

FOCUS-EU

HEALTH

March 2021

Overview of EU and global policy developments

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European Health Union

A new proposal on European Health Union has been put forward by the European Commission after the pandemic highlighted the importance for coordination and investment in health systems together with the training needs of the healthcare workforce.

The Commission focuses on crisis preparedness and response measures such as:

- strengthening coordination at EU-level when facing crossborder health threats;
- expanding the mandates of the European Centre for Disease Prevention and Control and of the European Medicines Agency;
- setting up <u>HERA Incubator</u>, a new EU agency for biomedical preparedness.

<u>A new pharmaceutical strategy</u> aims to modernise the regulatory framework and support research and technologies that reach patients. It rests on four pillars:

- Fulfilling unmet medical needs
- Supporting a competitive and innovative European pharmaceutical industry
- Enhancing resilience through diversified supply chains, environmental sustainability, and crisis preparedness
- · Promoting high standards for medical products globally

<u>Europe's Beating Cancer Plan</u> aims to prevent cancer and ensure a high quality of life for cancer patients, survivors, their families and carers. The plan taps into various EU policies, in digitalisation, research and innovation and includes a number of flagship initiatives across the entire disease pathway.

Source: https://ec.europa.eu/european-health-union

European Parliament

New EP Interest Groups in Health

MEPs fight AMR Group

The new MEP Interest Group on antimicrobial resistance (AMR) is composed of fifteen MEPs from across the political spectrum. The group champions a One Health approach in human, animal and environmental health with a strategic work programme for the parliamentary term 2019-2024 focusing on raising AMR awareness and mobilising dedicated financial support for AMR-related investments among other.

Sources: https://epha.org/amrInterestGroup https://www.theparliamentmagazine.eu/AMREPGroup

Interest Group on Integrative Medicine and Health

The MEP group aims to promote inclusion of CAM (Complementary and Alternative Medicine) as part of Integrative Medicine & Health in all possible European Parliament public health policy. The group has agreed to the Guiding Principles in alignment with the declarations on T&CIM in Stuttgart Convention and the WHO Traditional Medicine Strategy 2014- 2023.

T&CIM (Traditional, Complementary and Integrative Medicine) defines the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness

Source: https://cam-europe.eu/mep-integrative-medicine-health/





European Commission

Reorganising the DG-RTD

The European Commission's research directorate (DG-RTD) has been reorganised with a focus on policy development and the reform of national research systems and implementation of the European Research Area. Newly created executive agencies will overlook the implementation of EU research programmes bringing the number of EU executive agencies from 29 to 48. The new agencies are:

CINEA - European Climate, Infrastructure and Environment Executive Agency;

HaDEA - European Health and Digital Executive Agency,

REA - European Research Executive Agency,

EISMEA - European Innovation Council and SMEs Executive Agency,

ERCEA - European Research Council Executive Agency and EACEA - European Education and Culture Executive Agency.

Source: https://eur-lex.europa.eu/EUagencies
Further reading on the new agencies:
https://sciencebusiness.net/rd-policy

European Partnerships

Two out of the ten new <u>European Partnerships</u>, put forward by the European Commission, are dedicated to health. The new partnerships will build on existing <u>joint undertakings</u> and the learnings from the European Innovation Partnerships (EIP) of the Horizon 2020 such as the EIP on Active Healthy Ageing (EIP AHA). The health Partnerships are:

- 1. Global Health EDCTP3 aims to deliver at least two new technologies by 2030 to tackle infectious diseases in sub-Saharan Africa, and strengthen research capacities to prepare and respond to re-emerging infectious diseases in the region and across the world. It also aims to develop and deploy, and support at least 100 research institutes in 30 countries to develop additional health technologies against re-emerging epidemics.
- Innovative Health Initiative aims to create an EU-wide health research and innovation ecosystem that translates scientific knowledge into tangible innovations on prevention, diagnostics, treatment and disease management.

All the ten partnerships are between the European Union, Member States and/or the industry. The goal is to speed up the transition towards a green, climate neutral and digital Europe, and to make European industry more resilient and competitive. The EU will provide nearly €10 billion of funding matched by the partners with at least an equivalent amount of investment.

Source: https://ec.europa.eu/IP 21 702

2021 ERC work programme

The <u>ERC work programme</u> is approved under Horizon Europe with a budget of €1.9 billion to support 1,000 researchers and 6,860 postdoctoral researchers, PhD students and other research staff employed in ERC-funded teams. Most of the funding (66%) is earmarked for early- to mid-career scientists and scholars. The work programme does not foresee any 'Synergy Grants' or 'Proof of Concept Grants' until 2022.

Interviews are introduced as part of 'Advanced Grant' evaluations similarly to 'Starting' and 'Consolidator Grants'. A new mentoring scheme targeting countries with low ERC participation and success rates will aim to identify ERC grantees and former evaluation panel members to serve as external mentors and strengthen local support programmes for applicants. ERC grantees will have to follow an Open Science policy and submit a data management plan during the first six months of their project. Applicants, hosted in Horizon 2020 associated countries or third countries negotiating an association to Horizon Europe are eligible to apply; the funding will depend on the agreement between the EU and the host country.

Sources: https://erc.europa.eu/HorizonEurope

https://erc.europa.eu/mentoring-scheme

ECDC for Africa CDC

The European Centre for Disease Prevention and Control (ECDC) and the Africa Centres for Disease Control and Prevention (Africa CDC) launched a new partnership to strengthen the capacity of Africa CDC to prepare for and respond to public health threats. The four-year project 'EU for health security in Africa: ECDC for Africa CDC', funded by the EU, will facilitate harmonised surveillance and disease intelligence, and support implementation of the public health workforce strategy of Africa CDC.

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

European Council

The EU institutions agree on future of EIT

The European Council and the European Parliament have informally agreed on measures to align the activities of the European Institute of Innovation and Technology (EIT) with EU priorities such as the Green Deal, the post-COVID recovery plan, strategies for small businesses and industry, the Union's strategic autonomy and the United Nations' Sustainable Development Goals. Key amendments focus on financial sustainability and openness of Knowledge and Innovation Communities (KICs) with measures to broaden their geographical coverage and bridge the funding gap between western and eastern Members States, stronger principles for monitoring and evaluation and the role of





the member states in the governance of the EIT; increased flexibility for KICs working on the COVID-19 recovery, and a stronger focus on projects involving small and medium enterprises.

Sources: https://www.consilium.europa.eu/EIT

https://www.europarl.europa.eu/EIT council

EU on COVID-19

HERA

The Commission has proposed a new agency HERA, European Health Emergency Preparedness and Response Authority. HERA will provide a permanent structure for risk modelling, global surveillance, technology transfers, manufacturing capacity, supply chain risk mapping, flexible manufacturing capacity and vaccine and medicine research and development. The Commission has also launched "HERA Incubator", the European bio-defence preparedness plan against COVID-19 variants which will engage researchers, biotech companies, manufacturers and public authorities in the EU and globally. The HERA Incubator will serve as a blueprint for the EU's long-term preparedness for health emergencies focusing on detecting new variants, provide incentives to develop new and adapted vaccines, speed up the vaccine approval process, and ensure scaling up of manufacturing capacities.

Source: https://ec.europa.eu/HERA Other reading:

The future HERA: What is at stake?

A Science|Business article on HERA's creation, funding & work.

New procedure to facilitate and speed up approval of adapted vaccines against COVID-19 variants

The Commission has introduced a measure to speed up the authorisation of adapted COVID-19 vaccines. Provisions in the relevant EU legislation will allow companies to focus on gathering the necessary evidence in time and enable the authorisation of adapted vaccines with a smaller set of additional data submitted to the European Medicines Agency. This action is under the HERA Incubator.

Source: https://ec.europa.eu/Corona Virants

COVID-19 Vaccine roll-out overview

The European Centre for Disease Prevention and Control have updated their tools on monitoring vaccination progress in all EU/EEA countries. Access the ECDC's Vaccine Tracker for information on national uptakes of first and second doses of COVID-19 vaccines by age and selected target groups such healthcare workers and residents in long-term care facilities and by vaccine products per country. Information is provided as maps, graphs and charts and can be exported as data.

Source: https://www.ecdc.europa.euvaccine-tracker

Temporary Reintroduction of Border Control

Click here to access the notifications per country

Other

AMR

The European Commission has published its progress report on the EU's Action Plan to address the challenges of AMR.

Source: https://ec.europa.eu/health/AMR_progressreport_en.pdf

Is your software a medical device?

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) has produced an infographic on decision steps to assist in the qualification of Medical Device Software (MDSW). To view the infographic, click here.

Health Inequalities Portal

A new online portal for information and resources on health inequalities in Europe, www.health-inequalities.eu has been launched by EuroHealthNet. The portal is for public health professionals to exchange ideas and experiences, and for civil servants, educators, and people working on environment, social, and employment issues to find resources to help address inequalities in their fields. The database includes an e-Guide for Financing Health Promoting Services and provides 600 examples of initiatives, policies, research, and publications at European level and on the ground. Users are able to submit their own work to contribute to the knowledge base.

Source: https://eurohealthnet.eu/health-inequalities

Horizon Europe health research in line for €948M in 2021

A Science|Business article on the post COVID-19 recovery, with leaked draft work programme indicating that in 2021 researchers can expect six calls for proposals on topics ranging from mental health to improving healthcare systems

EU considers tougher rules to promote gender equality in Horizon **Europe**

A Science|Business article on the obligations to gender balance in research groups and its stricter monitoring for grant recipient organisations.

Bologna with Student Eyes 2020: A new perspective

A study published by the European Students Union (ESU) on the Bologna Process has shown that students feel as though the higher education institutions are gradually silencing or even ignoring their voices. The report has also found that there are consistent discrepancies between countries on the automatic recognition of degrees throughout the EHEA with only half of the participant institutions stating that the recognition procedures are fair and transparent. The recommendations call for policymakers to include social aspects and issues when creating policies, from early childhood education to lifelong learning; for member countries to consider students as full members in internal and





institutional quality assurance processes; for diploma supplements to be issued free of charge to enable access to quality tertiary education particularly for refugees and asylum seekers. In addition the report states that the future of the Bologna Process should be aiming towards tuition-free and accessible higher education with student involvement in governance structures, a supportive and inspiring learning environment, flexibility of curriculum, individuality and interactivity.

The ESU publishes the Bologna with Student Eyes report every two to three years since 2003. It is co-funded by the European Commission and aims at offering official institutions, Higher Education Institutions (HEI) and public bodies a reality check of the students' perspective on education policies and specifically on the implementation of the Bologna Process. The report collects students' opinion from institutions across the European Higher Education Area on: Student participation in higher education governance, social dimension, quality assurance, recognition, internationalisation and mobility, structural reforms, financing of higher education, student-centred learning and the future of the Bologna Process.

Source: https://www.esu-Publication WEB2.pdf

Digital Compass

The European Commission has issued a new Communication on *Digital Compass*, a set of digital principles, to rapidly launch important multi-country projects, and to prepare a legislative proposal for a governance framework, to monitor progress towards the digital transformation of Europe by 2030. The *Digital Compass* evolves around four points which should be achieved by 2030:

- Digitally skilled citizens and highly skilled digital professionals; at least 80% of all adults should have basic digital skills, and there should be 20 million employed ICT specialists in the EU with more women taking up such jobs;
- Secure, performant and sustainable digital infrastructures; all EU households should have gigabit connectivity and all populated areas should be covered by 5G; the production of cutting-edge and sustainable semiconductors in Europe should be 20% of world production; 10,000 climate neutral highly secure edge nodes should be deployed in the EU; and Europe should have its first quantum computer;
- **Digital transformation of businesses**; three out of four companies should use cloud computing services, big data and AI; more than 90% SMEs should reach at least basic level of digital intensity; and the number of EU unicorns should double;
- **Digitalisation of public services**; all key public services should be available online with all citizens accessing their e-medical records; and 80% citizens using an eID solution. The Compass sets out a joint governance structure with Member States with monitoring system and annual reporting in the form of

traffic lights. The targets will be enshrined in a Policy Programme to be agreed with the European Parliament and the Council.

Source: https://ec.europa.eu/commission/P_21_983

Calls

A note to our readers

click on the Call and Consultation title to access details on topic conditions, documents & submission service.

<u>Call for expression of interest - Executive Agency for Small and Medium-sized Enterprises (EASME/EISMEA)</u>

Deadline: 12 April

ERC Consolidator Grants Deadline: 20 April

Consultations

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

<u>Drug resistance – criteria for identifying antimicrobial</u> <u>medicines reserved for treating humans</u>

Deadline: 23 April

Evaluation and revision of the general pharmaceutical legislation Deadline: 27 April

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