FOCUS-EU

HEALTH

December 2017

Overview of EU and global policy developments

European Council

Digital Europe

The European Council "is ready to do what it takes for Europe to go digital" and has asked the European Commission (EC) to develop an approach to artificial intelligence in early 2018. 'Digital Europe' is a priority for the Heads of state and government with Horizon 2020 and the European Fund for Strategic Investments (EFSI) being instrumental in supporting the digitalisation of industries and services.

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

'Tallinn Call for Action'

The Estonian Presidency of the Council of the EU has asked the EU and national governments to increase expenditure in research and innovation; to prioritise efforts to increase the impact of R&I investments; and build trust between research and society and within the R&I system.

Source: tallinn_call_for_action_2017.pdf

European Parliament

EFSI 2.0

The European Parliament (EP) and Member States have agreed on a new draft of European Fund for Strategic Investments (EFSI), referred to as EFSI 2.0 Regulation. The draft proposes an extension of the EFSI's term to 2020 and an increased investment from €315 billion to at least half a trillion euros by 2020 to support sectors additional to health. The draft regulation is now awaiting for a formal adoption by the EP and the Council.

The EFSI is the core of the Investment Plan for Europe and a EU financing initiative from the European Commission and European Investment Bank Group (EIB). It is a €16bn guarantee from the EU budget, complemented by €5bn of the EIB's own capital. It increases the volume of higher risk projects supported by EIB Group financing and addresses the market failure in risk-taking which hinders investment. It focuses on projects which could not have been carried out, or not to the same extent, by the EIB under its existing financial instruments.

Source: http://www.europarl.europa.eu/efsi

10 year report on the Paediatric Medicines Regulation

The European Parliament and the Council are considering a report on progress made in children's medicines.

Source: http://europa.eu/rapid/-17-4121_en.htm

European Commission

Horizon 2020 work programme 2018-2020

The final Horizon 2020 work programme (WP) 2018-2020 has been released. The remaining €30 billion of the €77 billion research and innovation funding programme Horizon 2020 will support fewer topics with more funding. The final WP includes a €2.7 billion kick-start of the European Innovation Council (EIC)

and it will focus on high-risk, high-gain innovation and on making the SME instrument fully bottom-up. Open science will receive increasing importance with €2 billion and an additional €600 million allocated to the European Open Science Cloud, European Data Infrastructure and High Performance Computing.

Source: http://europa.eu/rapid/press-release_IP-17-4122_en.htm

Lump Sum Pilot

The establishment of the Lump Sum Pilot is planned for the period 2018-2020. Two funding options will be tested and evaluated in view of the post-2020 programme aiming to remove all obligations on cost reporting, and remove the need for time sheets and financial ex-post audits on costs incurred.

Source: https://ec.europa.eu//lump_sum__2018-2020_0.pdf

State of health in the EU

The 28 Country Health Profiles and the Companion Report, are now available. They are prepared by the European Commission in cooperation with the OECD and the European Observatory on Health Systems and Policies. Some key findings are:

- Unbalanced investments in prevention and social inequalities need to be tackled;
- Strong primary care efficiently guides patients through the health system and helps avoid wasteful spending;
- Integrated care ensures that a patient receives joined-up care;
- Proactive health workforce planning and forecasting needs sound recruitment policies, new skills, and technical innovation;
- Digital transformation of health and care will enable real-world outcomes and experiences that matter to patients, potentially improving the effectiveness of health systems.

Source: http://europa.eu/IP-17-4722_en.htm
Country profiles: https://ec.europa.eu/health/state/
Companion report: https://ec.europa.eu/companion_report_en

Updated list for NFPs for 3rd Health Programme

The list of the National Focal Points (NFP) for the Health Programme is now available. The national experts appointed by member states and participating countries assist the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) in:
- Health Programme implementation at national level
- Health programme dissemination of results
- Information on the impact generated by the Health Programme in their respective countries

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

Changes to Orphan Drug Rules

The European Commission has proposed changes to its orphan drug regulation in view of the rise of cell therapies and other advanced medicinal products.

Source: http://www.raps.org/

EOSC

The European Commission has launched the European Open Science Cloud (EOSC) Declaration, calling all scientific stakeholders for their endorsement and commitments to the realisation of the EOSC by 2020. The EOSC aims to promote the co-ordination and progressive federation of open data infrastructures developed in specific thematic areas (e.g. health, environment, food, marine, social sciences, transport). The initiative will implement a common reference scheme to ensure FAIR (Findable, Accessible, Interoperable and Reusable) data uptake and compliance by national and European data providers in all disciplines. FAIR
The launching of the EOSC is planned for November 2019 under the Austrian Presidency of the Council of the European Union.

Source: https://ec.europa.eu/open-science-cloud

FAIR data principles: https://www.force11.org/fairprinciples

Reports on Open Science

The European Commission is encouraging a shift to an open science system in research. The Directorate-General for Research and Innovation (DG RTD) has set-up an Open Science Policy Platform (OSPP) to develop open science policy through a structured discussion with the main stakeholders. The OSPP has discussed the set-up of an Open Research Publication Platform (ORP). The European Commission (EC) will soon launch a call for tender for a stand-alone platform for peer-reviewed articles and a pre-print repository as service to Horizon 2020 beneficiaries.
The OSPP has so far considered the findings of reports on research metrics, research skills and research careers. The reports provide information on researcher assessment and career framework; open data, open peer review and citizen science; various understandings of altmetrics in evaluating quality and impact of research activities. The reports propose the creation of an Open Science Career Assessment Matrix (OS-CAM) and a 'European Skills and Qualifications Matrix for Open Science'.

Open science covers the cycle of research from conceptualizing to analysing and publishing. It addresses all types of scientific knowledge, from research data to journal articles to presentation slides, and all manner of stakeholders: researchers, funders, policymakers, citizens, enterprises, and publishers.

Research quality and impact: https://ec.europa.eu/research/

Research careers: http://ec.europa.eu/rewards

Research skills: http://ec.europa.eu//os_skills_

European Medicines Agency

EMA relocation to Amsterdam

The European Medicines Agency (EMA) will relocate to Amsterdam by 30 March 2019 under a joint governance structure with The Netherlands to steer and oversee the relocation.

Source: http://www.ema.europa.eu/

UK and Marketing Authorisation

Rapporteurs from the UK for new medicines will fail to meet EMA's definition of "available" expertise as the UK is set to leave the EU on 30 March, 2019. Centralized evaluations of initial marketing authorization applications can take more than one year and the UK may have left the EU by the time they are finished.

Source: http://www.ema.europa.eu/.pdf

EMA and EUnetHTA: Joint work plan for 2017-2020

The EMA and the European Network for Health Technology Assessment (EUnetHTA) have published a joint work plan for the next three years with key areas of collaboration to include:

- a joint platform for parallel consultation to facilitate alignment of data requirements;
- information exchange at market entry on the outcome of the regulatory assessment as part of EUnetHTA's new framework for production of relative effectiveness assessments (REAs);
- post-authorisation data generation by optimising tools, such as patient registries.

Further synergies will be created in unmet medical need; therapeutic innovation; and understanding conceptual similarities and differences regarding the benefits of orphan medicines.

Source: http://www.ema.europa.eu/

Work Plan: http://www.ema.europa.eu/.pdf

Antimicrobial indicators

The EMA, the European Food Safety Authority (EFSA), and the European Centre for Disease Prevention and Control (ECDC) have developed indicators to measure reduction of antimicrobial resistance and antimicrobial consumption in EU in the community, in hospitals and in food-producing animals.

Source: http://www.ema.europa.eu/

Harmonized Path for Antibiotics

Regulators from the EMA, US Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency are working on a single development plan for new antibiotics.

Source: http://www.ema.europa.eu/.pdf

EU action on Advanced therapies

The EMA and the Commission services have launched a joint action plan on the development of advanced therapy medicinal products (ATMPs), aiming to streamline the procedures and better addressing the specific requirements of ATMPs developers. The new action plan focuses on manufacturing practices for ATMPs; the interplay between the legislation on genetically modified organisms and on medicines; new EMA scientific guidelines on ATMPs, including investigational ATMPs; and continuous awareness and training sessions on related topics.

Source: https://ec.europa.eu/advanced-therapies_en

Public Consultations

Consultation on SPCs and patent research exemptions

The consultation aims to evaluate the legislation and impact assessment of modifications to the Supplement protection certificate (SPC) and patent exemption framework in the EU for pharmaceutical and other industries whose products are subject to regulated market authorisations'.

Deadline: 4 January 2018.

The SPC allows an extension (of up to 5 years) to the term of a patent right (of 20 years) to offset the loss of effective patent protection due to the compulsory and lengthy testing and clinical trials required for regulatory marketing approval. The 'Bolar' patent exemption aims at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval, even when the SPC of the reference medicine is still in force. The scope of the EU Bolar exemption has been updated in some EU countries, to meet new pharmaceutical-related requirements among other things.

Source: https://ec.europa.eu/info/-spcs-en

Consultation on 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

Call for health projects under Horizon2020

Approx. €2 billion are to fund projects on personalised medicine, decoding the role of the environment for health, infectious diseases and improving global health, innovative healthcare industry, integration of care, digital transformation/eHealth, and big data solutions for cybersecurity in health and care.

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

Applications at: Participant portal

COCIR Digital Health Summit: 6 December

The event is organised by the European Coordination Committee of Radiological, Electronical and Healthcare IT Industry (COCIR).

Source: https://ec.europa.eu/cocir-digital-health-summit

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

The General Assembly of the EIP AHA will review the action plans of the Action Groups and the Reference Sites Collaborative Network and their alignment with the EU policy on "Transformation of health and care in the Digital Single Market".

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://ec.europa.eu/EIPAHA

Across the World

FDA and suffixes

The US Food and Drug Administration (FDA) began adding four-letter meaningless suffixes at the end of newly approved biologics' nonproprietary names. The FDA believes that distinguishing suffixes are key in identifying specific products in spontaneous adverse event reporting and in reinforcing accurate product identification in billing and claims records used for active pharmacovigilance.

Source: http://www.raps.org/

FDA Unveils New Regenerative Medicine Framework

The FDA has launched a new policy framework for regenerative medicine to bring new cell, stem cell and tissue products to patients as efficiently as possible while managing the proliferation in the emergence of unproven therapies. The released guidance documents focus on ways to expedite approvals for regenerative medicines for serious conditions; medical devices used with regenerative therapies; exceptions in cell and tissue-based products and the regulatory definitions of "minimal manipulation" and "homologous use."

Source: https://www.fda.gov/

Devices Referencing Drugs

The FDA held a public hearing to look into the scientific, regulatory and legal challenges posed by devices referencing drugs (DRDs) and a proposed approach on their regulation.

Source: FDA

Other

Health indicators

Indicators on medical technologies (MRI units and CT scanners) updated with 2015 data (ECHI 66)

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

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