FOCUS-EU

HEALTH

May-June 2021

Overview of EU and global policy developments

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Horizon Europe Programme Guide is now public

Online Manual for funding opportunities

Overview of Horizon Europe

Gender Equality as a ranking criterion in calls

Consideration of gender will be mainstreamed in the Horizon Europe and be applied at three stages of a proposal. At the eligibility stage, the programme will request gender equality plans (GEP) from the institutions of participants as a self-declaration with a grace period of one year from 2022 deadlines onwards. The integration of a gender dimension in the research plan is an award criterion under excellence for Research and Innovation Actions (RIA) and Innovation Actions (IA). This refers to analysing and taking into account the possible differences between men and women, boys and girls, or males and females, in the research and innovation content of the project. The gender balance in human resources, i.e. balance between women and men in the research teams, will also be a ranking criterion.

Other funding organisations are also to incorporate the gender dimensions in their structure. In particularly, the European Research Council (ERC) has adopted its new Gender Equality Plan for the duration of Horizon Europe from 2021-2027 aiming to achieve gender balance at all levels and throughout its processes. A series of measures with agreed targets are to address structural gender differences aiming among others to identify and remove any potential bias in ERC evaluation procedures; monitor possible differences in gender specific careers and academic posts following ERC grants; and more importantly improve gender balance among applicants and ERC peer reviewers and other decision–making bodies.

Sources: https://ec.europa.eu/gender-equality_R&I
https://www.swisscore.org/ERC_gender

European Parliament

HTA Regulation

A political agreement on the Health Technology Assessment (HTA) Regulation has been reached by the European Parliament and the Council. The Regulation will ensure efficient use of resources and strengthen the quality of HTA across the EU by improving the availability of innovative medicines, medical equipment and diagnostics, etc. It will also facilitate business predictability, reduce duplication of efforts and ensure the long-term sustainability of EU HTA cooperation.

The Regulation will replace the current system of EU-funded project-based cooperation between Member States on health technology assessment with a permanent framework for joint work. The new framework will work on joint clinical assessments, cover joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. Member States will continue to be responsible for the management of their health services, including pricing and reimbursement.

Source: https://ec.europa.eu/IP_21_3142

EU EYE and TRANSFORM Alliance

The EU EYE has joined the European Alliance for Transformative Therapies, with the aim to explore the opportunities, challenges and the policy changes involved in the safe and timely access to cell and gene therapies. The TRANSFORM Alliance is supported by the TRANSFORM MEP Interest Group, an informal group of cross-party Members of the European Parliament committed to improving access to innovative therapies. The alliance has launched its Recommendations for Action for Cell and Gene Therapies in the context of the European Pharmaceutical Strategy

For information and the launch: https://transformalliance.eu

Erasmus +

MEPs have adopted ERASMUS+, the 2021-2027 edition of the EU's flagship programme for education, training, youth and sports. The programme, which has demonstrated its significant role in fostering European identity, will have almost double the funding in 2021-2027 (over 28 billion EUR from different sources) compared to previous years.
The new Erasmus+ will offer more tools and resources to support inclusion with top-up grants and up-front payments for those who do not have sufficient means to cover the initial costs to take part in the programme. The Commission and member states are to formulate action plans to improve access to learning and mobility for people who historically have had fewer opportunities to participate – people living with a disability, people living in poverty, in a remote location, people with a migration background, and more. Time spent in a different EU country will be expanded up to six months for students in adult education. Erasmus+ will have a simpler application process and will support innovative models of education such as the European Universities initiative enabling students to obtain a degree by combining studies in several EU countries.
The UK opted out of the scheme during Brexit negotiations and it is currently setting up its own £100 million university exchange programme, the Turing Scheme. The Irish government volunteered to fund students and teachers from Northern Ireland wishing to participate in Erasmus+, which is expected to cost the country around €2.1 million a year.

Sources: https://www.europarl.europa.eu/erasmus+
https://www.rte.ie/erasmus-northern-ireland/

European Commission

EU4Health

The adoption of the health work programme EU4Health has been finalised. Its 2021 work programme will provide €312 million for crisis preparedness, disease prevention, health systems and the healthcare workforce, and digitalisation. Funded projects will cover among other disease surveillance, preventing shortages of medicines, European Reference Networks for rare diseases, and preparing a European Health Data Space.

Source: https://ec.europa.eu/health/funding/wp2021.pdf

AI legislation

The launch of the draft legislation on artificial intelligence (AI) by the European Commission (EC), has received a mixed welcome. It is deemed too limiting by some and not restrictive enough by others and discussions will continue on facial recognition, biometric surveillance and predictive policing. Despite the introduction of a risk-based approach and special measures for SMEs and start-ups, many stakeholders voice concerns on:

- the actual feasibility of requirements on transparency and high-quality datasets;
- imprecise definitions and broad exceptions to the prohibition for facial recognition AI systems, means that there is no real ban;
- although the text prohibits 'AI systems that may cause harm to people by manipulating their behaviour, opinions or decisions', its implementation, like in social media, is not clear;
- although the differentiated system of managing high risk applications recognises that one-size does not fit all, it will be challenging to reduce the burden on businesses and developers.

MEPs agree that the text does not provide sufficient protection to workers who may be subjected to AI systems in their recruitment process or daily monitoring. Uncertainly also is generated as the EC retains the right to amend the list of high-risk AI systems through delegated acts to adapt to technological developments.

Access the proposal: https://eur-lex.europa.eu/legal-AI
Sources: https://ec.europa.eu/IP_21_1682
https://www.swisscore.org/AI

Adequacy decision for UK data

The EU has recognised UK data protection standards as adequate for personal data transfers from the EU to the UK.
Source: https://www.pinsentmasons.com/uk-data-adequacy-EU

Unique Device Identification (UDI) Helpdesk

A new Helpdesk is launched to support the economic operators in implementing the obligations and requirements introduced by the new Unique Device Identification (UDI) system. The Helpdesk provides support on UDI assignment, labelling and registration of devices. It also provides support on the use of the European Medical Devices Nomenclature (EMDN), available to manufacturers and other natural or legal persons required by the MDR and IVDR to use it.

The UDI system has been introduced under Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), and are applicable since May 2021. The UDI system helps the fight against counterfeit devices; it makes it easier to trace medical devices when necessary and increases the effectiveness of post-market safety-related activities such as incident reporting, targeted field safety corrective actions.

Access the Helpdesk here.

Source: https://eu-udi.zendesk.com/hc/en-150

Across the World

The FDA has granted de novo authorization to Lumenis for its intense pulsed light device for the dry eye disease management. De novo provides a route to classify novel devices of low to moderate risk.
Source: https://www.healio.com/dry-eye-disease

Other

WHO: Report on AI in health

The World Health Organisation (WHO) has issued their report on Artificial Intelligence (AI) with six guiding principles for its design and use. Entitled Ethics and governance of artificial intelligence for health, the report cautions against overestimating the benefits of AI for health, especially when this occurs at the expense of core investments and strategies required to achieve universal health coverage. The report acknowledges the benefits of AI in increasing access to health services for resource-poor countries and rural communities in addition to the multiple benefits for wealthier countries such as self-management of health care; improved diagnosis, clinical care and drug development, etc. It also points out the challenges and risks such as unethical collection and use of health data; biases encoded in algorithms, and risks of AI to patient safety, cybersecurity, and the environment. For example, while private and public sector investment in the development and deployment of AI is critical, the unregulated use of AI could subordinate the rights and interests of patients and communities to the powerful commercial interests of technology companies or the interests of governments in surveillance and social control.

The report also emphasizes that systems trained primarily on data collected from individuals in high-income countries may not perform well for individuals in low- and middle-income settings. AI systems should therefore be carefully designed to reflect the diversity of socio-economic and health-care settings. They should be accompanied by training in digital skills, community engagement and awareness-raising, especially for millions of healthcare workers who will require digital literacy or retraining if their roles and functions are automated, and who must contend with machines that could challenge the decision-making and autonomy of providers and patients.

The report includes six principles as the basis for AI regulation and governance that works for all countries.

Protecting human autonomy: Privacy and confidentiality should be protected, and patients must give valid informed consent through appropriate legal frameworks for data protection.

Promoting human well-being and safety and the public interest. The designers of AI technologies should satisfy regulatory requirements for safety, accuracy and efficacy for well-defined use cases or indications. Measures of quality control in practice and quality improvement in the use of AI must be available.

Ensuring transparency, explainability and intelligibility. Transparency requires that sufficient information be published or documented before the design or deployment of an AI technology. Such information must be easily accessible and facilitate meaningful public consultation and debate on how the technology is designed and how it should or should not be used.

Fostering responsibility and accountability. It is the responsibility of stakeholders to ensure that they are used under appropriate conditions and by appropriately trained people. Effective mechanisms should be available for questioning and for redress for individuals and groups that are adversely affected by decisions based on algorithms.

Ensuring inclusiveness and equity. AI for health must be designed to encourage the widest possible equitable use and access, irrespective of age, sex, gender, income, race, ethnicity, sexual orientation, ability or other characteristics protected under human rights codes.

Promoting AI that is responsive and sustainable. Designers, developers and users should continuously and transparently assess AI applications during actual use to determine whether AI responds adequately and appropriately to expectations and requirements. AI systems should also be designed to minimize their environmental consequences and increase energy efficiency. Governments and companies should address anticipated disruptions in the workplace, including training for health-care workers to adapt to the use of AI systems, and potential job losses due to use of automated systems.

These principles will guide future WHO work to support efforts to ensure that the full potential of AI for healthcare and public health will be used for the benefits of all.

Source: https://www.who.int/first-global-report-ai-in-health

EXPH: Public procurement in healthcare systems

The Expert Panel on 'effective ways of investing in health' (EXPH) has adopted its opinion on public procurement in healthcare systems. The EXPH examines the tendering of pharmaceuticals, health technology and e-Health. In each case, they identify a series of challenges relating to the complexity of the procurement process, imbalances in power on each side of transactions, and the role of procurement in promoting broader public policy objectives.

The EXPH is an interdisciplinary and independent group established by the European Commission to provide non-binding independent advice on matters related to effective, accessible and resilient health systems.

Access the full opinion: https://EXPH_public_proc_health.pdf

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**

FORTHCOMING CALLS

Staying healthy (Two stage - 2022) (HORIZON-HLTH-2022-STAYHLTH-01-two-stage)

Planned open date: 06 October 2021

Deadline dates: 01 February 2022; 06 September 2022

Consultations & Events

European Health Data Space **Deadline: 26 July**

Crossborder healthcare - Evaluation of patients rights

Deadline: 27 July

ICH guideline S12 on nonclinical biodistribution considerations for gene therapy products

Deadline: 24 October

ERN-EYE Webinars

All the ERN-EYE Webinars are now publicly accessible.

EU on COVID-19

EMA updates on COVID-19 vaccines

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.

Strategy on COVID-19 therapeutics

The European Commission has complemented the EU Vaccines Strategy with a strategy on COVID-19 therapeutics to support the development and availability of COVID-19 therapeutics, including treatments for 'long COVID'. The Strategy covers the full lifecycle of medicines from research, development and procurement and it is part of the European Health Union, in which all EU countries prepare and respond together to health crises. The Strategy includes among others:
-investment of €90 million in population studies and clinical trials to establish links between risk factors and health outcomes to further inform public health policy and clinical management, including for long-COVID patients;
- setting up a 'therapeutics innovation booster' by July 2021 to support the most promising therapeutics from preclinical research to market authorisation;
- investment of €5 million under the EU4Health programme to generate better, high-quality safety data in clinical trials;
- joint procurement and financing for the purchase of authorised therapeutics by the end of the year.

The therapeutics innovation booster, matchmaking events and preparatory action to support flexible manufacturing and access for COVID-19 therapeutics under the EU Fab project, will feed into the HERA, for which a proposal is due later in the year. The pilot project on access to health data will feed into the European Health Data Space proposal expected later this year.

Source: https://ec.europa.eu/strategy-covid-19-therapeutics_en

COVID-19 Therapeutics portfolio

The first portfolio of five therapeutics for COVID-19 has been announced. Four of these therapeutics are monoclonal antibodies under rolling review by the European Medicines Agency. Another one is an immunosuppressant, which has a marketing authorisation that could be extended to include the treatment of COVID-19 patients. The products are:
A new COVID-19 indication for existing medicines:

- baricitinib immunosuppressant (a medicine that reduces the activity of the immune system) from Eli Lilly: an application for extension of marketing authorisation for COVID-19 indication is under assessment;

Newly developed monoclonal antibodies under rolling review:
- combination of bamlanivimab and etesevimab (Eli Lilly);
- combination of casirivimab and imdevimab (Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche, Ltd);
- regdanivimab (Celltrion);
- sotrovimab (GlaxoSmithKline and Vir Biotechnology, Inc.).

Rolling review - a regulatory tool to speed up the assessment of a promising medicine during a public health emergency

Source: https://ec.europa.eu//ip_21_3299

Temporary Reintroduction of Border Control

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