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HEALTH

March 2020

Overview of EU and global policy developments

European Commission

Digital Strategy for Europe: data and AI

The European Commission (EC) published a new five-year Digital Strategy for Europe, which focuses on promoting innovative technologies, a data-driven single market and a digitalised society for the EU. The strategy aims to make the digital transformation of the European society work for people and businesses, while helping to achieve its target of a climate-neutral Europe by 2050. The strategies for data and the human-centric development of Artificial Intelligence (AI) are the first steps towards achieving these goals while encouraging businesses to work with, and develop, these new technologies, while at the same time making sure that they earn citizens' trust.
The Commission will present later this year a Digital Services Act and a European Democracy Action Plan, propose a review of the Electronic Identification, Authentication and Trust Services Regulation (eIDAS), and strengthen cybersecurity by developing a Joint Cyber Unit. Europe will also continue to build alliances with global partners, leveraging its regulatory power, capacity building, diplomacy and finance to promote the European digitalisation model.

Source: https://ec.europa.eu/strategy/europe-fit-digital-age_en

Direct healthcare professional communications

The European Medicines Agency (EMA) has launched their web service for direct publication of healthcare professional communications (DHPCs) as agreed at European Union (EU) level with links to national registers. Marketing authorisation holders may send DHPCs to healthcare professionals to inform them of important new safety information about a medicine and any actions they should take.
DHPCs serve to inform healthcare professionals of, for example:

- a suspension, withdrawal or revocation of marketing authorisations for safety reasons;
- an important change, e.g. restriction of indication, new contraindication or change in the recommended dose;
- a medicine supply shortage;
- quality problems with a medicine.

A competent authority may disseminate or request the marketing authorisation holder to share a DHPC whenever this communication can benefit public health.
DHPCs will be published on the EMA website at the time of national dissemination. The new webpage also includes links to national registers of DHPCs.
More information on DHPCs:
guideline on GVP Module XV – Safety communication

Source:https://www.ema.europa.eu/direct_HCP_communications

EU science ministers want reciprocity in international R&D cooperation

A Science|Business article by Florin Zubașcu on how third countries could join Horizon Europe, if they respect EU values.

Source: https://sciencebusiness.net/framework-programmes

Capacity building: ERN-Clinical Guidelines Programme

The Commission has introduced a new project to provide technical assistance to the European Reference Networks (ERNs) for the development, appraisal and implementation of Clinical

Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDSTs). The 4 year contract will enable the ERNs to adopt a common methodology and develop their own decision-making tools: 48 new CPGs are expected and 120 existing CPGs will be adapted to the specific rare diseases they are addressing.

Most of the ERNs are already active and are either producing or adapting existing CPGS or CDSTs. So far the ERNs have adopted more than 650 CPGs and CDMTs, written 11 new CPGs and 54 new CDMTs. However, they present different levels of maturity and organisational approaches: some ERNs are in the phase of implementation or adaptation of decision-making tools, whereas others are starting to set their priorities and plans. Needs are quite diverse, depending on the rare diseases concerned: whereas some decision-making tools sometimes do exist for some diseases and only need to be disseminated, in other cases it is necessary to adapt existing clinical guidelines to the specificities of the diseases. In other cases, there is simply not enough evidence to draft clinical practices guidelines and other decision-making tools like consensus of experts or recommendations are needed.
Starting from the ERNs' needs and the state of the art, the consortium will propose to work on a common methodology and will deliver training activities, to propose a harmonized way of proceeding across the ERNs and to support their own capacities to produce decision-making tools. Key aspects will be taken into consideration such as copyrights when existing CPGs are owned by scientific societies.

Source: https://ec.europa.eu/health/sites.pdf

Update on Joint Procurement Agreement

Poland and Sweden are the latest countries to sign the Joint Procurement Agreement (JPA) of medical countermeasures approved by the Commission in 2014. The agreement gives participating countries more leverage when purchasing medical countermeasures like vaccines because negotiations with providers are made as a group rather than by individual countries, helping to secure better prices and ensuring more equal accessibility for citizens. The JPA:

- Determines the practical arrangements governing the mechanism
- Defines the decision-making process with regard to the choice of the procedures
- Organises the assessment of the tenders and the award of the contract

Source: https://ec.europa.eu/joint_procurement/jpa_signature_en

EMA organisational changes come into effect

A new EMA organisation chart has been published. The main, high-level change is the integration of operations in the area of human medicines into one Human Medicines Division. The Veterinary Medicines Division remains unchanged.

Four mission-critical task forces have been established to support the human and veterinary medicines divisions, bringing together expertise to drive transformational change in the following high-priority areas:

- The Digital Business Transformation task force responsible for driving complex, digital change initiatives which include adapting EMA operations to fundamental changes brought by legislative initiatives, digital technologies and global trends to meet stakeholders' needs and expectations.
- The Data Analytics and Methods task force responsible for building up capability and capacity within EMA and across the network, to deliver robust evidence for benefit-risk decision-making.
- The Regulatory Science and Innovation task force will enable the continuous 'future-proofing' of the Agency and the network by addressing key scientific and technological trends and their translation through the development of EMA's regulatory science strategy, planning and governance.
- The Clinical Studies and Manufacturing task force responsible for developing and guiding Agency strategy at EU and global level to support the facilitation of clinical studies and manufacturing.

Source: https://www.ema.europa.eu/organisational-changes

Across the World

FDA: Contact Lenses: CDRH Drafts Guidance on Performance Criteria to Support 510(k)s

A Regulatory Focus article by Zachary Brennan on the new draft guidance to help firms planning to submit a 510(k) using the Safety and Performance Based Pathway for soft (hydrophilic) contact lenses (Class II lenses).

Source: https://www.raps.org/contact-lenses

FDA approves Pataday eye allergy products for OTC use

Source: https://www.healio.com/therapeutics/news/

HHS rules give patients 'unprecedented' access to health data

A Healio article on the rules of the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for

Health Information Technology (ONC) and CMS to allow patients to access their health data using apps so that they can make better health care decisions.

Source: https://www.healio.com/patients-access_data

Other

Vision deterioration in type 2 diabetes tied to smoking, severe hypoglycemia

A Healio article on the research on the risk for vision loss for adults with type 2 diabetes who smoke.

Source: https://www.healio.com/endocrinology/diabetes/

Can you sue an algorithm for malpractice? It depends

A First Opinion article by J Saurabh.

Source: https://www.statnews.com/can-you-sue-AI_algorithm

Calls

DHE 2020 Call for Twinnings Scheme
Deadline 4 May 2020.
DigitalHealthEurope (DHE) is aiming to scale up digital health and care innovation across European Regions. The Call for Twinnings will fund 28 projects in three priorities: citizens' secure access to and sharing of health data across borders, better data to advance research, disease prevention and personalised health and care, and digital tools for citizen empowerment and person-centred care. All health and care organisations across Europe are eligible. Funding per scheme ranges from €5,000 to €43,000.

For more information: http://bit.ly/Call4Twinnings

European Reference Networks (ERNs)
Deadline: 11 May 2020
Call for tender to promote short term mobility and exchanges of healthcare professionals working in the ERNs

Source: https://etendering.ted.europa.eu/

Open Call SC1-HCO-19-2020: Reliable and Accessible Information on Cell and Gene-Based Therapies
Deadline: 7 April 2020

For topic conditions, documents and submission service: https://ec.europa.eu/funding/sc1-hco-19-2020

Call for proposals on new infrastructures (ESFRI)
Deadline: 5 May 2020

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

Health Research Infrastructures: http://esfri

Open Call SC1-HCO-19-2020: Reliable and Accessible Information on Cell and Gene-Based Therapies
Deadline: 7 April 2020

For topic conditions, documents and submission service: https://ec.europa.eu/funding/sc1-hco-19-2020

Open Call SC1-HCO-20-2020: Coordination of Clinical Research Activities of the European Reference Networks
Deadline: 7 April 2020

For topic conditions, documents and submission service: https://ec.europa.eu/funding/sc1-hco-20-2020

Open Call SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of High-Risk Medical Devices
Deadline: 7 April 2020

For topic conditions, documents and submission service https://ec.europa.eu/funding/sc1-hco-18-2020

IMI 20th Call
Deadline: 21 April 2020
Rules and how to apply: IMI website.
IMI webinars to inform about the open topics: here.

Source: https://www.euresearch.ch/IMI

Open Call DT-ICT-12-2020: AI for the smart hospital of the future
Deadline: 22 April 2020

For topic conditions, documents and submission service: https://ec.europa.eu/fundingdt-ict-12-2020

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
For topic conditions, documents and submission service:
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
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu//funding-tenders//sc1-bhc-06-2020

Open Call SC1-BHC-20A-2020:
Pre-Commercial Procurement (PCP) for Integrated Care Solutions
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding-tenders/sc1-bhc-20a-2020

Open Call SC1-DTH-12-2020:
Use of Real-World Data to Advance Research on the Management of Complex Chronic Conditions
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/info/funding-tenders/sc1-dth-12-2020

Open Call SC1-HCO-19-2020:
Reliable and accessible information on cell and gene-based therapies
Deadline: 7 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding/sc1-hco-19-2020

Open Call SC1-DTH-06-2020:
Accelerating the uptake of computer simulations for testing medicines and medical devices
Deadline: 22 April 2020

For topic conditions, documents and submission service:
https://ec.europa.eu/funding/sc1-dth-06-2020

Consultations & Events

White Paper on AI
Deadline: 31 May 2020

The White Paper on Artificial Intelligence is published by the European Commission. It sets out principles for a legislative framework for trustworthy AI and it is open for comments.
Source: https://ec.europa.eu/info/consultations_en

JRC 2nd Call for Expressions of Interest for the Collaborative Doctoral Partnerships
Deadline: 3 May 2020

The Joint Research Centre (JRC) has opened a call in many fields, including Health promotion and prevention of non-communicable diseases (NCDs). The call is open to higher education institutions/universities from EU Member States and countries associated to the EU Research Programme Horizon 2020.
Source:
https://ec.europa.eu/jrc/doctoral-partnerships/universities

Call for proposals of EU Health Programme - Support to reforms in health workforce - initiative on task shifting
Deadline: 10 June 2020

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

Free online course on AI

Finland offers European citizens with free access to an online course, the Elements of artificial intelligence available in all the official EU languages. This initiative by the Finnish Presidency aims to respond to the challenges posed by the transformation of work and to reinforce the digital leadership of the EU.

Access the course: https://www.elementsofai.com
Source: https://ec.europa.eu/finland-skills-basicsAI-

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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