

Biomedical Alliance in Europe

UPDATE June

2019

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1. Workshop on Medical Device Registries



The BioMed Alliance organised a joint workshop on Medical Device Registries with the European Society of Cardiology (ESC) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) on 17 June. The programme included speakers from the European Commission, member societies, a notified body, industry, the European Medicines Agency and experts who manage successful registries across Europe.

The all-day workshop provided an overview of different perspectives on registries and was attended by around 65 participants representing regulatory authorities, medical device companies, registries and medical societies. The presentations showed that there are some successful registries in Europe and that regulators and industry representatives see the added value of having access to high-quality registries. Nonetheless, regulatory and practical barriers remain and hinder the realisation of their full potential.

The following day, the second meeting of the taskforce on regulatory affairs and medical devices took place. Taskforce members discussed the workshop, ongoing participation in EU Commission working groups, the Medical Devices Regulation (MDR) and the future activities of the taskforce. They were joined by Paul Piscoi from DG GROW, who provided key insights on the MDR implementation.

The EU Medical Devices Regulation will apply in 2020 and proposes stricter control on medical devices. Therefore, the discussion on the role of registries in providing advice to regulators is very relevant.

2. EU Call for experts – Medical Device Regulation



The European Commission has shared the [announcement](#) of its call for clinical experts to take place in expert panels on medical devices and in vitro diagnostic devices. The call will be published later this year.

The new Medical Devices Regulation will regulate the development, authorisation and post-market surveillance of medical devices. A new element under this regulation is the establishment of expert panels that will play a role in assessing high-risk medical devices and advising regulators.

It is essential that a broad variety in experts from different disciplines takes place in these panels to ensure that the safety of medical devices on the European market is guaranteed. The call, including information about conditions and reimbursements, will soon be launched. We encourage our members to already identify potential candidates and prepare for the European Commission call for recruitment in advance.



3. President elect speaks at annual EFPIA Conference



President-elect Prof. Wilfried Ellmeier has been invited to speak at the annual EFPIA Conference '[Connecting Healthcare](#)' taking place in Brussels on 27 June. He will discuss our activities to promote health research and our activities within the [EU Health Coalition](#).

4. BioMed Alliance Coordinated Statement on research budget



Ahead of discussions on the new Multiannual Financial Framework (EU Budget for 2021-2027) during the European Council Summit on 20-21 June, the BioMed Alliance together with the EU Health Coalition partners published [a statement](#) advocating for a more substantial EU research budget. The BioMed Alliance called upon Member States to adopt a bigger

MFF and thus a higher Horizon Europe budget with appropriate funding allocated to the Health Cluster. This is essential to strengthen the European research sector, facilitate innovation and improve public health.

The BioMed Alliance leads the Research and Innovation Group within EU Health Coalition, which brings together different stakeholders in the healthcare field. Jointly with partners, we drafted these recommendations with the ultimate aim to enhance the health research landscape in Europe. The statement calls for an increased EU budget for health research, setting-up a cross-sectorial health research Public Private Partnership and better coordination and support for health research.

5. Open Letter with EPF and ESC on MDR implementation



PATIENTS AND DOCTORS CALL FOR URGENT INVESTMENT
TO ENSURE THAT THE EU MEDICAL DEVICES REGULATION IS IMPLEMENTED ON TIME

OPEN LETTER TO EU HEALTH MINISTERS

It is now less than one year to 25 May 2020, when the new EU Regulation on Medical Devices (EU 2017/745) must be applied.

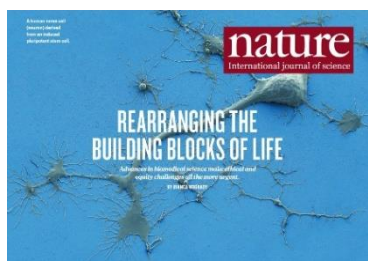
The Regulation mandates stronger safety requirements for high-risk medical devices, greater transparency of clinical evidence, and strengthened post-market surveillance.

The BioMed Alliance jointly with the European Society of Cardiology (ESC) and the European Patients Forum (EPF) published an [open letter](#) on 7 June calling for an on-time implementation of the Medical Devices Regulation (MDR). The open letter addresses EU Health Ministers and was written ahead of the Council of the European Union meeting on 13-14 June, where the regulation was discussed.

The open letter highlights that progress in implementing the regulation is currently slow, but that its timely implementation is essential in ensuring patients and healthcare professionals have access to safe, innovative and effective technologies.



6. Nature article on added value of health research



An [article](#) published by the journal 'Nature' shows how progress in biomedical science has led to breakthroughs in healthcare, but that challenges including ethical and financial challenges persist.

BioMed Alliance president-elect Wilfried Ellmeier was interviewed for this article and referred to one of the ethical challenges in biomedical research, the appropriate use of the CRISPR–Cas9 technology which is used to edit genomes.

7. Upcoming

- In a few 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](#)**
- The next meeting of the **CME Experts Permanent Committee** will take place on 26 September in our office (Square de Meeus, 29, Brussels)
- The [European Patients Forum Congress](#) 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

