Biomedical Alliance in Europe

9 April 2020

BioMed Alliance Statement on the postponement of the application of the Medical Devices Regulation

The Biomedical Alliance in Europe (BioMed Alliance) welcomes the postponement by the European Commission of the date of application of the Medical Devices Regulation (MDR) by one year to 26 May 2021. Considering the current situation with COVID-19, this will relieve some of the pressure on authorities and stakeholders and allow more time to implement all components of the MDR fully.

We believe that it is important to ensure a smooth transition to the new regulatory framework, to guarantee that patients will continue to benefit from a timely access to safe and high-quality devices. **We thus call upon all stakeholders, authorities and policy makers to continue preparations for the MDR and IVDR to the maximum extent that the current situation allows.**

In case of a delay of the application date of the MDR, the following elements are essential:

1. The new regulatory system will not fully operate without **a functioning EUDAMED portal**. Therefore, the European Commission should try to operationalise the system **by May 2021**, and not postpone its implementation until the date of application of the IVDR in 2022 (as was previously announced).

2. For healthcare professionals and patients, **transparency** throughout the new system is a top priority. Public access to clinical information (e.g. Summaries of Safety and Clinical Performance shared through EUDAMED) will help clinicians to select optimal treatments. Although the European Commission had previously announced that the **implementation of the clinical aspects of the EUDAMED portal** was being delayed, we believe it is extremely important that they be implemented ahead of the new application date.

3. The delayed application date also allows more time to ensure that the Expert Panels have the necessary support to carry out their important new role within the regulatory system. The members of **the Expert Panels should receive sufficient education and training**. In addition, the system should be tested to ensure that all aspects can run smoothly.

The 33 medical and research societies that form the BioMed Alliance consider the Medical Devices Regulation and the In Vitro Diagnostics Regulation (IVDR) to be essential regulations that will significantly enhance the safety and efficacy of medical devices and in vitro diagnostic devices. We will be pleased to continue to provide the European Commission with scientific and clinical advice on the implementation of different aspects of the regulation.

About the Biomedical Alliance in Europe:

The Biomedical Alliance in Europe is a unique initiative between 33 leading European medical societies that together include more than 400,000 researchers and health professionals. It is a not-for-profit organisation committed to promoting excellence and innovation in the European healthcare field with the goal of improving the health and well-being of all European citizens.