FOCUS-EU

HEALTH

September 2019

Overview of EU and global policy developments

EU EYE

EIP ON AHA PARTNER

Ophthalmology in European Innovation Partnership Active and Healthy Ageing

Two eye clinics, Clinica Oculistica, San Martino Hospital, Genova, Italy and Tays Eye Centre, Tampere, Finland have been awarded 2 and 3 stars respectively in the 2019 Call for Reference Sites of the European Innovation Partnership of Active and Healthy Ageing (EIP-AHA).
The two eye clinics have joined a total of 77 regional and local organisations that have demonstrated regional innovation in active and healthy ageing bringing together a wide range of stakeholders based on a "Quadruple Helix" model that includes representatives from government authorities, academia, civil society and industry at a regional and local level. This work is aligned with the strategic objectives of the EIP on AHA and the relevant strategic developments including the Transformation of Health and Care in the Digital Single Market.

Sources: https://ec.europa.eu/eip/77-reference-sites-2019
https://ec.europa.eu/EIP-AHA

The EU EYE is a partner of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) with a commitment to the B3 Action Group on Integrated care accessible at: https://ec.europa.eu/eip/b3/

European Council

Economy of wellbeing - a Finnish Presidency priority

The Finnish Presidency of of the Council of the European Union is championing the narrative of the 'economy of wellbeing', an interplay between economic and social policies that advocates investing in well-being even in times of economic downturn. To this purpose Finland's Ministry of Social Affairs and Health organised a high-level event to examine the relationship between well-being and the economy. The learning from the conference will be fed in the forthcoming Council conclusions on the 'economy of well-being'.

Finland holds the EU Presidency together with Romania and Croatia.

The European Council (the heads of state or government of the member states, the President of the European Council and the President of the European Commission) defines the EU's political direction and priorities.

Source: https://www.eurofound.europa.eu/economy-well-being

European Parliament

€100 million boost for research and Erasmus

MEPs approved a €100 million top-up for the EU's research programmes (€80 million for Horizon 2020) and youth mobility (€20 million for Erasmus+). They also agreed to return a €1.8 billion budget from 2018 to the EU member states, through a decrease in the countries' contributions to the EU budget. This reflow is an annual exercise, the surplus usually stemming from

default interest and fines received by the Commission, as well as under-implementation of EU programmes.

Source: https://www.europarl.europa.eu/boost-research-erasmus

European Commission

New responsibilities for DG SANTE

DG SANTE will oversee the regulation of medical devices and pharmaceuticals, previously under the competence of the Internal Market and Industry as the *Biotechnology and Food Supply Chain, of the* Unit GROW.D.3, dealing with pharmaceuticals, and the *Health Technology and Cosmetics of Unit GROW.D.4,* dealing with medical devices, will move from DG GROW to DG SANTE.

Source: https://ec.europa.eu/commission/allocation-portfolios.pdf

New Health Commissioner

The new Health Commissioner-designate (Stella Kyriakides) is expected to present a multi-purpose legislative proposal for a new regulatory framework on medical devices: protect patients and address new and emerging challenges; achieve a balance between ensuring a steady supply of affordable medicines and maintaining the status of the EU pharma industry as a world leader in innovation. In addition Stella Kyriakides will prepare Europe's Beating Cancer Plan, a support tool to improve national cancer prevention and care systems; maintain a strong focus on delivering the United Nations Sustainable Development Goals (SDGs) for health and ensure continuity with the mandate of the previous Health Commissioner such as the e-health development, the commitment to the European One Health Action Plan, vaccines promotion, and reducing dependency on pesticides.

Source: https://www.euractiv.com/kyriakides-top-priority/

Horizon Europe - a mission-oriented approach

The mission boards of Horizon Europe held their first meeting in September 2019. Horizon Europe will put €100 billion into clearly defined targets (missions). Each mission board consists of a maximum of 15 independent high level individuals with broad expertise from across Europe and beyond, including relevant end-users' representatives. By the end of 2019, the boards will identify the first possible specific missions on

- cancer
- climate change
- healthy oceans
- climate-neutral cities
- healthy soil and food

Each mission has also an assembly that gathers a larger number of high-level experts. The assemblies provide an additional pool of ideas, knowledge and expertise that will be actively called upon to contribute to the success of the 5 missions. The members of the mission boards are appointed by the Commission, following an open call for expressions of interest. The term of office of mission board members shall be up to five years, renewable once.

Sources: Presentation outlining Horizon Europe (in 23 languages)

https://ec.europa.eu/info/horizon-europe

https://ec.europa.eu/strategy_on_research_and_innovation.pdf

https://ec.europa.eu/mission-oriented-policy-horizon-europe_en

ERN-EYE

The ERN-EYE has submitted a proposal to the call for Rare disease registries for the European Reference Networks (ERNs). The proposed action aims to support the development of rare disease registries for the ERNs. Patient registries and databases constitute key instruments to develop clinical research in the field of rare diseases, to improve patient care and healthcare planning.

The European Reference Network (ERN) scheme is a joint initiative of the European Commission and Member States with support from the European Parliament. The ERNs are networks for clinicians and researchers to share expertise, knowledge and resources across the EU. Their aim is to address common challenges in diagnosis and highly specialised care provision in complex, rare or low prevalence diseases. The ERNs are organised in disease groupings and are part of the legal framework of the EU Directive on Patients' Rights in Cross-Border Healthcare Directive adopted in 2011.

Sources: ERN-EYE https://www.ern-eye.eu/ern-eye

https://ec.europa.eu/research/2019_en.pdf

General information on ERNs: https://ec.europa.eu/health/ern_en

The EU EYE continues to call for:

- Proactivity and clarity in informing the public (providers and citizens) about the ERN mandate
- synergies with existing disease registries

Access the position of EU EYE on ERNs at
http://www.eueye.org/wp-content/uploads/2018/10/

Repurposing Framework - not-for profit organisations

Drug repurposing focusses on new indications for well established (off- patent) medicines in areas of unmet medical need that could offer additional therapeutic options to patients. STAMP (Safe and Timely Access to Medicines for Patients): expert group of the European Commission with Member states and EMA, have proposed to provide a visible supportive framework to not-for-profit organisations and academia (referred to as Champions), who have evidence and scientific rationale for

a new indication of an already authorised medicinal product: the product must be off-patent and out of regulatory protection and the new indication must be outside its authorisation with the aim of bringing a new indication on-label. The framework is to provide advice and support to facilitate appropriate evidence generation and filing of new uses. Currently a pilot is overseen by a voluntary virtual group (Repurposing Observatory Group) led by Spain and composed of Champion interest groups, industry and regulatory representatives.

Sources: https://www.ema.europa.eu/repurposing.pdf
https://ec.europa.eu/committee/pharm773_repurposing_en.pdf

EXPH

The *Expert Panel on Effective Ways of Investing in Health* (EXPH) has made available the following Opinions:
- Task shifting and health system design

Access: https://ec.europa.eu/health/EXPH_023_taskshifting_.pdf

- Defining value in "value-based healthcare"

Access: https://ec.europa.eu/EXPH_024_defining-value-.pdf

The EXPH supports the European Commission in identifying specific aspects to be considered and tangible results that should be achieved in reforming health systems and investments at EU level. The EXPH hearings gather views from experts on public health and stakeholders in health services and health-related areas (industry, research, economy).

ERC 2020 Work Programme

The Work Programme 2020 of the European Research Council (ERC) will support over 1,000 researchers with €2.2 billion under four core schemes: Starting; Consolidator; Advanced; and Synergy Grants. The biggest ever annual injection of funding in blue-sky research has 61% earmarked for early- to mid-career researchers and supports jobs for around 8,000 postdoctoral researchers, PhD students and other research staff in ERC-funded teams. There is alignment of the ceilings of the amounts covering extraordinary costs exceeding the normal grant ceilings of Starting, Consolidator and Advanced Grants up to €1 million for all of the three grants and €4 million for Synergy Grants.

The annual Work Programme for the European Research Council is the legal document which sets out how the ERC will allocate its funding for the corresponding year. It is established by the Scientific Council of the ERC and subsequently adopted by the European Commission.

Source: https://erc.europa.eu/news/erc-2020-work-programme

ERC Work Programme 2020 https://ec.europa.eu/wp/2020.pdf

Calls, Consultations & Events

Clinical Trials: Calling sponsors to use EU database

The European Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) continue to call all sponsors of clinical trials conducted in the European Union to make summaries of results of concluded trials publicly available in the EU Clinical Trials Database.

Source: https://www.ema/publish-CTR-eu-database.pdf

Civil Societies - EMA PDCO Committee

The Commission has launched a selection procedure to appoint the Civil Society representatives to the Pediatric Committee (PDCO) of the European Medicines Agency (EMA), in Amsterdam. Three members and alternates representing health professionals and three members and alternates representing patients' associations will be appointed for a three-year-mandate starting 1 August 2020. The Commission will appoint the alternates after consultation with the European Parliament.

Source: https://ec.europa.eu/ema_calls/ema_pdco_2019.pdf

Open Call SC1-BHC-06-2020:
Digital Diagnostics - Developing Tools for Supporting Clinical Decisions by Integrating Various Diagnostic Data

Score: https://ec.europa.eu//funding-tenders//sc1-bhc-06-2020

Preparedness of medicines' clinical trials in paediatrics

Feedback is collected on potential gaps in the draft framework on "preparedness of medicines' clinical trials in paediatrics". Trial preparedness, in this context, is defined as a structured assessment of factors that could increase the likelihood of a smooth and timely course of a study. This assessment targets the wider community of paediatric clinical research sites, investigators, networks, sponsors, patients and anyone involved in the preparation and conduct of paediatric clinical trials.

Deadline: 15 November 2019

Comments by e-mail: enpremasurveys@ema.europa.eu

Across the World

ICH E17 Guideline training materials

The ICH E17 Guideline on General Principles for Planning and Design of Multi-Regional Clinical Trials (MRCT) is an extensive set of training materials including 7 modules developed to promote the efficient and consistent implementation of the E17 Guideline in the context of an evolving drug development environment.

Access E17 & Training Materials:

www.ich.org/-e17-training-materials

Other

Guide for an economy of wellbeing

EuroHealthNet has launched an information guide for financing health promotion services. EuroHealthNet believes that public services (health services, health-enhancing and preventative measures, strong social protection, education, and training services) are chronically underfunded and increasing demand calls for maximising the use of public funds and the added value of private investments within ethical and sustainable frameworks. The EuroHealthNet demonstrates how to make transitions from spending on cures and treatments to investing in preventative approaches for better health and wellbeing. It explores how resources and capacities can be mobilised to help finance these transitions and contribute to an 'economy of wellbeing'. The guide encourages to recognise health as an asset and explores how funds can be increased through smarter taxation, boost investments and innovative thinking with examples from cross-sectoral case studies. It presents a set of public health-focused investment criteria for potential investors or financial managers. The guide has been developed in collaboration with WHO Regional Office for Europe and the WHO Coalition of Partners. An interactive online tool will be launched at the end of 2019.

EuroHealthNet is a not-for-profit partnership of organisations, agencies and statutory bodies working on public health, disease prevention, promoting health, and reducing inequalities.

Source: https://eurohealthnet/finance-health-promoting-services-

PMS and Postmarket Clinical Follow-up

An article by Adina Chen Bar in *Regulatory Focus* on the scope of postmarket surveillance (PMS) activities as set out in Medical Devices Regulation (MDR 2017/745), explaining postmarket clinical follow-up, transparency, accountability and documentation.

Source: https://www.raps.org/pms-and-postmarket-clinical-fo

Regulating for bias - pharma Code of Practice

A number of European organisations have issued a joint statement to highlight the shortcomings in the new European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice. The response raises concerns about the privileges granted to pharmaceutical companies under the new Code of Practice. The updated self-regulatory Code allows the pharmaceutical industry to influence the content of medical education and to conceal promotional activities under the guise of education.
"Much of the medical education is currently funded by the pharmaceutical and medical device industries. This practice carries a significant risk to public and personal health, especially if it is not adequately safeguarded by a high standard of accreditation," says the response signed by doctors, healthcare professionals, medical students, medical education stakeholders, mental health advocates and users of mental healthcare. To preserve scientific integrity, safety and quality of care, signatories call for independence in medical education.

Sources: https://www.mhe-sme.org/medical-education-COI free

https://www.mhe-sme.org/Joint_EFPIA_Code_11092019.pdf

WHO, Plan S and cOAlition S

The World Health Organization has joined cOAlition S, a growing group of national research funding agencies and charities that fund scientific research and are supported by the European Commission and the European Research Council (ERC). The coalition's so-called Plan S aims to implement the open-access requirement for all of their funded research beginning January 1, 2021. Plan S with its 10 principles allows research funders to mandate that access to research publications that are generated through research grants that they allocate, must be fully and immediately open and cannot be monetised in any way. Results from research funded by public or private grants provided by national, regional and international research councils and funding bodies must be published in Open Access Journals, on Open Access Platforms, or made immediately available through Open Access Repositories without embargo.

Source: https://www.coalition-s.org/

Committee for Medicinal Products for Human Use

EMA's human medicines committee (CHMP) recommended granting a marketing authorisation for **Rhokiinsa** (netarsudil) for the treatment of patients with glaucoma or ocular hypertension at its September 2019 meeting.

Source: https://www.ema.europa.eu/-human-use-september-2019

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