FOCUS-EU

HEALTH

October 2019

Overview of EU and global policy developments

WHO World Report on Vision

The World Health Organisation has launched its first World Report on Vision, a roadmap for future priorities and interventions. The report aims to improve awareness and increased political will and investment to strengthen eye care globally. Its main findings are:

- Globally, vision impairment could have been prevented for over 1 billion out of 2.2 billion people with vision impairment or blindness, or have yet to be treated; addressing this backlog would cost US $14.3 billion.
- Global demand for eye care may triple by 2050 due to population growth, ageing, and lifestyle changes.
- The burden of visual impairment weighs more heavily on low- and middle-income countries, on rural communities, older people, women, people with disabilities, ethnic minorities and indigenous populations.

A key recommendation is to scale up 'people-centred eye care' within national health services in a care continuum of promotive, preventive, treatment and rehabilitation, across the entire spectrum of eye conditions. However, most countries have poor coverage of rehabilitation services. Recommendations additional to universal eye health coverage and integrated people-centred eye care are:

- High-quality implementation and health systems research complementing existing evidence for effective eye care interventions.
- Monitor trends and evaluate progress towards implementing integrated people-centred eye care.
- Raising awareness and engaging and empowering people and communities about eye care needs.

Access the report: https://.who.report_vision/

European Council

ESFRI launching Roadmap 2021 Update

The European Strategy Forum on Research Infrastructures (ESFRI) has launched the process for the Roadmap 2021 Update. The ESFRI roadmap describe the progress in implementing Research Infrastructures (RIs) of pan-European interest. The new roadmap will address growing demands in meeting social and global challenges as reflected in the Sustainable Development Goals. It will include a comprehensive analysis of the current infrastructure landscape including ESFRI Landmarks (successfully implemented RIs), review progress of ESFRI Projects (RIs currently being implemented and provide strategic guidance on issues of general interest to national governments and Research Infrastructures themselves. The focus is on clustering of Research Infrastructures, their horizontal linkages and the projection of the Open Science concept. Its aim is to maximise the impact of Pan-European investments in RIs in terms of science, European and international collaboration and innovation.

The European Strategy Forum on Research Infrastructures (ESFRI) is a strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach. It was established in 2002, with a mandate from the EU Council to support a coherent and strategy-led approach to policy-making on research infrastructures in Europe, and to facilitate multilateral initiatives leading to the better use and development of research infrastructures, at EU and international level.

Sources: https://www.esfri.eu https://esfri-roadmap-2021

Research Infrastructures relevant to health:

http://roadmap2018.esfri.section-1/health-challenge/

European Commission

Evaluation blood, tissues and cells legislation

The Commission has published its first Evaluation on the EU blood, tissues and cells legislation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). The evaluation assessed whether the legislation achieved its original objectives and whether it is still fit for purpose. Any decision on follow-up actions will be taken by the next Commission.

Access the Executive Summary in English, French, German.

Source: https://ec.europa.eu/blood_tissues_organs/evaluation

ATMPs: GUIDELINES on Good Clinical Practice

The European Commission have published the final specific guidelines for the Good Clinical Practice for Advanced Therapy Medicinal Products (ATMPs). The Guidelines cover Clinical Trial design, non-clinical studies, quality of investigational ATMPs, safe conduct of clinical trials, upstream interventions on subjects and administration procedures, traceability, retention of samples, protection of research subjects, safety reporting and monitoring.

Source: https://eudralex/vol-10/atmp_guidelines_en.pdf

Rule 11 - New guidance on software medical devices

The Medical Device Coordination Group (MDCG) of the European Commission has released its Guidance on Qualification and Classification of Software under the new EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). At the centre of the guidance is Rule 11 which addresses risks related to the information provided by an active device and describes and categorizes the "*significance of the information provided by the active device to the healthcare decision (patient management) in combination with the healthcare situation (patient condition)*."
Rule 11 contains the following provisions:
"*Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:*

- *Death or an irreversible deterioration of a person's state of health, in which case it is in class III; or*
- *Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.
All other software are classified as class I."

Source: https://ec.europa.eu/37581?locale=en

Calls, Consultations & Events

Civil Societies - EMA PDCO Committee

The Call is for Civil Society (health professionals and patients' associations) representatives to the Pediatric Committee (PDCO) of the European Medicines Agency (EMA), in Amsterdam. for three years starting 1 August 2020.

Deadline: 8 November 2019

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

Call to join the European Reference Networks

The 2019 call is the first one for new members to join existing 24 European Reference Networks (ERNs). The ERN EYE is the ERN dedicated to Rare Eye Diseases. Anyone wishing to join need to contact one's national representatives in the ERN Board of own Member State. The national representatives provide specific information on their national endorsement process.

Deadline: 30 November 2019

Call details: https://ec.europa.eu/2019_call_ERN

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 info on ERNs: https://ec.europa.eu/health/ern_en

Call for experts on medical devices and in vitro diagnostic medical devices (2019/C 323/05) - Up to five experts in Ophthalmology

The European Commission is looking for experienced clinical, scientific and technical experts in the area of medical and *in vitro* diagnostic devices. If selected, experts will be appointed to expert panels in relevant clinical and other areas for a three years term, which may be renewed. The maximum appointed in Ophthalmology is five. Applicants that are not appointed to an

expert panel may be included in a central list of available experts that will be used for replacements or temporary assignments.

Deadline: 10 November 2019

Source: https://ec.europa.eu/documents/37702?locale=en

The application form link:

https://call-expression-interest-expert-panels-md-vdmd

Source: https://eur-lex.europa.eu.2019.323.01.0093

Call for proposals on new infrastructures (ESFRI)

The ESFRI invites the research community to propose new Research Infrastructures that will be included on the 2021 ESFRI Roadmap. To this purpose the ESFRI has published the ESFRI Roadmap 2021 Guide. The Guide offers support to proposers preparing a new submission and to the projects and landmarks involved in the update procedure. The Guide contains the definitions, models, methods and describes the procedures applied for the update.

Deadline: 5 May 2020

ESFRI Guide: https://ESFRI-Roadmap2021-Public-Guide.pdf

Research Infrastructures relevant to health:

http://roadmap2018.esfri.section-1/health-challenge/

Nine Calls for HPB Projects

The Human Brain Project (HBP) has launched nine calls for new projects to directly contribute to the development of its research infrastructure EBRAINS. The selected projects will increase the scope of its application in terms of innovation, neuroscience and clinical research.
Six ICT research Platforms currently form the heart of the HBP infrastructure: Neuroinformatics (access to shared brain data), Brain Simulation (replication of brain architecture and activity on computers), High Performance Analytics and Computing (providing the required computing and analytics capabilities), Medical Informatics (access to patient data, identification of disease signatures), Neuromorphic Computing (development of brain-inspired computing) and Neurorobotics (use of robots to test brain simulations).

Deadline: 2 December 2019

The Human Brain Project (HBP) is building a research infrastructure to help advance neuroscience, medicine and computing. It undertakes targeted research and theoretical studies and explores brain structure and function in humans, rodents and other species; and the ethical and societal implications of its work. The HBP is one of four FET (Future and Emerging Technology) Flagships, the largest scientific projects ever funded by the European Union.
The 10-year Project began in 2013 and directly employs some 500 scientists at more than 100 universities, teaching hospitals and research centres across Europe.

Access the nine calls at: https://www.HBP/-final-phase-opened/

Consultation on clinical trials in paediatrics

Feedback on the draft framework on “preparedness of medicines’ clinical trials in paediatrics is collected from anyone involved in the preparation and conduct of paediatric clinical trials including researchers, sponsors and patients”.

Deadline: 15 November 2019

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

Consultation document: preparednessclinical-trials-paediatrics

Horizon Europe: European Partnership for Innovative Health

The European Commission opened a survey about the 12 proposed European Partnerships for the upcoming research framework Horizon Europe.

Deadline: 6 November 2019.

Access consultation document:

https://ec.europa.eu/consultation-institutionalised-partnerships

Open Call SC1-HCC-10-2020: Towards a Health Research and Innovation Cloud: Capitalising on Data Sharing Initiatives in Health Research

Deadline: 7 April 2020

Source: https://ec.europa.eu/sc1-hcc-10-2020

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

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

Deadline: 7 April 2020

European Policy Dialogue on employment and chronic conditions

The Policy Dialogue on Employment and Chronic conditions is part of the activities under the CHRODIS PLUS Work Package 8 on Employment and chronic conditions, The aim of this policy dialogue is to bring together stakeholders and develop jointly a European road map towards inclusion, integration and reintegration of people with chronic conditions in the workplace, as well as present the CHRODIS Plus Toolbox on Employment and Chronic Conditions developed within this EU Joint Action. The event is free and open to the public and it requires

compulsory online registration.

Date: 12 November 2019
Location: European Parliament, Brussels, Belgium
Deadline for compulsory registration: 5 November 2019

Source: http://chrodis.eu/policy-dialogue-employment-and-CD/

EXPH Conference

The *Expert Panel on Effective Ways of Investing in Health* (EXPH) will close the mandate of its current membership with a conference that reflects on the Panel's work, based on this experience, more broadly on the role of evidence-based expert's advice in policy making. It will be an opportunity to take stock of the Panel's opinions and their interaction with health policy making and exchange views and experience on developing evidence based advice.
Main topics of the EXPH event are:

- Evidence based policy making
- The Panel experience - Universal health coverage and access to healthcare
- Measuring performance of health systems
- Lessons learned for science and evidence-based health policy making

Date: 8 November 2019, Brussels, Belgium

Online registration at http://www.cvent.com/EXPH

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).

Source: https://ec.europa.eu/expert_panel/ev_20191108_en

Across the world

WHO on digital strengthening of health systems

The World Health Assembly has recognised the value of digital technologies in advancing universal health coverage and other health aims of the Sustainable Development Goals. The WHO Resolution on Digital Health urges health ministries to assess their use of digital technologies for health and to prioritize, as appropriate, the development, evaluation, implementation, scale-up and greater use of digital technologies. The WHO are concerned about the rolling out of digital interventions in the absence of a careful examination of the evidence base on benefits and harms for people's well-being and health systems including health equity. The WHO call for a rigorous evaluation of eHealth to ensure that investments do not inappropriately divert resources from alternative, non-digital approaches.

The term digital health is encompassing eHealth and emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence". eHealth is defined as "the use of information and communications technology in support of health and health-related fields" with mobile health (mHealth) as a subset defined as "the use of mobile wireless technologies for health".

Source: https://apps.who/10665/311941/9789241550505-eng.pdf

Patients Say Ask before Using Medical Records for Research

A study by University of Michigan using the novel democratic deliberation methodology finds that even when patients understand the overall benefit to society, they still want to be able to give consent at least once before their de-identified data is used for research. The feeling was especially strong among racial and ethnic minorities. There was higher support for academic medical centers or community hospitals seeking to improve quality than for insurance and drug companies or hospitals using the data for marketing purposes.

Sources: https://ascopubs.org/doi/10.1200/JCO.19.01693

http://www.ehealthnews.eu//5962-patients-say-ask-before-using

FDA Revises Guidance on Postmarketing Studies to Reflect ARIA System, SUPPORT Act

An article by Michael Mezher in Regulatory Focus RF on the US Food and Drug Administration (FDA) revision of its draft guidance on postmarketing studies and clinical trials in the light of the FDA's active risk identification and analysis (ARIA) system.

Source: www.raps.org//2019/10/fda-guidance-on-PM

The EU EYE continues to be 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/

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