FOCUS-EU

HEALTH

September - October 2021

Overview of EU and global policy developments

Gender Equality Plans Implementation in Horizon Europe

All public bodies, higher education institutions and research organisations have to comply with the Gender Equality Plan (GEP) eligibility criterion for calls with deadlines in 2022 and onwards. A GEP must meet 4 mandatory process-related requirements or 'building blocks':

- **Be a public document**: The GEP should be a formal document signed by the top management, and disseminated within the institution. It should demonstrate a commitment to gender equality, set clear goals and detailed actions and measures to achieve them;
- **Have dedicated resources**: Resources for the design, implementation, and monitoring of GEPs may include funding for specific positions such as Equality Officers or Gender Equality Teams as well as earmarked working time for academic, management and administrative staff;
- **Include arrangements for data collection and monitoring**: GEPs must be evidence-based and founded on sex or gender-disaggregated baseline data collected across all staff categories. This data should inform the objectives, targets, indicators, and ongoing evaluation of progress;
- **Be supported by training and capacity-building**: Actions may include developing gender competence, tackling unconscious gender bias among staff, leaders and decision-makers, establishing working groups dedicated to specific topics, and raising awareness through workshops and communication activities.

At first proposal submission stage, a self-declaration is requested through a dedicated questionnaire. An organisation may not yet have a GEP at proposal submission stage, but it must have a GEP in place at the time of the Grant Agreement signature.

Source: https://op.europa.eu/gender_equality_Plan

European Parliament

Extending ECDC's mandate beyond CDs

During the September 2021 plenary session in Strasbourg, the European Parliament (EP) debated the legislative proposals for health and disease prevention regarding boosting EU defences against cross-border health threats; and the extension of the mandate of the European Centre for Disease Prevention and Control (ECDC) beyond communicable diseases (CDs) to cover those with a wide societal impact such as cardiovascular and respiratory diseases, cancer, diabetes, and mental illness. Inter-institutional negotiations will begin on the two proposals.

Source: https://www.europarl.europa.eu/ECDC_crossborder

EURAMET: AI, imaging scans and discomfort glare

Inter-institutional negotiations have started on EURAMET, the European Partnership on Metrology with the aim to launch the partnership early 2022. The research partnership hopes to harmonise European efforts in the field of metrology, and it is the only one out of the eleven partnerships of Horizon Europe in which member states and the European Commission join forces to boost innovation in a particular field.
Metrology, the science of measurement, is key in public health and in developing therapies or medical technologies that are safe, reliable and effective as for example AI tools to interpret imaging scans. EURAMET will manage its own budget and launch its own calls.

Among EURAMET's first priorities, is the establishment of a firm metrological foundation for the measurement of light and lighting with a call dedicated on the standardisation of luminance distribution measurements for assessing glare and obtrusive light. Such research puts a sharper focus on the social problems related to glare (such as traffic safety and security surveillance) and potentially may decrease workplace inefficiency caused by glaring work lighting.

The partnership on metrology is the continuation of a collaboration of the national metrology institutes dating back to 2009. It is expected that Member States will contribute up to €300 million, matched by funding from the EU research programme, Horizon Europe, over the next seven years.

https://www.europarl.europa.eu/metrology

European Council

Global Approach to R&I: 'as open as possible, as closed as necessary'

The European Council has agreed on a global approach to research and innovation (R&I) proposed by the European Commission. Europe's strategy for international cooperation in a changing world aims to address social, environmental, health, digital and economic challenges at global level by being 'as open as possible, as closed as necessary'. The Ministers called for international cooperation based on shared fundamental values and principles, openness being balanced by prudence, and **rules-based multilateral cooperation among Member States;** the set-up of mechanisms for cooperation in the fields of science, innovation and cultural diplomacy, and the need to protect researchers whose freedom of scientific research is under threat. Next steps will focus on the adoption of the Council conclusions on the governance of the European Research Area by the end of 2021 and the launch of a multilateral dialogue at international level in early 2022.

Source: https://data.consilium.europa.eu/global_approach_R&I

European Commission

EU Missions are launched

The Commission has launched five new EU missions, to deliver sustainable solutions by 2030 on challenges in health, climate and the environment with initial funding from Horizon Europe up to €1.9 billion until 2023. The missions bring together several Commission services under the authority of nine College members and connect directly to citizens, engaging them in their design, implementation and monitoring.

Source: https://ec.europa.eu/missions/IP_21_4747

EUDAMED modules

The expert panels in medical devices and in vitro diagnostic medical devices have started accepting submissions from notified bodies for the Clinical Evaluation Consultation Procedure and the Performance Evaluation Consultation Procedure respectively.

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

Knowledge valorisation for society and the economy

The European Commission has launched the EU Knowledge Valorisation Platform for enabling knowledge exchange and sharing best practices and is preparing a set of `Guiding Principles for Knowledge Valorisation'. The new platform aims to to facilitate the uptake of research results in society and the economy and connect researchers across the EU. A number of Horizon Europe Calls for proposals 2021-2022 are also to increase the visibility and the use of research and innovation outcomes and in particularly to raise awareness of intellectual asset management and promote standardisation.

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

Across the World

Health apps as healthcare providers

The U.S. Federal Trade Commission FTC, has clarified that developers of health apps and connected devices are considered healthcare providers, and if they disclose sensitive information without authorization that would be considered a breach of HIPA Act. A breach must be reported regardless of whether it was the result of malicious action. Any unauthorized access, including sharing information without consent, may trigger the Health Breach Notification Rule that requires entities not covered by HIPAA to notify consumers if private health information is compromised.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

Source: https://www.ftc.gov/health_apps_connected_devices.pdf

Sameness of gene therapies

The US Food and Drug Administration (FDA) has released a series of guidance documents on:

- Interpreting the sameness of gene therapies;
- Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial

Source: https://www.raps.org/fda_guidance-gene-therapies

Other

Location and ratifications of UPC

Germany and Slovenia have ratified the Unified Patent Court (UPC) agreement. One more country is needed to ratify the agreement before the EU can set the rules for recruiting judges for the new court.
Discussions are now focusing on the post-Brexit location of the third UPC seat of the UPC Central Division with Milan being a candidate. Until the third seat is confirmed, Paris will take the content that would have gone to the London seat dealing with patents related to: human necessities and pharmaceuticals/ chemistry including genetic engineering and metallurgy.

Unified Patent Court (UPC) agreement is an international treaty which creates a patent court with exclusive jurisdiction for litigation relating to European patents. The UPC has local divisions, regional divisions and a central, division. The latter has three seats, each dealing with cases dependent on the subject matter of the patent. The main seat of the central division is Paris; another in Munich and the third remains to be located in another Member State following Brexit.

Sources: https://sciencebusiness.net/germany-and-slovenia-UPC
https://www.herbertsmithfreehills.com/upc-rules

EDF on a horizontal equal treatment directive

The European Disability Forum (EDF) has called for the adoption of a horizontal equal treatment directive prohibiting disability-based discrimination in access to healthcare. Having reviewed national legislations on disability discrimination and websites of the National Contact Points for cross-border care, the EDF concluded that:

- Patients seeking cross border healthcare face difficulties finding information on their rights under the Patient Mobility Directive due to incomplete, inaccurate or unclear content of websites;
- Limited to no disability specific information is provided to patients with disabilities on the NCPs websites;
- Accessibility of information for patients with disabilities is not guaranteed as NCPs websites are not digitally accessible to patients with disabilities, including those using assistive technologies like screen readers; other accessibility formats such as videos in sign languages and Easy to Read formats are not provided;
- Almost no NCPs websites provide information of the reimbursement of additional disability related costs;
- Disability based discrimination in access to healthcare is not fully prohibited in almost half of the EU Member States.

Source: https://www.edf-feph.org/health_revised-accessible.pdf

Innovative Health Initiative

The Innovative Health Initiative (IHI) is a multi-sector public-private partnership expected to launch the first calls at the end of 2021. The IHI will succeed the IMI, the Innovative Medicines Initiative (IMI), launched in 2008 and renewed as IMI2 in 2012.

EXPH: Solidarity in public health emergencies

The draft opinion of the EXPH on European solidarity in public health emergencies explores the challenges in implementing EU solidarity and the transformations needed at EU, national and regional level in order to operationalise EU solidarity in public health emergencies. The document calls for solidarity to become a guiding principle for regulations/institutions/practices; and for data solidarity through transparent, accountable governance of public and private sector data.

The Expert Panel on effective ways of investing in health (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: Draft opinion, recording of hearing and related report

Key Figures on Europe 2021

The fourth edition of *Key figures on Europe* with intuitive visualisations, innovative data presentations and concise text.

A note to our readers

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

Consultations & Events

EMA draft guideline on computerised systems & electronic data in clinical trials

Deadline: 17 December

ICH guideline S12 on non-clinical biodistribution considerations for gene therapy products

Deadline: 24 October

How to Optimize Cross-border Cooperation to Support Equitable Access to Advanced Therapies?

Date: 09 November – 15h00-16h30 CET
Webinar organised by the TRANSFORM MEP Interest Group.

Access the Recommendations for Action for Cell and Gene Therapies already launched by in the context of the European Pharmaceutical Strategy.

The TRANSFORM Alliance aims to explore the opportunities, challenges and the policy changes involved in the safe and timely access to cell and gene therapies. The TRANSFORM Alliance runs a series of awareness raising events on the topic together with the TRANSFORM MEP Interest Group, an informal group of cross-party Members of the European Parliament committed to improving access to innovative therapies.

ESFRI Stakeholders Forum

Date: 08 December 2021 **Type of event: hybrid**

Location: Ljubljana, Slovenia

The first ESFRI Stakeholders Forum meeting is hosted by the Slovenian Presidency of the EU. The launch of the ESFRI Roadmap 2021 will take place the day before and focusses on eleven new research infrastructure projects; the merits of the Open Science concept; and how to address global challenges as reflected in the UN Sustainable Development Goals.

The European Strategy Forum on Research Infrastructures (ESFRI) is a strategic body established in 2002 by the Council of the EU to support policy making on Research Infrastructures (RIs) in Europe. The ESFRI updates regularly its roadmaps on large-scale RIs. Its ESFRI Stakeholders Forum aims to link traditional RIs with different actors, such as researchers, educators, policy makers, citizens, businesses, etc.

Calls

Open Call HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub

Deadline: 21 April 2022 **Single stage**

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

Deadline dates: 01 February 2022; 06 September 2022

SNSF Transitional Measure for ERC Advanced Grant

Following Switzerland's non-association to Horizon Europe as of 2021, the Swiss National Science Foundation (SNSF) has introduced a transitional measure – the SNSF Advanced Grants – for those who intended to apply for an ERC Advanced Grant in 2021. Proposals will be evaluated similarly to the ERC Advanced Grants.

Preregistration by: 01 November 2021

Deadline for application: 01 December 2021

EU on COVID-19

Q & A on COVID-19 tests

A publicly accessible Questions & Answers document on the types and performance of COVID-19 tests, 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.

ECDC: COVID-19 situation update for EU/EEA

EMA Press briefings on COVID-19

The European Medicines Agency (EMA) has resumed its fortnightly regular press briefings on COVID-19 activities.

EMA updates: authorisations of COVID-19 vaccines US-EU_Joint Statement_COVID

A joint US-EU COVID-19 Manufacturing and Supply Chain Taskforce is to address issues around expanding vaccine and therapeutics production capacity through:

- monitoring global supply chains for COVID-19 vaccines and therapeutics;
- assessing global demand and identifying supply chain bottlenecks and other disruptive factors for global production;
- and coordinating initiatives to boost global production of COVID-19 vaccines, therapeutics and ancillary supplies.

Temporary Reintroduction of Border Control

Click here to access updated notifications per country

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