



UPDATE JULY

2020

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1. ESCMID joins BioMed Alliance



The BioMed Alliance continues to grow and is excited to welcome ESCMID to its membership base. The European Society of Clinical Microbiology and Infectious Diseases joined in the end of July. It is the 34th member of the Alliance.

ESCMID was founded in 1983 and its mission is to improve the diagnosis, treatment and prevention of infection-related diseases.

This is achieved by promoting and supporting research, education, training and good medical practice. It brings together microbiologists and infectious disease specialists and currently has more than 8,500 individual and 30,000 affiliated members around the world.

2. Teleconference helped share experiences with virtual congresses



On 30 June, the BioMed Alliance organised a virtual meeting on the lessons learned from virtual congresses and it was chaired by Prof. David Vodusek (chair of the CME Experts Committee) and included presentations from Monica Fontana (ERA-EDTA), Florian Klett (EULAR) and Julia Rautenstrauch (EULAR). The meeting was attended by around 50 participants.

Presentations focussed on decision making processes, challenges associated to virtual congresses, timelines, technical considerations, key figures and general advice. The minutes and recording have been sent to registered participants, please contact the office if you would like to receive them as well.

3. Widely supported letter calls for European Leadership in health research



An open letter to the European Commission signed by 48 Members of the European Parliament and a large number of health stakeholders (including BioMed Alliance) calls for strengthened leadership that addresses silos in health research. The letter was published on 9 July and highlights the value of biomedical research while stressing the need for a more coordinated European approach

to health research.

MEP Dr. Petra de Sutter (GREENS/EFA, Belgium) initiated the letter, and the BioMed Alliance office supported her and her staff in finalising and promoting it. The letter argues that the COVID-19 crisis demonstrated that a coordinated response to health challenges requires prior planning and a long-term commitment based on a comprehensive vision. This can be driven by a credible body, in the form of a European Health Research Council.

The full letter is available <u>here</u>.

4. Regulatory framework IVDs requires action



The BioMed Alliance also published a new statement calling for urgent action to ensure optimal implementation of the EU In Vitro Diagnostic devices regulation (IVDR). The statement calls on the European Commission to take into account a number of actions that should be completed as soon as possible.



The application date for the new regulation on 26 May 2022 is approaching and adaptation to the new regulatory system is time consuming and requires a concerted effort from the European Commission, Member States and stakeholders. At the moment there are many steps that still need to be taken to ensure the regulatory system will be ready to continue guaranteeing the availability of novel and high-quality diagnostic tests.

Read the statement here.

5. Contribution to consultation on new pharmaceutical strategy



The BioMed Alliance has submitted feedback for the consultation on the new Roadmap for the Pharmaceutical Strategy for Europe. In the response, we stress the need for coordinated action in a number of policy areas that are crucial in the lifecycle of pharmaceuticals including support for biomedical research, academic clinical trials, health data sharing and cooperation on Health Technology

Assessment.

The Pharmaceutical Strategy is a new European Commission initiative intended to coordinate efforts to help ensure Europe's supply of safe and affordable medicines that meet patients' needs. The Strategy covers the whole life cycle of pharmaceutical products from research & scientific discovery to authorisation and patient access. The Commission continues the consultation process with a more general consultation and is expected to publish its proposal by the end of the year.

Read the BioMed Alliance feedback to the Roadmap on the Pharmaceutical Strategy here.

6. EU MFF: significant budget cuts for health & research



Following the updates provided in previous editions of the newsletter, negotiations on the next Multiannual Financial Framework (MFF) and the recovery plan from the COVID-19 crisis have now been concluded and entail major cuts for health and research funding.

The European Council met 17-21 July to discuss the package of proposals that were proposed by the European Commission in May.

They came to a political agreement substantially amending the original proposal. The financial envelope for the implementation of the Horizon Europe programme for the period 2021-2027 has been reduced to €75.9 billion. In addition, the programme will benefit from €5 billion from the recovery instrument 'Next Generation EU'. EU leaders also decided to cut the budget of the new Health Programme, EU4Health, by almost €8 billion to €1.6 billion.

	Programme	Budget	Comment
Research	Horizon 2020 (2014- 2020)	€80 billion	
	Horizon Europe (2021-2027)	€80.9 billion	The amount is more than €13 billion lower than in the European Commission's proposal from May (€94.4 billion). The lack of funding will add extra pressure on how the budget will be divided within Horizon Europe and might



			undermine promising health research initiatives.
Health	EU Health Programme (2014-2020)	€449.4 million	
	EU4Health (2021-2027)	€1.6 billion	A dramatic cutdown of the EU4Health programme, from €9.4 billion proposed by the European Commission (in May) to €1.6 billion. Even if EU4Health has a higher budget than the previous programme, the amount is not enough in the context of COVID-19 crisis and cannot cover all the ambitious objectives of the programme.

Negotiations were complex and the positions of countries differ greatly, but the agreement represents a significant blow to the European health & research sectors. The BioMed Alliance has shared its concerns in two EU health coalition statements; one right before the summit asking for an appropriate budget and one after expressing concern about the proposed budget cuts.

Members of the European Parliament have expressed their disapproval of the budget cuts in a new resolution, arguing they do not accept the current political agreement as it stands. They argue that the proposed cuts to health and research programmes are dangerous in the current context and MEPs will engage in negotiations to improve the proposal. The MFF proposal will be adopted according to the consent procedure, meaning the Parliament cannot amend the proposal but it must approve or reject the final text.

7. Upcoming

- We are organising another call of the **Policy Officers Committee** on 12 August
- The second EU Health Summit will take place on 26 October 2020. This event is
 organised by the EU Health Coalition, of which the BioMed Alliance is an active
 member.
- The **General Assembly** will be held on 26 November 2020