



# UPDATE July 2019

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### 1. ERA-EDTA joins the BioMed Alliance



The latest organisation to join the BioMed Alliance is the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA). This new addition brings the total number of members to 31. We look forward to working with ERA-EDTA to continue promoting heath research and to improve health-related policy at EU level.

<u>ERA-EDTA</u> is specialised in nephrology and represents more than 7.000 physicians. It is active in Europe and the Mediterranean and it aims to promote fundamental clinical advances in the field of nephrology, dialysis, renal transplantation, hypertension and related subjects.

#### 2. Statement on Health Technology Assessment



Medical societies urge Member States to support EU-level HTA

The legislative proposal on health technology assessment (HTA)\* has received strong backing from the European Parliament\* and across-the-board stakeholder support from patients\*, physicians\* an industry\* affice.

Today, as the incoming Flarish I/U Presidency prepares to take up the iff A legislative decisier, the Binnedical Alliunce in Europe (BlooMed Alliunce), representing tens of thousands of healthcare professionals making daily use of health technologies, commends the decidation of previous EU Presidencies and it calls on the Council of the European Union to support the legislative proposal so that As the Finnish Presidency took the lead of the Council of the EU in the beginning of July, the BioMed Alliance published a <u>statement</u> urging Member States to support joint Health Technology Assessment (HTA) at EU level. A proposal for joint HTA is currently being discussed by the institutions but progress is stalled.

Our statement commends the dedication of previous EU Presidencies and it calls on the Council of the European Union to support the legislative proposal so that there can be a robust and effective framework for collaborative EU-level HTA.

Cooperation on joint health technology assessments is currently facilitated by EUnetHTA, which will end in 2020. After that there will be no more official framework for cooperation at EU level, unless the legislative proposal on Joint HTA is implemented.

#### 3. Horizon Europe Consultation is now open



The European Commission launched a public consultation on the Strategic Plan for Horizon Europe (the next EU research & innovation framework programme). Input can be provided on research objectives and feedback will feed into Strategic Plan which will guide the implementation of Horizon Europe from 2021-2024.

The European Commission is also organising the European Research and Innovation Days on 24-26 September to involve stakeholders in the implementation of Horizon Europe.

Anyone with an interest in research can participate in the consultation, so both individuals and organisations. The consultation is open until 8 September 2019 and available here: <a href="https://ec.europa.eu/eusurvey/runner/HorizonEurope\_Codesign\_2021-2024">https://ec.europa.eu/eusurvey/runner/HorizonEurope\_Codesign\_2021-2024</a>



#### 4. European elections: developments in EU institutions

Even though summer has arrived in Brussels, activities have not slowed down at EU level and there have been significant changes in leadership announced. Below is an overview of the main developments in the 'EU Bubble' following the EU Elections of last May.



Member states and the European Parliament have approved the future **European Commission President**. Ursula von der Leyen (EPP, German) was previously the German defence minister and will lead the European Commission for the next 5 Years. She has extensive experience in German politics and holds a medical degree. She will also be the first female Commission President.



The **European Council** has elected a new **president-elect**, Charles Michel (Renew Europe, Belgian). He was the Belgian Prime Minister until recently and will take over the lead of the Council from Donald Tusk.



The **European Parliament** has also elected its own future **president** and appointed vice-presidents and committee chairs. The next president is David Maria Sassoli (S&D, Italian) and he will lead the EP until January 2022. Chairs of the different committees have also been appointed. The Environment, Public Health and Food Safety (ENVI) Committee will be chaired by Pascal Canfin (Renew Europe, French). The new chair of the Industry, Research and Energy (ITRE) Committee is Adina-Ioana Vălean (EPP, Romanian).



The **Finnish Presidency** has now officially taken up its role to preside Council of the EU meetings as part of the rotating presidency. The presidency will plan and chair meetings in the Council and represent the Council in relations with other institutions. In January 2020 it will pass on the baton to Croatia.

#### 5. In Vitro Diagnostics Working Group established



The BioMed Alliance Taskforce on Regulatory Affairs and Medical Devices has decided to create a working group on In Vitro diagnostics. A new EU regulation on In Vitro Diagnostics will come into effect in 2022 and will have a major impact on the evaluation and approval process of IVDs. In preparation for this, and to facilitate member society cooperation on the regulatory aspects of in vitro diagnostics, this taskforce is established.

The first meeting of the new In Vitro Diagnostics Working Group will take place on 12 November in the BioMed Alliance offices.



#### 6. Upcoming

- In the coming months (exact date not known), the European Commission will launch a
  call for experts to take part in the new EU Medical Device Regulation expert panels.
   These experts will play an important role in the evaluation process of high-risk medical
  devices.
- On 28 August, we are organising a webinar with EFPIA to provide input for the next public-private partnership for health at EU-level, the Innovative health Initiative. We are invited to discuss, provide input and address questions on the Strategic Research Agenda of this successor to the IMI.
- PARADIGM, PFMD and EUPATI are organising a patient engagement open forum
  in Brussels on 18 and 19 September. The two-day programme features a number of
  sessions exploring the different aspects of patient engagement.
- The next meeting of the **CME Experts Permanent Committee** will take place on 26 September in our office (Square de Meeus, 29, Brussels).
- On 7 November, the BioMed Alliance and the Berlin Institute for Health organise an
  event on translational research in Berlin as part of the Berlin Science Week. The
  event will include a panel discussion with key speakers exploring different aspects
  related to the value of translational research.
- The first meeting of the In Vitro Diagnostics working group will take place on 12 November in our office.
- The <u>European Patients Forum Congress</u> will take place from 12-14 November in Brussels. BioMed Alliance Executive Director Michel Ballieu will participate as a panellist in the session on the role of patients in professional education on 14 November.
- We will organise a workshop on Horizon Europe (the EUs next Research and Innovation Framework Programme) with the EAU on 19 November from 14.00-18.00 in Brussels. More information will follow, please confirm your attendance to: office@biomedeurope.org
- The BioMed Alliance **General Assembly 2019** takes place on 20 November from 10.00-16.00.