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EU Health Research Policies

a. EU Parliament publishes guide to Horizon 2020 budget and implementation


The publication aims to provide a detailed description of the budget for the Horizon 2020 programme. It presents the different structures that play a role in the management and implementation of EU funds provided through the programme for the period 2014-20 based on data available in July 2015. It complements the EPRS briefing 'Overview of EU Funds for research and innovation', published in September 2015.

Recommendation

EAACI to inform members about the guide and its specific parts focused on health research.

b. EU Commission launches public consultation on Disruptive Innovation

The European Commission and the independent Expert Panel on Effective ways of Investing in Health (EXPH) have launched a public consultation on a preliminary opinion on Disruptive Innovation for health and health care in Europe. Interested parties are invited to provide comments before 16 December 2015.

Disruptive Innovation is a type of innovation that creates new networks and players that tend to displace existing structures and actors. It constitutes a paradigm shift in the organisation of healthcare and has the potential to reduce costs and complexity whilst providing better healthcare and patient empowerment.

Until now, this concept has been developed and mainly discussed in the US. The EXPH preliminary opinion studies how it can be applied in the European context. The five main areas of application identified by the EXPH are translational research, access to new innovative technologies, precision medicine, health professional education and health promotion.

The final opinion, which will reflect the results of the consultation, is expected by the end of February 2016.

Recommendation

EAACI leadership to consider answering to this consultation, especially because of its focus on precision medicine.

c. EU Commission announces the 7 scientists to lead its new Science Advice Mechanism

The European Commission has announced the names of the 7 leading scientists that will form the high level group at the head of the Commission's new Scientific Advice Mechanism (SAM). Carlos Moedas, Commissioner for Research, Science and Innovation, will oversee the group's work.

The announcement also marks the official launch of the Mechanism itself. The SAM high level group will draw on scientific advice and experience from Member States and around the world by creating a stronger link with national science academies and other bodies. A grant of €6 million has also been provided for the networks of academies and learned societies as part of the Commission’s Horizon 2020 Work Programme for 2016.

Recommendation

EAACI to share with full membership for their information.

d. Guido Rasi takes office as head of the European Medicines Agency
On the 16th November, Professor Guido Rasi has taken office as Executive Director of the European Medicines Agency (EMA).

Professor Rasi was nominated as Executive Director for a five-year mandate by the Management Board of the Agency on 1 October 2015.

From November 2014 to mid-November 2015, Professor Guido Rasi served as EMA’s Principal Adviser in Charge of Strategy, and he was previously EMA’s Executive Director. His full biography is available here, together with an information sheet explaining the process for the appointment of the EMA Executive Director.

**Recommendation**

EAACI to share with full membership for their information.

**EU Public Health Policies**

**a. Major reshuffling of DG Santé in the European Commission**

DG SANTE of the European Commission is experiencing a massive shake-up involving key changes in staff and structure. As you will recall DG SANTE is responsible for both health policies and food safety. It counts therefore with two Deputy Director General: Martin Seychell, responsible for the Heath area, and Ladislav Miko, in charge of the food safety area. Both report to DG SANTE's Director General, Xavier Prats, who took office very recently (in September). These three highest level position within the DG have been maintained in the undergoing reconfiguration, but everything underneath this level is experiencing a major reshuffling.

See below the main highlights:

- Creation of a new directorate in the area of food safety to deal with stakeholders and international relations
- The number of Units has been reduced from 40 to 37
- Two of the so-called Horizontal Units (reporting directly to the Director General) disappear, notably Unit 02 “Economic Analysis”, which was the promotor of the multimorbidity dossier. The dossier will be now responsibility of the Chronic Diseases Unit.
- Amongst the 37 remaining Units, 31 will change Head of Unit. The reason given by the Commission is that most of the Heads of Unit had been holding the same position for more than 4 years and, following general Commission policy to assure independence, they needed to rotate.
- There are still Units without Head and former or acting Heads of Unit with no position assigned yet.
- Jonh Ryan will continue as Acting Director for Public Health in Luxembourg, but all his Heads of Unit rotate: Stefan Schreck will be now in charge of the Chronic Diseases dossier and will have to deal with the Chronic Disease framework, which still seems to be in a very early phase. Philipppe Roux deals now with ‘Country Knowledge and scientific Committees’; Michael Huebel will be responsible for ‘Crisis management and preparedness in health’ and John Ryan –apart from Acting Director- will be the Head of Unit ‘Health determinants and inequality’
- However, the key Directorate for EU health policies will not be Ryan’s, but Directorate B, which will gather together Health Systems Performance Assessment (HSPA) and Health Technology Assessment (HTA), two of the three priorities of DG SANTE. The third priority is antimicrobial resistance (AMR). AMR is currently addressed by means of a task force (gathering together
officials from different Units) led by Koen Van Dyck; it is still to be seen if he will continue with the task now that he also changed positions. In any case, the task forces on AMR and Endocrine Disruptors will continue working.

- The Unit called ‘Substances of Human Origin and Tobacco Control’ will be split. Tobacco control will go to ‘Health in all policies, global health and tobacco control’.
- Sabine Juelicher, until now Head of Unit for medicinal products (authorisation and monitoring) has been upgraded to Director for Food and feed safety and innovation.
- Head of Unit Maria Iglesia Gomez moves from Healthcare Systems to Food Process and Novel Foods

The official organigram officiating these changes shall be published shortly.

Recommendation

EAACI to inform leadership about the reshuffling and communicate official organigram as soon as it becomes available.

b. Slow progress in the medical devices dossier

According to our sources in the Council, November has seen slow progress in the inter-institutional negotiations on the medical devices regulations dossiers. The initial idea of closing an agreement before the end of the year seems now difficult to achieve.

- The Council and the EP have not come closer regarding the issue of pre-market scrutiny of medical devices, which will be on the agenda of future meetings.
- Regarding classification of medical devices, the EP and the Council are negotiating a big amount of technical details and it seems that the negotiations will go on for a while.

- As per the ban of hazardous chemicals in medical devices proposed by the European Parliament (EP), the Council believes the EP’s position goes too far and that it is unrealistic.

So far, 4 trilogues have taken place. The meeting on 10 November was focused on in-vitro medical devices. Agreement was made in principle on the companion diagnostic definition. Additionally, there was discussion on genetic counselling, prescription rules, in-vitro diagnostic classification rules and in-house exemption.

The meeting on the 18 November addressed outstanding issues from previous trilogues, but agreement could only be reached on the inclusion of aesthetic devices, in-house exemption, the definition of health institutions and the electronic storage of Unique Device Identification (UDI).

The fifth trilogue is taking place 3 December.

Recommendation

EAACI to continue to follow the negotiations on the medical devices dossiers

c. Innovative Health Systems Reform: the role of the EU in advancing innovation

The second meeting of the European Parliamentary Interest Group on Innovation in Health and Social Care took place on the 11th November in Brussels.

Members of the European Parliament and stakeholders discussed how they can work together to encourage Member States to look at investment, rather than just cost-containment, in health systems.

The question at the heart of the debate was why there is not enough short term investment on innovations for efficiency that have proven to be cost-effective in the long term. Suggestions to incentivise investment in proven innovations included greater reliance on health technology assessment to measure cost-efficiency, limiting
unnecessary procedures, making use of information and communication technologies, and changing health system governance.

Nevertheless, the group recognised that it will be a challenge to convince Member States to invest in innovations for efficiency now, since efficiency increases will not bring enough savings for fiscal sustainability in most health systems.

**Recommendation**

EAACI to monitor activities of the EP Interest Group on innovation in health and social care and explore possible collaboration with IG on Allergy and Asthma

d. **Commission launches new European Core Health Indicators (ECHI) data tool**

On the 12th November, at the Expert Group on Health Information (EGHI) meeting in Luxembourg, the Commission launched a new version of the European Core Health Indicators (ECHI) data tool, which replaces the existing “Heidi” data tool.

The new tool keeps the main features of the previous version, and presents relevant and comparable information on health at European level in an interactive way.

The major improvement is that more than one indicator can be selected at the same time in order to make further comparisons and/or analyses of data. The five groups of indicators covered by the new tool are: demographic and socio-economic factors; health status; health determinants (smoking, alcohol, etc.); health interventions/health services and health promotion.

**Recommendation**

EAACI to share with full membership for their information.

**Environmental Health**

a. **COP 21 has started**

The United Nations Climate Change Conference COP 21 started on 30 November and will last until 11 December. As you are aware, the aim of the
conference is to achieve a legally binding and universal agreement on climate, with the objective of keeping global warming below 2°C.

The official opening took place on Monday 30 November with the ‘Leaders event’. It is too early to extract any conclusions, but in these few days of COP 21 we can highlight the declaration of the Climate Vulnerable Forum calling to make the 1.5°C target real and the announcement of Bill Gates’ Mission Innovation.

In addition, a very first draft of the Paris agreement was already circulating on 2 December and a final one should be ready by the end of the first week of December, before the Heads of States and Governments come back to finalise the agreement.

Recommendation
EAACI to share with full membership for their information.

b. Long awaited report on fragrance allergens published

The long-awaited summary of responses to the public consultation on ‘fragrance allergens in cosmetic products’ has finally been published by the European Commission. Please see here the link.

The European Commission received 214 replies. The most numerous contributors were individual consumers (136 replies); industry submitted 57 replies, most of which came from the cosmetics industry. Seven replies were from citizens’ organizations: four from patients’ organizations, two from consumer organizations and one from an organization for the environment and health protection.

See below the main highlights:

- Respondents generally supported the idea of providing consumers with information on additional fragrance allergens contained in a cosmetic product. Industry was united in putting forward its proposal for e-labelling, meaning that certain information about a product would be accessible by electronic means (for example on the brand’s website) and not indicated on the package of a cosmetic product.

- Please note that the vast majority of individual consumers, citizen’s organizations as well as the medical community did not express their opinion on e-labelling, because this proposal was put forward by industry and was not part of the Commission services’ proposal submitted to the public consultation

- Ban of HICC, atranol and chloroatranol: There was a strong difference of opinion between individual consumers, who were against the ban of these three fragrances, and all other stakeholders’ groups, who were either in favour of the ban or did not comment on it.

The Commission services will decide on the follow-up to the consultation, which may take the form of a proposal for an amendment to the Cosmetics Regulation (early in 2016).

Recommendation
EAACI to monitor closely the follow-up from the Commission to the consultation in view of putting in place advocacy activities if needed.

Annexes

Parliamentary Questions

Questions answered in November

- The EU role in Global Health (Programme for Action)
- Link between air pollution and respiratory disease

Questions tabled in November
• European supervision of doctors

EU events tracker

• 4 December, Global Green and Healthy Hospitals, Conference on Climate change and healthcare, Paris
• 7-10 December, Knowledge4Innovation, 7th European Innovation Summit, Brussels
• 9-10 December, 4th Conference of Partners: "Accelerating market uptake of innovation for active and healthy ageing across Europe", Brussels
• 14 December, EBE and EMA, 4th Annual Regulatory Policy Summit – From laboratory to patient use, London
• 16 December, DG SANTE and International Fragrance Association (IFRA), IDEA 3rd annual review workshop, Luxembourg
• 18 December, European Medical Organisations, “Continuing Professional Development for Doctors - Improving Healthcare”, Luxembourg
• 10-12 May 2016, Conference Health 2.0 Europe 2016, Barcelona