Contents

EU Health Research Policies

a. IMI: European public-private partnerships deliver first socio-economic impacts........2
b. Agreement reached on Data Protection Regulation..............................................2
c. Scientific Panel for Health will present initial findings at a public conference in January....3
d. Extension of deadline for BioMed Alliance’s survey on experiences with Horizon 2020.....3
e. Commission opens call on ICT for Health under Horizon 2020..................................3
f. MEPs and Scientists team-up to promote science-based policy making..................4

EU Public Health Policies

a. Commission DG SANTE launches mid-term evaluation on the 3rd Health Programme.....4
b. Commission publishes report of the 2nd conference on European Reference Networks...5
c. Update in the Parliament on ongoing inter-institutional negotiations on Medical Devices and In-vitro Diagnostic Medical Devices........................................................................5
d. Highlights on the Dutch Presidency’s health priorities..............................................5
e. Preliminary conclusions of the Luxembourg’s Presidency of the Council of the EU........5
f. EMA and national Medicines Agencies adopt common strategy for the European medicines regulatory network.........................................................................................6
g. Priorities for a European policy on multimorbidity – Outcomes of the EU Conference on multimorbidity 27th October 2015..............................................................................................7
h. Highlights from the EU Joint Action CHRODIS Conference on health promotion.........7

Environmental Health

a. Council reaches common position on NEC Directive..............................................8
b. Commission, Council and European Parliament assess outcomes of COP21 ..............8
c. WHO Europe places environmental sustainability as core element of health systems.....9
d. EU blacklist of invasive alien species finalised......................................................9

Annexes

Parliamentary Questions .........................................................................................10
EU events tracker.....................................................................................................10
EU Health Research Policies

a. IMI: European public-private partnerships deliver first socio-economic impacts

Relying on the results presented during the European Innovation Summit, the IMI (Innovative Medicines Initiative) reports that Innovative European public-private partnerships (PPPs) have demonstrated successful scientific outcomes and delivered practical applications in areas that are vital for Europe’s competitiveness.

IMI highlights that PPPs are demonstrating socio-economic impacts in key industrial sectors such as aviation, electronic components & systems, health, and fuel cells and hydrogen for transport & energy solutions.

The Clean Sky project is delivering significant results in terms of pollution reduction while in the health sector, IMI projects are developing tools to speed up drug development, particularly in challenging areas such as brain disorders, diabetes, and antimicrobial resistance. They are also establishing new research resources, networks and infrastructures.

Bringing together all the relevant players from a specific community operating in the activity field of the project (industry, researchers, and other stakeholder groups), the PPPs provide innovation-driven research communities to address the main challenges that are faced in the EU.

Recommendation

EAACI to inform members about IMI’s achievements.

b. Agreement reached on Data Protection Regulation

On the 16th of December, an agreement was reached in trilogue between the European Parliament, the Council of the EU and the European Commission on the Data Protection Regulation.

Main elements of the compromise and updates include:

- Safeguards must be in place for the research provisions to apply (A.83). The nature of the safeguards are left for Member States to develop, but anonymous data must be used where possible. Pseudonymisation is suggested as another possible safeguard, provided that the research can be fulfilled with pseudonymised rather than fully identifiable data.

- Researchers will be able to use special categories of data, including data concerning health, without consent, as long as this is based on Union or Member State law (A.9(2)(i)).

- Further processing of data collected for another purpose for research is to be deemed ‘not incompatible’, which means there are fewer restrictions on its re-use (A.5(1)(b)).

- The key derogations for research from the Commission’s text are maintained in the agreed compromise. There are derogations:
  - to allow longer storage periods for research (A.5(1)(e));
  - from the right to notify data subjects about processing where someone else had collected the data initially (A.14a(4)(b));
  - from the right to be forgotten (A.17(3)(d));
  - Subject to additional safeguards, Member States may create further derogations from data subject rights in Articles 15 (data subject access), 16 (rectification), 17a (restriction of processing) and 19 (object).

- Where consent is used as the legal basis, this must be ‘specific’, but recital 25aa suggests that broader forms of consent may be acceptable in scientific research.

- Clearer definitions of data concerning health and genetic data are given.

- There is no longer an independent legal basis for research as A.6(2) has been deleted. However, many member states operate without one at present. It will be important in implementation to make sure that there are other legal bases in A.6 (e.g. legitimate interests) that are clearly available to research.
• ‘Pseudonymisation’ is now defined in the text (A.4(3b)). Recital 23 suggests that data that has been pseudonymised should be considered personal data. This would be a departure from the current approach in some Member States, including the UK. It will be interesting to see how this is interpreted further in implementation.

Read the entire final compromise here.

**Recommendation**

**EAACI to share final compromise with full membership highlighting the areas of interest for medical research**

c. **Scientific Panel for Health will present initial findings at a public conference in January**

The Scientific Panel for Health (SPH), established a year ago by the European Commission under EU Horizon 2020 programme for research and innovation, is an expert group of 31 high-level European scientists in charge of advising the European Commission on challenges and dead-ends in health research, providing solutions to address them on the basis of a long-term approach.

In the framework of the Scientific Panel’s mandate, three working groups (WG) have been established to address the different aspects of the Panel’s missions:

- WG1 focuses on enabling research from discovery to implementation;
- WG2 examines long-term challenges and opportunities,
- WG3 centres on the research work force.

On 21 January 2016, the SPH will present its initial findings and interact with stakeholders from the health sector during a public conference aimed at discussing on the means of improving health research. Keynote speakers include Carlos Moedas, EU Commissioner for Research, Science and Innovation at the European Commission and eminent Professors in the field. The event will build on four sessions, respectively dealing with cross-border research, multidisciplinary collaboration in research, the regulatory framework for research and innovation, the role of stakeholders in guiding research policy.

More information on the SPH here.

**d. Extension of deadline for BioMed Alliance’s survey on experiences with Horizon 2020**

The BioMed Alliance is calling for additional answers to its survey aimed at monitoring and collecting experiences of biomedical researchers with applying for and implementing Horizon 2020 projects. The preliminary results of the survey were presented at the BioMed Alliance General Assembly and are already showing “interesting and promising” outcomes according to the Alliance. However, input from all specialties and diverse experiences with Horizon 2020 are needed to deliver the best results and allow the dedicated appointed task force to carry out its monitoring role.

For this purpose, the deadline for providing feedback has been extended to January 10, 2016. The 10 minute-long survey is available here.

**Recommendation**

**EAACI leadership to encourage its membership to participate in the BioMed Alliance survey.**

e. **Commission opens call on ICT for Health under Horizon 2020**


The €178 million total funding scheme addresses new areas including big data for public health policies, digital security of health related data, public procurement of
innovative solutions for active and healthy ageing and pre-commercial procurement in e-health for patient empowerment.

Read the full announcement here and check all the ICT related calls here.

The previously published calls of interest under the 2016-2017 programme are:

- **New therapies for chronic diseases**
- **Global Alliance for Chronic Diseases (GACD)**
- **Comparing the effectiveness of existing healthcare interventions in the adult population** (including also relevance for chronic diseases)
- **Towards an ERA-NET for building sustainable and resilient health system models** (aimed at implementing a cross-cutting approach to address chronic diseases, multi morbidity, obesity and mental health issues)
- **Multi-omics for personalised therapies addressing diseases of the immune system**
- **Actions to bridge the divide in European health research and innovation** (health research)
- **Coordinating personalised medicine research** (health research)
- **New concepts in patient stratification**

**Recommendation**

EAACI to disseminate the information on the Horizon 2020 calls for 2016-2017 amongst full membership.

**f. MEPs and Scientists team-up to promote science-based policy making**

The European Parliament’s Science and Technology Options Assessment set up in 2011 a scheme aimed at promoting science-based policy making in the EU and develop a structured dialogue between scientists and policy makers and a mutual understanding of their respective work. The updated list of MEPs-scientists pairs was published in December and the pairing scheme will be launched on 25 January 2016 when the 33 scientists will present their research activities to their MEP counterparts and follow their committee work and political group meetings during that week.

All political groups in the European Parliament are represented in this scheme with the exception of the far-right political group ENF. Health and life sciences are a major sector of focus.

More information on the MEP-Scientist pairing scheme here.

**Recommendation**

EAACI to take note of the MEPs interested in health research in view of upcoming contact programmes.

**EU Public Health Policies**

**a. Commission DG SANTE launches mid-term evaluation on the 3rd Health Programme**

The European Commission has launched a mid-term evaluation for the 3rd Health Programme which will run until 14 January 2016, as part of EU’s legal obligation from the Regulation (EU) n° 282/2014 establishing the third EU action in the area of health.

For this purpose, a roadmap has been prepared.

Please select the name of DG SANTE under Directorate General for having access to the concerned document with the title "Mid-term evaluation report on Health Programme 2014-2020".

Please note that the consultation is open until 14 January 2016.

Read the full announcement here.

**Recommendation**

EAACI to consider answering to the public consultation
b. Commission publishes report of the 2nd conference on European Reference Networks

The 2nd conference on European Reference Networks (ERN) took place in Lisbon on 8-9 October. The official report of the conference was published in December. It highlights the fact that policy-makers reiterated their support and political endorsement to the ERN concept.

The report particularly emphasizes the key role of the health community in the framework of ERNs and further highlights the specific contributions from patients groups and coordinators of existing pilot networks. Their insights allowed to give practical assistance to future EU-funded networks, while outlining the remaining challenges such as avoiding fragmentation of ERNs and ensuring their sustainability. Overall, participants agreed on the possible benefits of ERNs in improving access to specialised healthcare for patients and in reducing inequalities across the EU.

A session was particularly dedicated to ERNs’ potential in developing and implementing clinical guidelines for rare diseases as part of the overall goal to raise health standards across the EU. Clinically-led ERNs would strongly rely on a patient-centred approach, focus on healthcare delivery and interoperability building on the extensive use of IT tools. Though they are not primarily designed to be research consortia, it was noted that ERNs could foment research thanks to their connecting role between providers and patients. The importance of involving experts and patients with knowledge of rare diseases in research and drug development was repeatedly stressed. The conference also outlined the strategic role of Member States in supporting the development of ERNs especially because they are aimed at improving health services for European citizens.

The first call for ERNs is expected to be due in early 2016.

Read the full conference report here.

Recommendation

EAACI to share report with members for their information.

c. Update in the Parliament on ongoing inter-institutional negotiations on Medical Devices and In-vitro Diagnostic Medical Devices

During the meeting of the European Parliament’s ENVI committee on December 14, the Chair of the parliamentary committee Giovanni La Via (EPP, IT), gave an overview of the state of play of the inter-institutional negotiations on the Medical Devices and In-vitro Diagnostic Medical Devices regulations. He stressed that the fifth (and last under the Luxembourg Presidency) related trilogue was held on December 3, and concentrated on two main topics: Chapter V on the assessment procedure for the highest risk medical devices, for which the Parliament presented a compromise, and Chapter VII on vigilance, where the Parliament presented a compromise to merge the EP scope for the procedure with the case-by-case basis to be applied.

The sixth meeting will take place at the end of January or the beginning of February.

Recommendation

EAACI to share the update with membership for their information.

d. Highlights on the Dutch Presidency’s health priorities

In the area of public health, the Dutch Presidency has defined the issues it intends to address at political level. Main priorities include:

- Increasing access to innovative treatments for patients, faster and at a “socially acceptable cost”
- Aiming at reaching an agreement on the two proposals for reviewing the regulations concerning medical devices and in-vitro diagnosis medical devices, in the framework of the trilogue with the European Parliament and the European Commission.
- Fighting antimicrobial resistance and strengthen collaboration between health and agriculture Ministers and the European Commission on the issue.
Strengthening cooperation and financing in the area of health technology assessment (HTA)
Supporting the Commission's work on endocrine disruptors, especially in developing criteria for identifying the substances.

The Dutch Presidency also aims at better protecting employees against carcinogens in the workplace.

Additionally, the Dutch Health Minister Edith Schippers has announced that priority will also be given to enhance transparency in drug pricing in the EU. Calling for open and transparent negotiations on drug prices between EU countries and pharmaceutical companies, she has committed to take action to remove confidentiality agreements to make drug prices public, reduce pharmaceutical companies’ role in drug pricing negotiations with Member States, and simplify the authorisation procedures for new drugs. An action plan will be presented to EU Health Ministers over the course of the Dutch Presidency of the European Union.

**Recommendation**

EAACI to share the update with membership for their information and to identify opportunities for cooperation with the Dutch presidency

e. Preliminary conclusions of the Luxembourg’s Presidency of the Council of the EU

The Luxembourg Presidency of the Council of the EU published a preliminary report on the main results achieved over the past six months. In the field of health, the document reiterates the strong emphasis put on patients and innovation to address issues of public health. It summarises the outcomes of the Council meetings over the period, particularly highlighting:

- the conclusions of the Health Ministers’ December meeting, aimed at making access to personalised medicine effective in clinical practice. The Presidency has made progress in providing solutions to ensure better integration of personalised medicine in health systems, particularly giving orientations for further strategic thinking on the issue. Obstacles still remain to the integration of these targeted treatments in European health care systems and a dedicated framework will need to be set. The Presidency calls on the Commission and Member States to support the access to personalised medicine campaign which relies on a patient-oriented approach, through measures including the exchange of good practices or the promotion of appropriate training for health professionals.
- the Councils conclusions on improving the care of people living with dementia by adopting a transversal approach.
- the informal meeting of Health Ministers in September, which tackled dementia, healthcare for migrants, the cross-border healthcare Directive, and the role of health within the European Semester.
- the latest developments regarding medical devices and in vitro diagnostic medical devices and the related efforts to reach a political agreement in the framework of the trilogue negotiations with the European Parliament and the European Commission. Inter institutional common views include topics such as the introduction of an implanted card and the traceability of high-risk products.

Read the full report [here](#) and the press release dedicated to public health [here](#).

f. EMA and national Medicines Agencies adopt common strategy for the European medicines regulatory network

For the first time, a joint strategy for the European medicines regulatory network has been developed which will allow to tackle current and future challenges more effectively, drawing on the expertise of all members and avoiding duplication of work. The network includes all national medicines regulatory authorities for both human and veterinary medicines from EU Member States and the European Economic Area (EEA), and EMA (European Medicines Agency).

The strategy “**Shaping the future of human and animal health in the EU**” focuses on areas where joint collaboration can provide increased added value to human and animal health in the EU over the next five years. It builds on four key themes:

- Contribution to human health: framework to promote the development of new medicines addressing public health needs and patients access to
effective and safe medicines. It also aims at ensuring continued access to existing medicines by ensuring a strong supply chain and fostering the development of generics and biosimilars.

- Contribution to animal health and human health in relation to veterinary medicines: fomenting the availability of veterinary medicines, improve the functioning of the related EU internal market and limit the human and animal health potential risks related to antimicrobials.
- Optimising the operation of the network: focus on making the network’s scientific expertise available and operational to respond to health emergencies and crises.
- Contributing to the global regulatory environment: strong international role for the network in enhancing supervision of global supply chains, contributing to international convergence of regulatory standards, and promoting collaboration between regulatory bodies.

**Recommendation**

EAACI to share the strategy with membership for their information

**g. Priorities for a European policy on multimorbidity – Outcomes of the EU Conference on multimorbidity 27th October 2015**

On the 27 October 2015, the European Commission organised a multi-stakeholder conference on multimorbidity to share experiences and knowledge on the issue before defining recommendations on policy priorities to be considered.

To address the challenges of multimorbidity, the following policy priorities were outlined:

- change of paradigm from a medical-problem solving to a patient-centred approach, tailored to each individual’s needs.
- increase coordination between health and social care
- reorganize health systems to develop better integrated services
- increase research on diseases interaction and research on the cost-effectiveness of interventions addressing multimorbidity
- develop evidence-based good practices and create a platform to allow health professionals to share them
- improve patients’ health literacy and understanding of their disease and promote higher involvement of patients and families in disease management
- develop better standardisation of health care models
- to form multidisciplinary teams and improve the training of healthcare professionals.

Participants stressed the important role that can play innovative ICT solutions in implementing these priorities.

European Commission’s Director General for Health Xavier Prats-Monné introduced the Commission’s vision, especially highlighting the need to address multimorbidity through a holistic approach, the need to switch to a patient-centred model of healthcare and to increase cross border exchange of best practices between EU Member States.

Concluding the conference, Deputy Director General for Health Martin Seychell re-asserted the need for cooperation between stakeholders to establish a common framework on multimorbidity, and for an integrated approach to multimorbidity, which would also have a positive impact on health systems’ performance and cost-effectiveness.

Read the full conference report [here](#).

**Recommendation**

EAACI to continue its engagement with the Commission on this dossier

**h. Highlights from the EU Joint Action CHRODIS Conference on health promotion**

On 24-25 November, JA CHRODIS organised a conference on the state of health promotion and primary prevention in Europe.

Participants agreed on the need for increased cross-sectorial collaboration and funding to implement the recommendations from the European Union’s Reflection Process on Chronic Diseases, and for adopting a “health-in-all-policies” approach in policy and strategy making,
taking into account all social levels and gender equality. They highlighted the need to address health inequalities and to improve health funding, health monitoring and evaluation as well as the importance for health strategies to focus on national policy frameworks.

**Recommendation**

**EAACI to continue to follow developments on chronic diseases policies at EU level**

**Environmental Health**

**a. Council reaches common position on NEC Directive**

On 16 December, the Council of the European Union reached its common position on the National Emission Ceilings (NEC) Directive. The text will serve as a basis for negotiations with the European Parliament.

As you are aware, this legislative proposal reviews the annual caps per country for emissions of certain air pollutants, introducing new reduction commitments from 2020 to 2029 and from 2030 onwards.

Methane was left out of the proposal in the Council’s position, a move which it justified on the basis that it could overlap with future measures on climate and energy linked to emissions of greenhouse gases.

Regarding the 2025 intermediate emission levels proposed by the Commission, the Council introduced the possibility for member states to follow a non-linear trajectory in their reductions if this is more efficient.

The Council proposes also some additional flexibility for member states. For instance, it introduces the possibility to average annual emissions with emissions of the preceding year and those of the following. This can be applied when a member state is not in a position to fulfil its commitment one year, due to particularly cold or hot temperatures or to unforeseen economic variations.

The possibility to compensate for the non-compliance regarding one pollutant with an equivalent reduction of another for a limited time is also proposed for some cases. Moreover, a member state could be deemed to comply with its obligations in cases of exceptional interruptions or losses of capacity in power or heating supply.

Although the Council’s position represents lower level of ambition to protect health and environment than the Commission’s and the Parliament’s position, 4 countries (Germany, Denmark, Poland and Austria) voted against the text because it was too ambitious for them.

Only Sweden, Belgium, the Netherlands, Finland and the Czech Republic openly regretted the lower level of ambition but they still supported the deal.

Please read here the press release published by the The European Environmental Bureau (EBB) – with whom EAACI partners within the coalition towards cleaner air in Europe - , which heavily criticized the lack of ambition of the Council’s position.

**Recommendation**

**EAACI to continue its work with the EU health and environment community towards cleaner air in Europe in view of the upcoming inter-institutional negotiations on the proposal.**

**b. Commission, Council and European Parliament assess outcomes of COP21**

On December 15, the outcome of the international climate talks in Paris (COP 21) was reviewed by MEPs, the Council Presidency and Commissioner Miguel Arias Cañete.

Policy makers highlighted that the Paris agreement was an historic achievement, as this is the first time a universal climate agreement is passed that contains the necessary architecture to keep global warming well below 2 degrees Celsius and in which all the world’s countries agree to do their part.

Secondly, it was also agreed to come back every five years, to take stock, to look at the latest science, and to ramp up countries’ commitments accordingly. Under the Paris Agreement, countries also have a legally binding obligation to pursue domestic mitigation measures with a view to achieving their contributions.
In addition, the agreement includes a solidarity package which contains provisions on climate finance and on addressing needs linked to adaptation and to loss and damage. Developed countries will continue with their collective mobilisation goal of USD 100 billion per year until 2025, when a new collective goal will be set.

Policy makers also stressed the essential role the EU played in the deal - especially regarding the level of ambition - and the fact that the EU spoke with one voice during the whole process. However, they noted that the Paris Agreement is only a framework still to be defined and clarified on several points. There remains much work to do before the entry into force of the Agreement in 2020.

**Recommendation**

**EAACI to share with membership for their information and to follow the implementation of the Paris Agreement in the EU.**

c. **WHO Europe places environmental sustainability as core element of health systems**

WHO Europe organised a strategic meeting on environmentally sustainable health systems (ESHS) on November 11 and 12 in Bonn (Germany), gathering representatives of 19 European countries, medical and environmental experts, nongovernmental organization leaders and WHO representatives. The meeting aimed at discussing on a strategic approach towards environmentally sustainable health systems, on the basis of a draft proposal elaborated by WHO Division of Communicable Diseases, Health Security and Environment, and the Division of Health Systems and Public Health.

The essential role of health systems in promoting resilient communities and healthy environments was reiterated and participants agreed on the proposed vision of WHO which puts emphasis on the relationship between environment and health, and stresses the need to improve both in parallel.

Recommended strategic actions were highlighted, including the promotion of innovative models of care, the promotion of sustainable procurement or the reduction in the use of hazardous chemicals. A list of national examples of environmental sustainability actions in health systems was presented, such as the reduction of pharmaceutical waste, mobility management and low carbon transportation.

The meeting concluded in the importance of sharing information on the existing examples of environmental sustainability in health systems and good practices to foment future development.

WHO strategy will be further developed building on the inputs of the scientific community and stakeholders from the meeting in view of its introduction during the 66th session of the WHO Regional Committee for Europe and the sixth Environment and Health Ministerial Conference to be held in 2016, and its promotion in the relevant policy processes.

Read the full article on the outcomes of the meeting [here](#).

**Recommendation**

**EAACI to share with membership for their information**

d. **EU blacklist of invasive alien species finalised**

The first blacklist of invasive alien species to be targeted in the EU has been approved by member states for adoption by the European Commission. From 1 January on, National authorities will have to prevent species on the list entering their territory under the 2014 Invasive Species Regulation.

The list comprises 37 species, including hogweed, which can cause allergic reactions. The list has been criticized by NGOs for being too short. It does not include ragweed, notorious for causing allergic rhinitis.

**Recommendation**

**EAACI leadership to consider starting PA work towards the inclusion of ragweed in the next update of the blacklist. A first contact with the Commission to assess the state of play for ragweed is recommended.**
Annexes

Parliamentary Questions

Questions answered in December

- Question on the “application of Directive 2011/24/EU on cross-border healthcare by the Member States” - Soledad Cabezón Ruiz (S&D).

- Question on the “Reduction of the duration of the specialisation course in ear, nose and throat medicine” - Lara Comi (PPE).

Questions tabled in December

- Question on “Particulate filters” and impacts on health - Piernicola Pedicini (EFDD), David Borrelli (EFDD), Daniela Aiuto (EFDD), Eleonora Evi (EFDD), Isabella Adinolfi (EFDD), Dario Tamburrano (EFDD), Marco Affronte (EFDD).

EU events tracker

- 21 January 2016, Forum: “Better research for better health, a holistic approach to challenges and opportunities”, DG SANTE
- 27th-28th January 2016: The European Medical Devices Regulation, Hotel Metropole Brussels (include speakers such as Erik Hansson DG for internal market and SMEs)
- 16-18th March 2016, “Hospital Pharmacists taking the lead – partnerships and technologies”, European Association of Hospital Pharmacists
- 10-12 May 2016, Conference Health 2.0 Europe 2016, Barcelona