FOCUS-EU

HEALTH

January 2018

Overview of EU and global policy developments

ANNOUNCEMENT

The EU EYE has been officially accepted in the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) of the European Commission. This is a recognition of the efforts and the added value that the EU EYE brings to this collaborative network in creating a forum for integration of research priorities, policies and strategies in eye health. The EU EYE will explore potential synergy actions with members of EIP AHA who have similar interests and activities.

The commitment of the EU EYE was submitted to the B3 Action Group on Integrated Care of the EIP AHA in December 2017 and it has been now validated and publicly accessible at:
https://ec.europa.eu/eip/b3/

The EIP-AHA brings together key stakeholders in public health from universities, research groups, public authorities, health care providers, industry and non-governmental organizations representing citizens and patients. The following Directorate Generals are currently interested in the work of the EIP-AHA:
DG Connect (digital development of EU); DG SANCO (the public health unit); DG Research & Innovation; DG REGIO (managing the structural funds); and DG EMPL (DG Employment Social Affairs & Inclusion). The EIP-AHA has six thematic Action Groups:

- *Action Group A1: Adherence to treatment*
- *Action Group A2: Falls prevention*
- *Action Group A3: Functional decline and frailty*
- *Action Group B3: Integrated care*
- *Action Group C2: Independent living solutions*
- *Action Group D4: Age friendly environments*

European Council

Priorities on education and training

The European Council has called Member States, the Council and the European Commission to work on the following priorities:

- step up mobility and exchanges through a reinforced and extended Erasmus+ programme;
- strengthen partnerships between higher education institutions and encourage the emergence of twenty 'European Universities' by 2024, that enable students to combine studies in several EU countries and contribute to the competitiveness of European universities;
- encourage the learning of at least two European languages in addition to the mother tongue;
- promote student mobility and participation in activities through a 'European Student Card';
- promote cooperation on mutual recognition of higher and secondary education diplomas.

Source: https://www.consilium.europa.eu/.pdf

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.

European Parliament

Parliamentary Advocates for Rare Diseases

EURORDIS has launched the Parliamentary Advocates for Rare Diseases. The network aims to bring together members of

parliament to ensure strong international and local action, shape political input for current and future legislation, and integrate rare diseases into all relevant policies at all levels.

Source: http://parliamentaryadvocateforrare/.pdf

European Commission

ERN-EYE

A European Reference Network dedicated to Rare Eye Diseases (ERN-EYE) has been launched with 29 members in 13 countries of the EU and covering more than 900 rare eye diseases.

The 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.

Source: https://www.ern-eye.eu/

Health Work Programme for 2018

The Commission has adopted the Health Programme's Work Programme for 2018 (WP 2018) setting out the priorities and actions to be undertaken in 2018. The overall budget for 2018 is just over €62 million, with 64% being allocated to grants, 24% to procurement and 12% to other actions including prizes.The Work Programme 2018 will focus on the following areas:

- European Reference Networks for rare and complex diseases (29% of the budget);
- Health promotion and prevention of chronic and major diseases (15%);
- Mitigating cross-border health threats (15%);
- Implementation of medical devices legislation (7%)

Source: http://ec.europa.eu/

CPMS bringing specialised care to patients in Europe

Clinical Patient Management System (CPMS) is a secure web-based platform enabling the ERNs' healthcare professionals to discuss diagnosis and treatment of patients with rare or low prevalence complex diseases or conditions across national borders. Such cross-border virtual consultations will reduce patient travelling to highly specialised healthcare providers. All ERNs will focus on: enrolling the first patients into the CPMS; launching the first virtual panels; and familiarising themselves with the platform's functionalities. The CPMS will eventually allow for

doctors outside of the ERNs to enroll their patients for diagnosis, care and treatment advice from each ERN.

Introductory video on CPMS https://webgate.ec.europa.eu/mp4

and Access CPMS_for healthcare professionals

Standards for Rare Disease Registries

Registries across Europe are recommended to use, as the basis for their data collection activities, the uniform standard released by the European Platform on Rare Diseases Registration (EU RD Platform) to ensure comparability and interoperability for rare disease databases. The "*Set of Common Data Elements for Rare Diseases Registration*" describes sixteen essential data elements to be provided for research purposes together with instructions on how and in which format each data element should be registered. Such information is in addition to patients' personal data, diagnosis, disease history and care pathway.

The EU RD Platform has been developed by the Joint Research Centre and the Directorate-General for Health and Food Safety to tackle the issue of fragmentation of data regarding rare disease patients.

Sources: Set of data elements for rare diseases registration

Cross-border digital prescription and patient data

In 2018, twelve EU Member States will start exchanging patient data on a regular basis. Sweden, Finland, Portugal, Croatia, and Estonia will share electronic prescriptions. Five more countries are scheduled to join the network in 2019, and another wave is expected for 2020.

Source:https://ec.europa.eu/crossborder/prescriptionpatient-data-

Borderline medical devices

The European Commission has released an update to its manual on classifying "borderline" medical devices, which is a complement to *MEDDEV 2.1/3 Rev. 3*, the guidance document on products incorporating pharmacological or biological substances. The EU's new *Medical Devices Regulation* (MDR) and *In Vitro Diagnostic Regulation* (IVDR) will come into effect in 2020 and 2022, respectively. Borderline device decisions remain with each member state. The European Commission may make decisions on specific borderline products in consultation with the Medical Device Coordination Group (MDCG) and other relevant EU regulatory authority e.g. European Medicines Agency, European Chemicals Agency or the European Food Safety Authority.

Source: http://ec.europa.eu/26785/

Assessing educators' digital skills

The Digital Competence Framework for Educators (DigCompEdu) has been published by the European Commission to help

educators at all levels to self-evaluate their competence in relevant digital skills. DigCompEdu proposes twenty two elementary competences organised in six areas: professional engagement; digital resources; teaching and learning; assessment; empowering learners; and facilitating learners' digital competences. The framework further proposes proficiency levels from A1 (Newcomers) to C2 (Pioneer), in reference to the widely used language proficiency levels. The framework is part of a competence framework family that includes the Digital Competence Framework for individual citizens, the European Framework for Digitally Competent Educational Organisations, the Digital Competence Framework for Consumers and the Entrepreneurship Competence framework.

Source: https://ec.europa.eu/jrc/digcompedu

Public Consultations

EU funds for Research & Innovation and other areas

A public consultation on *Investment; Research & Innovation, Small and medium-sized enterprises and Single Market* has opened in parallel to consultations covering the entire spectrum of EU future funding in: Security; Migration and Asylum; Strategic Infrastructure; Values and Mobility. All consultation results will feed into the proposals for the post-2020 financial programmes.

Deadline: 8 March 2018.

Source: https://ec.europa.eu/public-consultation-eu-funds_en

Pharmaceuticals in the environment

The consultation seeks views for the development of the EU strategy to address the environmental impact of pharmaceuticals. Deadline: 21 February 2018.

Source: https://ec.europa.eu//PharmaInEnvConsultation2017

Calls & Events

Public call for expression of interest for ECDC

The European Commission has launched a public call for expression of interest for the Advisory Forum of the European Centre for Disease Prevention and Control (ECDC).

Deadline: 16 February 2018

Source: https://ec.europa.eu/health/ecdc_advisoryforum_en

Rare Disease European Joint Programme Cofund

A Call for the H2020 European Joint Programme Co-fund on Rare Diseases has been published with the overall objective the rapid translation of research results into clinical applications and uptake in healthcare.

Deadline: 18 April 2018.

Sources: http://ec.europa.eu/research/participants/2018.html

Call for health projects under Horizon2020

Approximately €2 billion are to fund projects on personalised medicine, decoding the role of the environment for health, integration of care, digital transformation/eHealth, and big data solutions for cybersecurity in health and care.

Deadlines depending on topic: 24 April 2018; 14 November 2018

Source: https://ec.europa.eu//horizon-2020-calls

Applications at: Participant portal

First Digital Opportunity Traineeships now open

The Digital Opportunity traineeship initiative is running its pilot phase giving to students of all disciplines the opportunity to get digital experience in fields demanded by the market. The scheme is financed by Horizon 2020 and implemented through Erasmus+ aiming to provide cross-border traineeships for up to 6,000 students and recent graduates between 2018 and 2020.

Source: https://ec.europa.eu/traineeships-digital-skills-job

Conference of Partners of EIP AHA: 27-28 February 2018

The European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) is a network of stakeholders in public health from universities, research groups, public authorities, health care providers, industry and non-governmental organizations.

Source: https://EIPAHA and Registration_Link_EIPonAHA2018

Cross border healthcare event - 27 February 2018

The event entitled "*Cross-border healthcare and centers of excellence to enhance patients' rights: access, information and innovation*" is organised by the Active Citizenship Network (ACN) in the European Parliament. The event focusses on the European Reference Networks and on patients' rights with regard to rare or complex disease and it is hosted by the MEP Patrizia Toia in the framework of the MEPs Interest Group "European Patients' Rights & Cross-Border Healthcare".

Registration mandatory by 15th **February** 2018.
Source & registration: https://docs.google.com/forms/d

Across the World

FDA Denies 3rd Allergan Citizen Petition to Block Restasis Generics

Article by Zachary Brennan on the third citizen petition on the Restasis (cyclosporine ophthalmic emulsion).

Source: http://www.raps.org/Restasis-Generics/

FDA Targets Multiple Review Cycles With New Draft Guidance, MAPP

Article by Zachary Brennan on FDA's new manual of policies and procedures (MAPP) for abbreviated new drug applications.

Source: http://raps.org/New-Draft-Guidance-MAPP/

Perspective: Regulatory Bill Could be Dangerous for FDA, Public Health

Article by Zachary Brennan on the Regulatory Accountability Act (RAA), which is currently considered by the USA Congress.

Source: http://www.raps.org/Perspective-Regulatory-Bill/

Summary of the RAA: https://www.congress.gov/bill/951

Other

Updated list of National Focal Points of Member States and participating countries - Third Programme Health (2014-2020)

https://ec.europa.eu/health/nfp_en.pdf

Report on economic impact of an ageing population

The Directorate-General for Economic and Financial Affairs (ECFIN) has published a report on the underlying assumptions and projection methodologies used to estimate the long-term economic and budgetary impact of an ageing population.

ECFIN is responsible for EU policies on economic growth, employment and public finances.

Source: https://ec.europa.eu/economy-finance/2018-ageing

New project partner search facility

A new project partner search facility operates on the Participant Portal for Horizon 2020 allowing participants to create new partner search requests or access the existing list for a given topic via individual call topics(open and forthcoming).

Source: http://ec.europa.eu/research/participants/portal/l

EURORDIS Summer School

The EURORDIS summer school trains forty expert patients annually on the regulatory process of orphan medicinal products with online and face-to-face components.
Location and dates: Barcelona, Spain; 11 - 15 June 2018

EURORDIS is a non-governmental alliance of 779 rare disease patient organisations in 69 countries.

Source: https://www.eurordis.org/

Soundscapes and vibrations helping blind people see

Glasses that translate images of physical objects into soundscapes and a belt that turns images into vibrations are helping to build up a real-time 3D picture of the world around blind people aim to hit the market in 2019.

Source: https://horizon-magazine.eu/.html

Disclaimer: The information given in this newsletter is based on information available; consequently the principal editor does not warrant that the information contained in this document is complete or correct and shall not be liable for any damages incurred as a result of its use. The mention of specific organizations, companies or products does not imply that they are endorsed or recommended by the principal editor in preference to others of a similar nature that are not mentioned.