies with an accelerator programme and a dedicated equity fund with around €3 billion of the EIC's budget, the [European Innovation Council Fund](#), to scale up innovative start-ups and small and medium-sized businesses (SMEs). The first opening funding opportunities are worth over €1.5 billion in 2021 and include:

- [EIC Accelerator](#) financing, worth €1 billion, for start-ups and SMEs/
- [EIC Pathfinder](#) for multi-disciplinary research teams, worth €300 million, to undertake visionary research with the potential to lead to technology breakthroughs. Research teams can apply for up to €4 million in grants. The bulk of the funding is awarded through open calls with no predefined thematic priorities, while €132 million is allocated to tackle five Pathfinder challenges: self-aware Artificial Intelligence (AI), tools to measure brain activity, cell and gene therapy, green hydrogen, and engineered living materials.
- [EIC Transition](#) funding worth €100 million for turning research results into innovation opportunities. The first EIC Transition call will focus on results generated by EIC

Pathfinder pilot projects and European Research Council Proof of Concept projects, to mature the technologies and build a business case for specific applications.

- New measures are introduced to support **women innovators**, which include a female leadership programme. In partnership with the [Enterprise Europe Network](#), talented female innovators, as well as all innovative SMEs from lesser-known regions, will be supported to apply, helping to overcome the innovation divide.

All projects of the European Innovation Council have access to [Business Acceleration Services](#), which provide coaches, mentors and expertise, partnering opportunities with corporates, investors and others, and a range of services and events. The activities of the EIC are overlooked by the [EIC Advisory Board](#).

Source: https://eic.ec.europa.eu/index_en

Access here the [EIC annual work programme](#)

European Council

The European Council has published its position on establishing Erasmus+, the EU Programme for Education, Training, Youth and Sport 2021-2027. It includes all three new initiatives proposed by the European Commission:

- the European Universities Initiative (EUI),
- Centres of Vocational Excellence (CoVEs) and
- DiscoverEU.

The Council gave more prominence to inclusion, and allowed for higher budgets for adult education and vocational education and training (VET). The budget ceiling for 2021 was defined at €2.85 billion. Higher education institutions will be allowed to use up to 20% of funds awarded for each mobility and VET project for outgoing mobility of students and staff to institutions in any Partner Country. The CoVE initiative becomes more open, any public or private organisation active in VET and established in a Programme Country or in any Partner Country can be involved as full partner, affiliated entity or associated partner. At the same time, applications still have to be submitted by entities from Programme Countries.

There are no calls yet under the European Universities Initiative, as the initiative will first be evaluated before it will be relaunched again.

The programme will be officially adopted after the voting of the European Parliament.

Source: <https://data.consilium.europa.eu/Erasmus+>

Access the [Erasmus+ Annual Work Programme 2021](#)

Across the World

FDA: Bad Ad Programme

The Food and Drug Administration (FDA) routinely checks advertisements about prescription drugs on television, magazines and medical journals, and they launched the Bad Ad Programme to enable tracking of closed-door sales tactics such as a chat inside a doctor's office or a sales presentation over a meal.

The outreach program is designed to raise awareness about potentially false or misleading prescription drug promotion and provides an easy reporting system. It is run by the Agency's Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) and targets physicians, physician assistants, nurse practitioners, nurses, pharmacists, pharmacy technicians, and trainees.

The FDA expects to continue and expand the programme in coming years with a web-based continuing education program focusing on students and early career healthcare professionals. The FDA will also be actively seeking opportunities to collaborate with the nation's medical, pharmacy, and nursing schools to enhance student education and will continue conducting presentations at U.S. teaching hospitals. Future activities will also include continued attendance of OPDP representatives at trade shows across the country, including those of the:

- American Academy of Physician Assistants
- American Academy of Nurse Practitioners
- American Academy of Family Physicians
- American Academy of Paediatrics
- American College of Gastroenterology
- American Society of Health System Pharmacists

Although anyone can submit a complaint to FDA, the core of the Bad Ad Program is focused primarily on healthcare providers as the majority of prescription drug promotion is directed towards healthcare providers. FDA maintains a separate [website for consumers](#) aiming to educate citizens about false or misleading direct-to-consumer promotion.

Sources: <https://www.fda.gov/bad-ad-program>
<https://www.fda.gov/media/138168/download>

Other

MDCG guidance while waiting for EUDAMED

The Medical Device Coordination Group (MDCG) has issued a Guidance on harmonised administrative practices and alternative

technical solutions until EUDAMED is fully functional. The document provides guidance to Member States and other relevant parties on the application of certain MDR provisions during the absence of EUDAMED. The proposed practices and solutions aim to enable Member States and other relevant parties to meet their obligations under the MDR effectively while minimising any potential additional burden on the parties concerned.

Source: https://ec.europa.eu/MDCG_Guidance

European Innovation Council prizes

Several prizes are integrated in the European Innovation Council to acknowledge European innovators:

- The [EU Prize for Women Innovators](#) recognises the women entrepreneurs from across the EU and countries associated to Horizon Europe.
- The [European Capital of Innovation Awards](#) (iCapital) recognises annually cities which best promote innovation in their communities.
- The [European Social Innovation Competition](#) aims to incentivise, support and reward social innovations that help people and organisations to identify, develop and strengthen the skills required for innovation.
- The [European Innovation Procurement Awards](#) aim to recognise public and private buyers who promote and implement innovation procurement.

The EU Prize for Women Innovators and the European Capital of Innovation Awards are now open for applications, while the other two will open later this year (more details in the Call section p. 4)

Source: [EIC_prizes](#)

[Is your software a medical device?](#)

Infographic on decision steps to assist in the qualification of Medical Device Software (MDSW).

BBMRI Work Programme

The 2021 Work programme of the Biobanking and BioMolecular resources Research Infrastructure (BBMRI) foresees an expansion of the BBMRI services in line with the visions of European Open Science Cloud (EOSC) and the European Open Data Space, with a focus on the requirements for digitalisation and open science for the management sensitive health data. The BBMRI research will address foremost disease areas of cancer, rare diseases, and COVID-19 while expanding on novel technologies to leverage the potential of sequencing and NMR spectroscopy advancements.

For more details access the [BBMRI Work Programme](#)

A note to our readers

Click on Call, Consultation, Event title for details on conditions, documents, registration & submission service

Calls

[Call for European Innovation Procurement Award for public and private procurers](#) **Deadline: 29 July**

[EU Prize for Women Innovators](#) **Deadline: 30 June**

[ERC Consolidator Grants](#) **Deadline: 20 April**

[Calls on Erasmus+](#) **Deadlines vary**

For deadlines see the [Erasmus Programme Guide](#)

[EIC Accelerator Challenge – Healthcare technologies](#)

This is a new funding tool of the Horizon Europe for AI-driven tools for early diagnosis; point-of-care diagnostics; novel approaches in cell and gene therapy; novel biomarkers for clinical prognosis, patient stratification or monitoring purposes across a wide spectrum of disorders; bioprocessing 4.0 (digitalisation of biodevelopment in biotech/biopharma industry); healthcare

intelligence services; e-health (including mobile health) solutions for healthcare systems, medical practice & Intensive Care Units.

Multiple cut-off dates: 9 June & 6 October

Consultations & Events

[ERN-EYE: Webinar on Papilloedema & COVID vaccination](#)

An interactive session on the differential diagnosis of papilloedema combining neurological and ophthalmological insights with novel AI approaches. **Date: 22 April**

[HERA - European Health Emergency Preparedness and Response Authority](#) **Deadline: 12 May**

[Guidance on tackling disinformation](#) **Deadline: 29 April**

[Criteria for identifying antimicrobial medicines reserved for treating humans](#) **Deadline: 23 April**

[General pharmaceutical legislation: Evaluation & revision](#) **Deadline: 27 April**

EU on COVID-19

[Q & A on COVID-19 tests](#)

The Directorate-General for Health and Food Safety (DG SANTE) has issued a publicly accessible Questions & Answers document on the types of COVID-19 tests available and their performance, the legal framework for COVID-19 *in vitro* diagnostic medical devices, and the roles and responsibilities of various actors in the COVID-19 testing process.

New hosts for rescEU medical supplies

Belgium, the Netherlands and Slovenia are added to the list of host countries responsible for the procurement for rescEU, the common European stock of lifesaving medical equipment (other countries: Denmark, Germany, Greece, Hungary, Romania, Sweden). A second medical reserve to be hosted by Germany.

Supplies now include millions of medical masks and FFP2 and FFP3 masks; medical gloves; medical gowns and aprons; and several thousand oxygen concentrators & ventilators.

The common European stock including storage and transport is financed by the European Commission and it is distributed across Europe by the Emergency Response Coordination Centre based on the needs expressed by countries requesting EU assistance under the EU Civil Protection Mechanism.

Additional to the medical capacity are aerial firefighting means and medical evacuation capacities. The rescEU reserve constitutes the “last resort” layer of the EU Civil Protection Mechanism, which can be activated for all types of natural and man-made hazards. EU Member States, Iceland, Norway, Serbia, North Macedonia, Montenegro and Turkey participate in the EU Civil Protection Mechanism.

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

Temporary Reintroduction of Border Control

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

