

FOCUS-EU

HEALTH

October 2018

Overview of EU and global policy developments

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European Innovation Partnership Active and Healthy Ageing

According to a new Commission Staff Working Document, the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) has fulfilled its primary mission of creating a cooperation platform for people involved in innovation for ageing well. 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 Commission highlights the importance of the Partnership in delivering on policy orientations, especially regarding its Communication on Digital Health and Care. The policy document describes how the initiatives of the partnership have contributed to deployment and scaling-up of digital innovation in the EU. The current mandate of the EIP on AHA is valid until 2020. The Partnership is now expected to reflect on its future in the period beyond 2020, and on how it can build further improve its functioning and results.

Source: <https://ec.europa.eu/partnership-active-and-healthy-ageing>

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

Priorities of the Austrian Presidency

The Austrian Presidency marks the end of the trio Presidency of the Council of the European Union, comprised of Estonia, Bulgaria and Austria. Austria focuses on three main areas:

- Reform of the Common Asylum system, and securing Europe's external borders;
- Completing the goals of the Digital Single Market, and avoiding over-regulation;
- Advocating for the development of an EU perspective for the region of Western Balkans/South Eastern Europe.

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.consilium.europa.eu/>

European Parliament

European Elections

The next election of the European Parliament will be between 23 to 26 May 2019. Currently the Parliament boasts 751 seats, which is the maximum number allowed by the EU treaties. In 2019 the number of MEPs to be elected will be 705; 27 of the UK's 73 seats will be redistributed to other countries with the

remaining 46 seats kept for future enlargements. European elections are held every 5 years.

Source: <http://www.europarl.europa.eu/html>

European Commission

EXPH: Application of ERN model beyond rare diseases

The *Expert Panel on Effective Ways of Investing in Health (EXPH)* has made available the Opinion on 'Application of the European Reference Network (ERN) model in European cross-border healthcare cooperation outside the rare diseases' area'. The opinion provides input for reflection on possible actions to be undertaken at the national and European levels.

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

Source: draft opinion on ERNs: <https://ec.europa.eu/health/pdf>

Report of ERN hearing: <https://ec.europa.eu/20180925.pdf>

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

ERN-EYE: <https://www.ern-eye.eu/>

The EU EYE participated in the ERNs hearing calling for:

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

Access the full input of EU EYE on ERNs at <http://www.eueye.org/>

Patients with rare and chronic diseases have a network of specialists at their service – but do they know?

An interview with Dr Franz Schaefer, Heidelberg University and the current Chair of the Coordinators of the 24 European Reference Networks (ERNs)

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://ec.europa.eu/health/newsletter-223-focus_en

ESF+: the future of EU Health programme in 2021-2027

The European Social Fund+ (ESF+) will be the main EU financial instrument in the EU budget for the period 2021-27 merging the existing EU Health Programme, the European Social Fund, the Youth Employment Initiative, the Fund for European Aid to the most Deprived and the Employment and Social Innovation Programme. This is a major step towards streamlining and simplifying existing rules across Funds and will help increase synergies between the different components of the Fund to ensure a better impact.

The overall figure is €101.2 billion; €100 billion is under shared management with the Member States with the remaining €1.2 billion under direct management assigned to the Employment and social innovation strand (€761 million) and the Health strand (€413 million). The two strands will support innovative solutions in a cross-border approach, for instance to support labour mobility in Europe and to help Member States to modernise their health systems.

Beneficiaries for health funding in the new ESF+ Programme are national health authorities, as well as public and private bodies, international organisations and non-governmental organisations active in the health area at EU level and which support the specific objectives of the programme.

Additional funds for health policies will come from other EU financial instruments (i.e. the [European Regional Development Fund](#), [Horizon Europe](#), [Digital Europe](#), [InvestEU Fund](#), [Connecting Europe Facility](#)).

Sources: http://europa.eu/MEMO-18-3922_en.htm

<https://ec.europa.eu/health/funding/>

ERC 2019 Work Programme

The Work Programme 2019 will support over 1,100 researchers with more than €2 billion under four core schemes: Starting; Consolidator; Advanced; and Synergy Grants.

- Synergy grants: €400 million will be made available, a 60% increase on last year's budget; one Principal Investigator per Synergy Grant group at any one time can be hosted or engaged by an institution anywhere in the world outside of the EU or Associated Countries.
- ERC Proof-of-Concept grants (PoC): €25 million will be available to ERC grantees to explore the innovation potential of their ERC-funded discoveries. This is a €5 million increase compared to last year.
- Open Access: the Work Programme now clarifies that preprints can be listed as part of an applicant's track record - if they are properly referenced and either a link to the preprint or a doi is provided.

In addition, Work Programme 2019 will pilot the award of Proof of Concept grants on the basis of a lump sum of €150,000 to test

efficiency and viability of a simplified funding mode for PoC compared to the current funding mode based on the declaration of actual costs.

Certain restrictions on applications will apply to the 2019 calls based on the outcome of the evaluation of previous calls.

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-2019-main-changes.pdf>

ERC Work Programme 2019 <http://ec.europa.eu/wp19.pdf>

Photochemical retinopathy and Light Emitting Diodes

The final Opinion on the potential risks to human health of Light Emitting Diodes (LEDs) published by the European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has concluded that although emissions may not be harmful, blue LEDs (between 400 nm and 500 nm), including those in toys, may be very dazzling and may induce photochemical retinopathy, which is a concern especially for children below three years of age. Older people may experience discomfort from exposure to light such as blue LED displays. It is also not yet clear whether disturbances to the circadian system leads to adverse health effects for example from exposure to light in the late evening such as LED lighting and/or screens. Since the use of LED technology is still evolving, the Committee believes that it is important to closely monitor the risk of adverse health effects from long-term LED use to the general population.

Source: <http://ec.europa.eu/LEDs>

European Healthcare networks

The high-level strategy group on industrial technologies has identified European Healthcare networks among a set of exemplary missions for future EU research and innovation investments. Cutting-edge technologies such as genomics, bioinformatics, genome editing, cell engineering and synthetic biology, in combination with data management, analysis and sharing can create secure networks such as a European bio-informatic system allowing for remote consultations, participative and preventive healthcare solutions, and equality of access to high quality healthcare. The group has also proposed artificial intelligence, and security and connectivity as two new key enabling technologies and advised to broaden biotechnology to 'life sciences'.

Source: <https://ec.europa.eu/022018.pdf>

Innovation Radar Platform

The European Commission (EC) has launched an Innovation Radar Platform (IRP) to identify high potential innovations and innovators in EU-funded R&I projects. The IRP is a real-time data-

based online tool to help match innovators with those who can help get their innovations to market and it is hoped that the tool will also serve as a policy tool for innovation management and commercialisation. It covers all countries participating in Horizon 2020, Australia, Brazil, Canada, the United States and Japan.

The tool has shown so far that EU-funded R&I projects result on average in two innovations with universities and research centres being the largest group of innovators in EU-funded projects.

Source: <https://www.innoradar.eu/>

Update on Health Work Programme for 2019

Six new calls have been added to the Health Work Programme which include a call *Towards risk-based screening strategies for non-communicable diseases*. The words 'mental and non-mental disorders' have been added to the title of call SC1-BHC-01-2019 (Understanding causative mechanisms in co- and multimorbidities combining mental and non-mental disorders).

Updated Health Work Programme 2019:

http://ec.europa.eu/h2020-wp1820-health_en.pdf

Source: <https://www.europegateway.update-2019-work->

Calls & Events

ERC Proof of Concept

Deadline: 22 January 2019

<https://ec.europa.eu/research/calls/erc-2019-poc.html>

ERC Consolidator Grant

Deadline: 07 February 2019

<https://ec.europa.eu/erc-2019-cog.html>

ERC Synergy Grant

Deadline: 08 November 2018

<https://ec.europa.eu/researcherc-2019-syg.html>

ERNs

The 4th Conference on European Reference Networks entitled ERNs in action

Dates: 21-22 November. Location: Brussels, Belgium.

Source: <https://ern-euro-nmd.eu/event/>

Across the World

Canada: Non-prescription Products & The Facts Table

The Health Canada's Plain Language Labelling Initiative has introduced new regulations including a Facts Table on the outer label of non-prescription drugs to address concerns not only about what appears on the label of a product but also the wording, how it appears and how easy it is to understand. The regulations will apply to all non-prescription drug products distributed in Canada. The Facts Table is mandatory for all new products since June 2017. For all existing non-prescription products, the Facts Table will be mandatory by June 30th, 2021.

Source: <https://www.globalvisioninc.com/facts-table/>

Other

IMCUSTOMEYE

The IMCUSTOMEYE project has been launched. The 4-year project is funded by the European Commission's Horizon 2020 Programme under the Photonics 2017 KET topic. It comprises 10 research institutions, universities and companies, coordinated by Agencia Estatal Consejo Superior de Investigaciones Cientificas (CSIC), Spain. IMCUSTOMEYE will develop a tool based on innovative photonics and modelling approaches in response to the need to personalize healthcare in ophthalmology, improve diagnostics and health outcomes, reduce costs and promote active and healthy ageing.

KET: Key Enabling Technologies (KETs) provide the basis for innovation in a range of products across all industrial sectors. KETs are a group of six technologies: micro and nanoelectronics, nanotechnology, industrial biotechnology, advanced materials, photonics, and advanced manufacturing technologies. They have applications in multiple industries and help tackle societal challenges.

Sources: <http://www.imcustomeye.eu/>

KET: http://ec.europa.eu/ket_en

AEGLE: Big data, the General Data Protection Regulation and health

The EU-funded AEGLE project reports on the situation of medical data processing for scientific research purpose in the EU within the new framework of the General Data Protection Regulation (GDPR), the new EU data protection rules.

Source: <https://ec.europa.eu/country-reports>

Scientific Committee on Consumer Safety (SCCS)

SCCS - Request for a scientific Opinion on Ethylzingerone with INCI name 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98 - CAS No 569646-79-3 - Submission II – Eye irritation

Source: https://scs2016_q_028.pdf

SCCS - Request for an Addendum to the scientific Opinion SCCS/1491/12 on the hair dye substance 2-Methoxy-methyl-p-phenylenediamine and its sulfate salt (CAS 337906-36-2 and 337906-37-3 respectively) (A160). Submission II – use in eyelashes.

Source: https://ec.europa.eu/scs2016_q_026.pdf

STAMP Expert Group

In December the STAMP Expert Group will identify activities to support the repurposing of established medicines on the basis of the following themes:

- Lack of interest from and difficulties in engaging with the pharmaceutical industry;
- Lack of accessible information / data in the public domain;
- Lack of a regulatory framework that recognises the challenges faced by non- industry researchers;
- Potential advantages of access to real world data not realised:

Drug repurposing is the process of identifying new uses for existing medicines in indications outside the scope of the original approved product information.

The Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) provides advice in relation to the implementation of the EU Pharmaceutical legislation to further improve safe and timely access and availability of medicines for patients.

Source: https://ec.europa.eu/stamp8_repurposing_establishd.pdf

