



Biomedical Alliance in Europe

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1. New MFF proposal contains greater focus on health



On 28 May, the European Commission presented the new revised proposal for the Multiannual Financial Framework (EU budget for 2021-2027) and, connected to that, the European recovery plan from the COVID-19 pandemic.

While the original proposal was already published in May 2018, it has now been revamped to support the recovery of the European Union from the COVID-19 pandemic. The proposed total MFF budget is €1100 billion (financed by member states) and the recovery plan 'Next Generation EU' would benefit from an additional €750 billion (financed by a construction where the Commission would borrow money on the markets).

The package of proposals is built around 3 pillars:

1. Supporting Member States to recover, repair and emerge stronger from the crisis
2. Kick-starting the economy and helping private investment get moving again
3. Learning the lessons of the crisis and addressing Europe's strategic challenges

Funding for health

Health plays a more substantial role in the new proposal. While health was originally supposed to be integrated in the European Social Fund (in the 2018 proposal), the proposal published on 28 May outlines the establishment of a separate EU Health Programme, EU4Health. The proposed budget of the programme is €9.4 billion, and it would support health security and resilience against future health crises. The Commission states that: *"It will help deliver a long-term vision for well-performing and resilient public health systems, notably by investing in disease prevention and surveillance, and improving access to healthcare, diagnosis and treatment"*. The European Commission published a useful factsheet on how funding will be allocated. More information is available [here](#).

In addition, health research will benefit from funding through Horizon Europe (the next EU research programme) for which the proposed budget is €94.4 billion. More clarification of the newly proposed Horizon Europe budget figures is expected in the coming days.

Recovery plan

The recovery plan 'Next Generation EU' is presented as a temporary emergency tool that will address the economic consequences of the COVID-19 pandemic and will help the European economy recover. Member States, and particularly those that are most seriously affected, can benefit from funding and loans to rebuild, and there is also support for companies and measures to incentivise private investment.

Next steps

Negotiations around the 2018 MFF proposal have been very lengthy and complex and the positions of EU countries continue to differ substantially. It is therefore expected that there will be more complicated negotiations ahead and it may take some time before the European Council amends and adopts the proposal. Some of the most likely controversial issues will be the foreseen amounts connected to the budget for the MFF and the recovery instrument, the conditions around providing recovery funding and the way in which the European Commission will generate the necessary funds for the recovery instrument.

More information is available on the European Commission's website [here](#).



2. Online edition of the Spring Meeting was well attended



The BioMed Alliance Spring Meeting took place on 13 May 2020 from 14.00-16.30 online via ZOOM and was attended by more than 60 participants.

The meeting started with updates of the different taskforces and committees and showed that the amount of BioMed Alliance activities is gradually expanding. Afterwards, members voted digitally on the 2019 accounts which were unanimously approved.

For the first time, there were two parallel breakout sessions where participants discussed the future of medical societies and health research. They were asked beforehand to prepare SWOT Analyses, which were compiled and presented. This exercise provided a better idea of both the opportunities and challenges that lie ahead. Participants also discussed joint follow-up activities, which will be carried out in the coming months.

The minutes are currently being drafted and will be shared in due time.

3. BioMed Alliance organises teleconference on COVID-19 H2020 calls



The BioMed Alliance organised a teleconference on Friday 29 May from 11.00-12.00 (CEST) to discuss opportunities for medical societies to get involved in Horizon-2020 calls on COVID-19.

Frédéric Suche, the Belgian National Contact Point for health research, informed participants of ongoing calls on COVID-19 including PHE-CORONAVIRUS-2020-2, for which he and his colleagues are currently collecting expressions of interest.

During the call we discussed opportunities for involvement for medical societies in this and other calls, what sort of support national contact points can provide and discussed questions that medical societies had. There are ample opportunities for medical societies to get involved and the deadline for the calls is on 11 June.

More information about the calls is available [here](#).

4. Medical Devices taskforce meets online



The BioMed Alliance organised a digital meeting of the taskforce on Regulatory Affairs and Medical Devices on 14 May. There were several items on the agenda such as new developments around COVID-19 & medical devices and the latest news on the implementation of the Medical Devices Regulation. Other taskforce activities were also discussed, including the BioMed Alliance participation in a consortium applying to a Horizon 2020

call on regulatory advice related to medical devices.



5. New UEG Journal article: Joining forces to strengthen European health research



BioMed Alliance Board Member Berthold Koletzko, Loredana Simulescu (BioMed Alliance) and Mathilde Ollivier (UEG) have published an article in the United European Gastroenterology Journal explaining how joining forces is essential to strengthen European health research. They highlight the successes of cross-border health research and European funding programmes,

explain how Horizon Europe is structured, stress the need for adequate funding and outline the activities of the BioMed Alliance.

The full article is available [here](#).

6. Urgent actions need to be implemented by the MDCG IVD WG



The European Commission's Medical Devices Coordination Group (MDCG) In Vitro Diagnostics (IVD) Working Group organised a meeting with stakeholders on 25 May. Board member and Chair of the BioMed Alliance IVDR WG, Elizabeth Macintyre attended the meeting on behalf of BioMed Alliance.

The meeting was a good occasion to present key insights on how the COVID-19 pandemic has impacted our members' activities and to highlight the crucial contribution that medical societies have made to tackle the crisis in the IVD field. While there was a lack of relevant IVD tests in the early stages of the pandemic, this was mitigated by deploying Lab Developed Tests (LDTs). Within one week after the release of the genomic sequence of SARS-CoV-2, LDTs were implemented in several laboratories across Europe. It is crucial to ensure that the ability of laboratories to implement, operate and troubleshoot LDTs will not be hindered by the implementation of IVDR requirements.

Therefore, Elizabeth Macintyre pointed out several calls to action which should be urgently implemented by the European Commission with the support of relevant stakeholders such as:

- Accelerate the activation of the LDT Taskforce under the MDCG IVD WG, with reference laboratory participation
- Alternative measures or exemptions → IVDR article 54 should be accompanied by clear guidance (the article concerns a derogation from conformity assessment procedures in exceptional cases relating to public health)
- Put in place mechanisms for the rapid dissemination of appropriately evaluated LDTs
- Facilitate the dissemination of rapidly evolving consensual diagnostic practice via Medical Societies
- Europe should have a European policy on (health!) risk management.

A meeting with the European Commission representatives responsible for the IVDR implementation will be organised in order to further discuss these calls to action.



7. Upcoming

- We are organising regular calls of the **Policy Officers Committee**, contact the office if you would like to join
- The **General Assembly** will be held on 26 November 2020