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EAMBES newsletter
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I. Parliamentary Questions on Biomedical Engineering

The month of August saw the publication of two Parliamentary Questions (PQs) on Biomedical Engineering (BME) addressed to the European Commission for Written Answer. This is a result of the advocacy work being carried out by EAMBES at the European level and, in particular, in the European Institutions. Both questions had been tabled by Ms. Lara Comi (Italy, EPP) and Mr. Nicola Caputo (Italy, S&D), Members of the European Parliament, on 20 July 2015,

The publication of these questions is noteworthy as PQs are a means by which MEPs can seek information or press for action from the institutions, in this case the Commission, in a particular direction. It represents a boost for EAMBES and demonstrates that the Alliance counts with allies within the European Parliament in the task of positioning BME in the EU scenario and ensuring a sustainable support for this discipline.

Under the title, "*Absence of biomedical engineering from Horizon 2020*", the first question inquires specifically as to the Commission's intention to include dedicated support for BME research and innovation in the forthcoming Horizon 2020 work programmes.

The question explains that Biomedical Engineering is a key growth sector for the European economy and that, whereas in the US BME is recognised as a standalone discipline with dedicated funding resources, the EU lacks a consistent approach. It calls for the Commission to

include BME in Horizon 2020 as a field considered distinct and separate from other health technologies, with dedicated research and innovation programmes.

The second question, entitled "*Recognising biomedical engineering within the Professional Qualifications Directive*", echoes one of the recommendations of the European Economic and Social Affairs Committee Opinion on promoting the European single market combining biomedical engineering with the medical and care services industry[(1)], where it stated that Biomedical Engineering should be included in Directive 2005/36/EC on the recognition of professional qualifications as a stand-alone discipline. The MEPs claim in the PQ that, while the USA has made significant progress in developing biomedical engineering education and training opportunities, the EU has not been able to establish uniform standards and rules in this field. In light of the above, Ms. Comi and Mr. Caputo ask the Commission if it intends to help recognise biomedical engineering within Directive 2005/36/EC.

The response by the Commission to both questions is due in September 2015.

The Parliamentary Questions can be found here:

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bWQ%2bE-2015-011613%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bWQ%2bE-2015-011612%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

II. EU budget 2016: further cuts in Horizon 2020?

The presentation of the Commission proposal for the EU budget for 2016 in June 2015 triggered the start of the budgetary procedure. On the table, the possibility of further reducing the budget allocated to Horizon 2020.

It needs to be remembered that the reduction of the budget for Horizon 2020 and the and CEF was already a controversial topic which received criticism during the negotiations on the Regulation proposing a European Fund for Strategic Investments (EFSI) -the "Juncker Plan"-, adopted in June 2015. The European Parliament had hoped to protect the Horizon 2020 and CEF budgets, with the Commission and the Council of the European Union both recommending cutting these mechanisms.

In its proposal for next year's budget, the European Commission suggested allocating €563.6 million for research commitments and €1.42 billion for payments for 2016. The Commission's draft budget was sent to the European Parliament and EU Member States, who will jointly decide on the final budget.

On 9 July 2015, the Council agreed its position on the draft 2016 EU budget (formally adopted on 4 September 2015), proposing to cut €73.2 million in research commitments – meaning the value of contracts that can be made during 2016, to be paid in future years – and €205.2 million in payments.

Meanwhile, the Parliament is working on its position prior to the interinstitutional negotiations, due to take place in October and November. These are not expected to be easy, with the

Parliament and the Council being likely to disagree about what amounts to set for commitments and payments.

A Parliamentary Question on the budget cuts in Horizon 2020 and Connecting Europe Facility (CEF) in the EU budget for the next year was published in August 2015. It was tabled Mr. Hans-Olaf Henkel MEP (ECR, Germany) –rapporteur of the Industry Research and Energy Committee of the European Parliament for the ongoing report on the EU Budget 2016-, on 17 July 2015.

Concerned about the impact of such measure, he announces that he will propose that the H2020 and CEF budget is restored to the levels from before the cuts for EFSI, and asks the Commission to explain on what basis it has made the cuts related to EFSI.

The Parliamentary Question can be found here:

http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2015-011468&format=XML&language=EN

III. New Scientific Committee on the Health, Environmental and Emerging Risks (SCHEER)

From April 2016, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) -whose areas of activity include medical devices and new technologies-, and the Scientific Committee on Health and Environmental Risks (SCHER) will constitute one single body: the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

This was adopted by the Commission in its decision released on 13 August 2015, establishing Scientific Committees in the field of public health, consumer safety and the environment, which replaces the Commission Decision 2008/721/EC, and which responds to the need to achieve efficiency, consistency, and to avoid duplication of efforts.

Scientific Committees provide the European Commission with sound scientific advice when preparing its policy and proposals relating to public health and draw its attention to new and emerging problems.

The structure and voting rules of the new committee will remain similar. The main changes include the following:

- Membership: The SCHEER will consist of a maximum of 19 members, two more than the SCENIHR. In order to ensure continuity of the membership, the Decision introduces a reserve list of suitable candidates who have not been appointed, drawn for potential replacements in the membership before due time.

  The Commission launched on 14 August the call to renew the membership, open until 2 November 2015. More information and the application form are available here.

- Term of office: The term of office has been extended from three to five years, renewable.

- Fields of competence: The fields of competence have been extended. As the SCENIHR, the SCHEER on request of Commission services shall provide opinions on questions concerning health, environmental and emerging risks and may be invited to address

questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have adverse effects for human health and the environment. In addition, the Committee will provide opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment (e.g., in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment).

It needs to be noted that as a result of the second intermediate evaluation on the functioning of the Scientific Committees, being carried out in 2015 and whose results are expected by beginning of 2016, a possible further reorganisation of the Scientific Committees may be undertaken.

The Commission Decision can be found here: http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf

IV. Progress on Health Technology Assessment and e-Health cooperation

Almost two years after the deadline for its transposition (October 2013), the EU Cross-border Healthcare Directive (the Directive, hereinafter) has enabled progress on Health Technology Assessment and e-Health cooperation, acknowledged the Commission in its report on the state of play of the implementation of the Directive, released on 4 September 2015.

This report is of relevance as it refers to a key health dossier with a significant impact on national health systems, the evolution of competences and the development of legislative initiatives in relevant topics. Indeed, the EU Cross-border Healthcare Directive, whose goal is to regulate access to healthcare by European patients beyond the border of their Member State of affiliation, constituted a groundbreaking piece of legislation in the field of health, as it included concepts that had not previous legal or legislative mentioning in EU dossiers. Moreover, it also covered items which, until its adoption, had fell under the competences of Member States.

The publication of the report responds to the requirement of Article 20(1) of the Directive, under which the Commission has to “draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council” by 25 October 2015, and every three years thereafter. It covers, in particular, information on patient flows, financial dimensions of patient mobility, the implementation of the European reference networks and national contact points. It needs to be noted that the report is not intended to provide a formal evaluation, but a study which can be used to guide the assessment and future evaluation efforts.

1. Health Technology Assessment (HTA)

With the aim to strengthen coordination between national authorities in the evaluation of new health technologies (i.e., medicinal products, medical devices, medical and surgical procedures or measures for disease prevention, diagnosis or treatment used in healthcare), the Health Technology Assessment Network was set up by article 15 of the Directive. Importantly, it

contributes to a reduction of the administrative burden of bringing a new product to the market by coordinating HTA procedures and avoiding duplication of efforts.

Since its establishment, the HTA Network, which meets twice a year and is supported on scientific and technical issues by the joint action EUnetHTA, has adopted a Strategy for EU cooperation on HTA in October 2014, and a reflection paper on reuse of joint HTA work in national activities in April 2015.

The Commission states in the report that, for the future, the focus will be on a stronger and more efficient scientific cooperation and to design measures to ensure the long-term sustainability of the network, as requested by Member States.

2. eHealth

The Cross-border Healthcare Directive was the first piece of EU legislation ever to mention "e*Health*".

The Commission adopted Implementing Decision 2011/890/EU concerning the eHealth Network on 22 December 2011. Like the HTA network, the eHealth Network, whose objective is to support cooperation between national authorities, meets twice a year and is supported operationally by a joint action under the Health Programme.

In the last four years, the Network has adopted guidelines on patient summaries data sets and on ePrescriptions and different position papers. Currently, it is working on guidelines on effective methods for enabling the use of medical information for public health and research.

The report is available here:

http://ec.europa.eu/health/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf

V. Survey on the introduction of robotic services in healthcare facilities

A public survey on the introduction of robotic services in healthcare facilities was launched in August, in the frame of the European project Robot-Era, a research project funded by the 7th Framework Programme whose goal is to develop an advanced, three-tier robotic system that can improve quality of life and care for elderly people and facilitate independent living.

Stakeholders are invited to participate in the survey, by the 25 September 2015.

The survey is available here: https://docs.google.com/forms/d/15phf0EI3mTEJ3ey6oEYQ-JJhAjULTctndzMJrdcKZYE/viewform

VI. The Human Brain Project, amongst the 5 brain technologies that will shape our future", according to World Economic Forum

The Human Brain Project, the ten-year, large-scale European research initiative whose goal is to understand the human brain and its diseases and ultimately to simulate its actual working, has been included by the World Economic Forum in the list of the "5 brain technologies that will shape our future".

The World Economic Forum (WEF) is a Swiss nonprofit foundation, based Geneva, recognised by the Swiss authorities as the international institution for public-private cooperation, whose mission is to "*improve the state of the world by engaging business, political, academic, and other leaders of society to shape global, regional, and industry agendas*".

In an article released on 19 August 2015, the WEF states that " *Ongoing projects, such as (...) the Human Brain Project (...) are paving the way towards not only a better understanding of how the brain works, but technologies that take advantage of these discoveries to improve society*".

The article is available here:

https://agenda.weforum.org/2015/08/5-brain-technologies-future/