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EU Health Research Policies

a. European Research Council announces 2016 budget and calls

On 28 July, the European Commission adopted the European Research Council (ERC) Work Programme 2016, under the Horizon 2020 Programme.

The ERC programme foresees €1.67 billion for grants to top researchers from anywhere in the world who are ready to come or to stay in Europe to pursue their breakthrough ideas.

The first call (Starting Grant 2016) opened on 29 July, with a budget of €485 million and deadline of 17 November 2015. This scheme is open to researchers with 2 to 7 years of experience since completion of PhD and a promising scientific track record.

Other call for proposals will follow in 2015 and 2016, according to the work programme's calendar. More information on the grants can be found on the ERC website.

b. Commission invites independent counsel to set up Scientific Advice Mechanism

On 6 July, the European Commission announced the composition of an Identification Committee that will help in selecting the members of the High Level Group of the new Scientific Advice Mechanism (SAM).

The three members of the Identification Committee are:

- Sir David King - Climate expert, former UK Chief Scientific Advisor
- Rianne Letschert - Victimology professor, Chair of the Dutch Royal Young Academy of Sciences
- António Vitorino - Former European Commissioner for justice

They will assist the Commission to define the criteria and method for identifying the seven members of the High Level Group, and recommend potential candidates for selection. The agreed methodology will be published on the webpage of the Scientific Advice Mechanism.

The High Level Group is expected to begin to work this autumn.

c. US and EU regulators reinforce collaboration to advance medicine development

On 14 July, the European Medicines Agency (EMA) and the European Commission announced the strategic priorities agreed in June with the United States Food and Drug Administration (FDA). At their regular bilateral meeting, both sides reviewed the ongoing cooperative activities and discussed strategic priorities for the next two years.

During the meeting, they decided to establish a new cluster on patient engagement to share experience and best practices regarding the involvement of patients in the development, evaluation and post-authorization activities related to medicines.

On rare diseases, EMA and FDA will establish a joint working group, the Team of International Global Rare Disease Experts (TIGRE), to better support the development of safe and effective medicines for children who suffer from rare diseases.

Other topics discussed included safety of medicines, biosimilars, paediatric medicines, diagnosis methods and timely access to new medicines, inspections and data integrity.

d. Call for experts to join new EC Health, Environmental and Emerging Risks Committee

The European Commission has decided to merge its Scientific Committees on Health and
Environmental Risks and on Emerging and Newly Identified Health Risks.

The new committee will start working next April and will be called the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

In addition, the Commission has published a new call for experts in order to renew the membership of its non-food Scientific Committees, including SCHEER. Applications are accepted until 2 November 2015.

The Scientific Committees provide the Commission with expertise and independent risk assessment and advice.

EU Public Health Policies

a. Luxembourg Health Minister presents Presidency’s priorities to the European Parliament

On July 16, Luxembourg Health Minister Lydia Mutsch presented the priorities of the Luxembourg EU Council Presidency to the European Parliament Committee on Environment, Health and Food Safety Committee (ENVI Committee).

Below you can find some key highlights from her presentation:

- **On Personalised medicine**, the Minister said that they would build on the messages of the 8 July conference “Making Access to Personalised Medicine a Reality for Patients”, to produce conclusions at the 8 December Health Council. The vision is to integrate innovation into clinical practice so all can obtain access to advanced personalised medicine. She also announced that the Dutch Presidency, starting its office on 1 January 2015, will also focus on innovation in medicines.

- **On Cross border healthcare**, she said that the Presidency will take stock of the implementation of the Cross border Healthcare Directive, based on the Commission’s implementation report, which is expected in September.

- **On Alcohol**, she said that reducing the damage caused by alcohol will continue to be a priority, and that the Council is pushing the Commission for a new alcohol strategy in 2016 (in line with the view expressed by the European Parliament).

- **On medical devices**, the Minister is hoping to start negotiations with the European Parliament by October and reach agreement by early December.


The Commission’s Directorate General for Health and Food Safety (SANTE) has published its Management Plan 2015. The document translates the priority initiatives and the strategic objectives of the Commission into concrete operations.

On public health, the main areas of action will be:

- Protecting citizens from health threats
- Promoting effective, accessible and resilient health systems
- Encouraging innovation in health
- Foster good health in an ageing Europe
- Investing in prevention and health as human capital
- Reducing health inequalities and fighting discrimination
- Mobility of health professionals – a potential opportunity for jobs in the future
- Globalization of health issues

The document includes a brief mention on allergens in the section dedicated to ‘Communication priorities’ (page 65). The Commission states that there will be a focus on the revised rules on food labelling (applicable as
of December 2014), which provide information on allergens. The management plan does not provide any further detail on this point. As a reminder, please note that the Commission is currently working on updating its guidelines on allergen labelling, on the basis of the results of a public consultation which took place early 2015.

c. Health commissioner suggest expansion of EU role in health policy

At the conference ‘Universal Health: Investing in Health and Well-being for All’ (29 June, Riga), the European commissioner for health Vytenis Andriukaitis told to the press about his desire to expand the role of the EU in health policy.

As it stands now, the European Union treaties give limited health-related competences to the EU (covering for instance prevention-type issues such as alcohol and tobacco), while a lot of areas remain a prerogative of the member states, including drug pricing. The Commissioner believes instead that managing health issues at EU level would be the most economically viable alternative.

For this reason, he would like to discuss the possibility of changing the European Union treaties in order to expand the EU competences in health policy. Despite his call for action, though, changing the EU treaties would be a major endeavor and at present there are no signs of upcoming developments in this direction.

Andriukaitis also proposed that the Commission could prepare reports on the state of health in each member state, and present them to the European Parliament over the next two or three years.

d. Cross-border Cooperation: Opinion adopted by Health Expert Panel

On 3 August, the independent Expert Panel, which advises the European Commission on matters relating to “effective ways of investing in health”, has adopted an opinion on Cross-border cooperation.

The Expert Panel have identified potential benefits of such cooperation, including greater freedom for patients to choose where to be treated, improved professional and vocational education and training for personnel, and enhanced mobility for health professionals.

The Expert Panel have also identified obstacles to successful cooperation in health care, which can be divided into three main categories:

1) Lack of information and transparency about treatments in another Member State
2) Uncertainty about payments and related reimbursement procedures
3) Arrangements for follow-up and post-treatment issues.

The Expert Panel finally suggests priority actions which could be taken at EU level to help overcome some of these obstacles. The most obvious priority is to put in place systems to provide data on the number of patients circulating, the types of treatment they are receiving, any problems they are experiencing and examples of how these can be overcome.

This opinion, as all advice given by the Expert Panel, is non-binding but very influential. The Commission’s Directorate General for Health and Food Safety (DG SANTE) is expected to present the first report on the implementation of the Cross-border Directive in September.

e. JA-CHRODIS, EOHSP and WHO call for more investment in prevention

JA-CHRODIS report

On 15 July, the Joint Action on Chronic Diseases and Healthy Ageing across the Life Cycle (JA-CHRODIS) published a new report on how investment in health promotion and primary
prevention is needed to reduce the burden of chronic diseases across Europe.

The report provides a comparative overview of key policies used to promote health and prevent chronic diseases across 14 European countries. All countries show comparatively low, stagnant, insufficient or falling proportions of national expenditures on health promotion and prevention. The most frequently identified needs relate to capacities and capacity development, evaluation, monitoring and research.

The outcomes of the report will be discussed by policy makers and stakeholders across Europe at the upcoming JA-CHRODIS Conference on “Joining Forces in Health Promotion to Tackle the Burden of Chronic Diseases in Europe”, that will take place on 24-25 November in Vilnius, Lithuania.

EOSHP book

The European Observatory on Health Systems and Policies has announced the publication of the book “Promoting Health, Preventing Disease: The economic case.” The complete book will become available in the autumn 2015, but the executive summary and sample pages are already available online.

The book provides an economic perspective on health promotion and chronic disease prevention, and gives a rationale for assessing the economic case for action. It provides a review of the evidence base in support of a broad range of public health interventions, addressing not only their effectiveness in improving population health, but also their implementation costs, impacts on health expenditures and wider economic consequences.

The European Observatory on Health Systems and Policies is an intergovernmental partnership hosted by the World Health Organization (WHO) Regional Office for Europe.

WHO paper

The regional office for Europe of the World Health Organisation (WHO) has published a paper entitled “The case for investing in public health”.

The report gives examples of interventions with early returns on investment and approaches with longer-term gains. It shows that prevention can be cost-effective, provide value for money and give returns on investment in both the short and longer terms. The areas of intervention mentioned include physical activity, healthy employment, vaccinations and screening programmes.

f. 10th Round of TTIP - Health

The 10th round of the negotiations for a Transatlantic Trade and Investment Partnership (TTIP) took place from 13-17 July in Brussels.

The talks covered a broad range of subjects across the three TTIP pillars: market access, regulatory cooperation, and rules.

On medical devices, the EU and US updated each other on the recent developments regarding the areas of cooperation under discussion in TTIP (Medical Devices Quality Management System audits, Unique Device Identification (UDI) and Regulated Product Submission (RPS). They acknowledged good progress made in these areas so far at international level. The Parties will reflect on how to translate these three agenda points into specific deliverables to be achieved within TTIP negotiations.

Market access discussions covered services, amongst others. Please click here to read the EU offer on services, which includes health services exemptions.

Next steps:

The 11th round will take place in the third quarter in the United States, the venue and dates remain to be confirmed. The Commission is expected to publish its proposal on environmental sustainability under TTIP before then.

EPHA publishes its position on TTIP

The European Public Health Alliance (EPHA) published its position on TTIP in August. Its main call to the Commission is to include addressing
the social and economic costs of Non-Communicable Diseases in its trade policy.

g. Medical Devices dossier – Council against the EDCs ban

As previously reported, the Council of the EU (Council) reached an agreement in June on its position on the medical devices dossier. Attention in July focused on the chemicals aspect of the dossier:

- The Council is against a ban on CMR (carcinogenic, mutagenic or toxic to reproduction substances) and EDCs (endocrine disrupting chemicals) in medical devices, as proposed by the European Parliament.

- The Council calls also for medical devices containing EDCs and CMR to be labelled as such, going further than the Commission’s original proposal.

- In addition, the Council calls for all devices containing nanomaterials to be classed as high risk devices.

Next Steps:

- September: The current Luxembourg Presidency of the Council of the EU to finalise the recitals of the Council’s position

- 8 September: Council to finalise its work on technical inconsistencies

- 15 September: Presentation of a consolidated text to the Council working group

- 5 October: Submission of the consolidated text for adoption by the Council

- Between 5 October and 8 December: trilogue meetings to reach final agreement on the dossier

h. EMA publishes recommendations on the use of adrenaline auto-injectors

On 14 August, the European Medicines Agency (EMA) published its recommendations for the correct use of adrenaline auto-injectors, after being endorsed by the European Commission.

EMA acknowledges that giving the medicine by injection into the muscle is the preferred way to obtain a rapid response in anaphylaxis. However, several factors may affect whether adrenaline is correctly delivered. These include: needle length, the skin-to-muscle depth, the way the auto-injector works (e.g. if it is spring loaded or not), the angle of placement on the skin and the force used to activate the device.

To overcome these potential issues, EMA recommendations focus on training of both patients and carers. Amongst the educational material to be developed, EMA mentions a training device that patients can practise with, audiovisual material and a prescriber checklist.

In addition and because of the uncertainties over drug delivery from adrenaline auto-injectors, EMA recommends that healthcare professionals prescribe 2 auto-injectors, which patients should carry at all times.

Environmental Health

a. EP Committee votes for stricter pollution limits

On 15 July, the European Parliament Committee on Environment, Public Health and Food Safety (ENVI) voted on the revised National Emission Ceilings (NEC) Directive. ENVI Members of Parliament proposed stricter pollution caps than the Commission’s original proposal for six main pollutants, such as sulphur dioxide, particulate matter and nitrogen oxides.

In addition, ENVI wants the intermediate targets for 2025 to be binding, except for methane. The MEPs also included emissions reduction ceilings on mercury.
The vote in ENVI has been perceived as a win by health advocates, given that the report was approved by a comfortable majority (38 to 28, with two abstentions). As you know, EAACI partnered with the patient organisation EFA to drive advocacy efforts in the Parliament ahead of the vote. EAACI also forms part of a broader alliance of the health and environment community seeking for more stringent emission ceilings under the NEC Directive.

The Parliament has now to adopt in plenary the report in order to start inter-institutional negotiations. This vote is scheduled for October. For more information, please read the European Parliament press release here.

**b. WAO study on the links between climate change and allergies released**

The World Allergy Organisation (WAO) released 14 July a comprehensive study stressing the rising incidence of allergic airway diseases and highlighting the facts on climate-related health impacts, including:

- deaths and acute morbidity due to heat waves and extreme meteorological events;
- increased frequency of acute cardio-respiratory events due to higher concentrations of ground level ozone;
- changes in the frequency of respiratory diseases due to trans-boundary particle pollution;
- distribution of allergens (pollens, molds, and mites); and some infectious disease vectors.

According to the report, these facts will not only affect those suffering now from allergic disorders, but also increase the incidence and prevalence of allergic respiratory conditions and asthma.

**c. Danish Consumer Council finds potential allergens in body care products**

The consumer organisation ‘Danish Consumer Council’ (DCC) has conducted two separate surveys on personal care products in Denmark. DDC claims that one in four body lotions contain allergens or endocrine disruptors (EDCs), whilst it is even higher in hand soaps.

Testing of hand soaps shows that every third contains problematic substances, including allergenic preservatives. The DCC tested 54 body lotions and 76 soaps.

Although the substances of concern (e.g. preservatives MCI and MI) are not prohibited from use by the EU legislation, the DCC recommends that consumers avoid them if they can. Please, click here to learn more.

**Annexes**

**Parliamentary Questions**

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**Questions answered in July and August**

- Establishment of a cooperative structure for chronic diseases
- European Research Area: greater transparency and more information about funding
- 2018 European Year for Health
- Role of prevention in the European Semester process
- Quality health services
- Role of health care in the European Semester
- Written question on Protecting EU citizens against serious cross-border health threats
- Facilitating access to healthcare across Europe
- Information on substances or products causing allergies or intolerances

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**Action Recommendation**

- EAACI to use the report and its data in its communications with decision makers.
Action Recommendation

- EAACI to share with membership for their information.

Questions tabled in July and August

- Horizon 2020 - Science Advice Mechanism (SAM)
- Health Claims Regulation
- Standardisation of medical services
- Additional measures to encourage Member States to comply with legal limits on air pollutant emissions
- European Union anti-allergy efforts
- Improving indoor air quality in European buildings
- Incorrect implementation of health directive

EU events tracker

- 2-3 September, EPHA 6th annual conference "Towards a European Union for Health — From Health in All Policies to EU Governance for Health and Well-Being?", Brussels
- 3-5 September, European Association for Predictive, Preventive and Personalised Medicine World Congress 2015, Bonn
- 9 September, ICLEI Europe, Second European Forum for procurement of Healthcare Innovation, Paris
- 15 September, EARIP Workshop ‘We Know how to curve down asthma in Europe: Lessons from National Programmes, Brussels
- 18 September, EPHA Strategic Policy Training on NCDs, Brussels
- 18 September, European Commission, Info Day Horizon 2020 - 'Health, demographic change and wellbeing’, Brussels
- 22 September, EConDA Workshop - Dissemination of Project Results, Brussels
- 28 September, European Commission, Conference “50 Years of EU Pharma legislation: Achievements and future perspectives”, Brussels
- 30 September, EPP Group “Towards an integrated EU policy approach for the pharmaceutical sector”, Brussels
- 30 September-2 October, 18th European Health Forum Gastein, Austria
- 8-9 October, European Commission, 2nd Conference on European Reference Networks, Lisbon
- 8-9 October, 2nd Transatallantic conference on personalized medicine, Rotterdam
- 14 October, AmCham, “Investing in Health for Europe 2020- How the Life Sciences Industry is key to health, wealth and growth”, Brussels
- 11-13 October, World Health Summit 2015, Berlin
- 12 October, EFSA, International meeting on regulatory science, Parma
- 14-17 October, 8th European Public Health Conference – Health in Europe – from global to local policies, methods and practices, Milan
- 27 October, European Commission, “Which priorities for a European policy on multimorbidity?”, Brussels