Biomedical Alliance in Europe

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European medical experts unite to improve scientific scrutiny of evidence for approval of high-risk medical devices in the European Union

Brussels − Today, experts from the Biomedical Alliance in Europe (BioMed Alliance) are advising the Joint Research Centre (JRC) of the European Commission in Ispra, Italy, on the clinical evaluation of high-risk medical devices. Representatives of the healthcare professions will discuss how scientists and clinicians can help to implement the new EU Medical Devices Regulation (MDR) and the new EU *In Vitro* Diagnostic Medical Devices Regulation (IVDR).

Recent publicity generated by the International Consortium of Investigative Journalists (summarised in the "Implant Files") highlighted clinical problems that have occurred with implantable medical devices (such as metal hips and heart valves) but ignored the major reform of the European system for evaluating medical devices that is taking place now.

The MDR and the IVDR will come into effect from 2020 and 2022. New measures to enhance the safety of medical devices include the creation of Expert Panels in all the major medical specialties.

In future, medical experts will have responsibility to advise manufacturers on clinical investigations, and to advise regulators about the quality of the clinical evidence presented by manufacturers when they seek approval of a new high-risk medical device.

At the meeting today, the BioMed Alliance will recommend to the European Commission how Expert Panels should be constituted, which specialties should be involved, how individual devices should be selected for expert review, and what criteria experts should apply when giving their opinions.

Later this year the European Commission will announce a call for individual scientists, engineers, and doctors to become members of these panels. Professor Alan Fraser, Chairman of the Biomedical Alliance Task Force on Regulatory Affairs and Medical Devices, said: "Doctors and patients have been campaigning for many years for higher standards of clinical evidence for new medical devices before they are approved. Now, it is essential that many colleagues apply for these important new roles, to ensure that patients have access not only to the most effective but also to the safest medical devices."

About the BioMed Alliance: The Biomedical Alliance in Europe (BioMed Alliance) is a non-profit organisation representing 29 leading European research and medical societies uniting more than 400,000 researchers and healthcare professionals. It is 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. It is proud to be a key partner in the discussions on the implementation of the new medical device regulations.

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