

Handover of expert panels on medical devices and *in vitro* diagnostics from the Commission's Joint Research Centre (JRC) to the European Medicines Agency (EMA)

On 1 March, the coordination Secretariat of the Commission's expert panels on medical devices and *in vitro* diagnostic medical devices has been handed over from the Commission's Joint Research Centre (JRC) to the European Medicines Agency (EMA).

The JRC had been entrusted by DG Health and Food Safety (DG SANTE) to establish the panels, define guidance documents, operational workflows and necessary IT tools as well as to launch their main advisory functions. During the last four years, JRC and DG SANTE have collaborated intensively to establish these 12 expert panels, which play an important role in improving the clinical evaluation of specific high-risk devices (e.g. implantable heart valves or SARS-CoV-2 assays) under the revised EU legislative framework for medical devices (Regulations (EU) 2017/745 and 746).

The background of the handover is the extended mandate of EMA on crisis preparedness and management of medicinal products and medical devices (Regulation (EU) 2022/123), developed as a reaction to the COVID-19 pandemic in the EU. It is expected that EMA's extended mandate will lead to a more integrated, synergistic and coherent approach to the management of availability of medicinal products, medical devices and *in vitro* diagnostic medical devices at Union level, and of the scientific panels for medical devices, thus improving public health protection for the entire Union.

Background the expert panels

The expert panels cover a broad range of relevant medical fields and *in vitro* diagnostics. Some of the panels are further structured in sub-groups addressing specific device technologies. The panels bring together more than 200 experts from all over the EU, ensuring that the diversity of scientific and clinical approaches within the EU is adequately reflected.

Importantly, the advice by panels on specific high-risk device dossiers will not only be used by notified bodies involved in the conformity assessment of these devices before they are placed on the market. The panel advice will also inform the so-called mechanism of scrutiny under the responsibility of competent authorities of the Member States which is another novel element of the medical devices legislative framework. This mechanism aims at ensuring that conformity assessments of high-risk devices are based on sufficient clinical evidence and that these devices are indeed both safe and performant.

During the first year of the operation of the panels about 25 dossiers on high-risk devices and *in vitro* diagnostics have been processed by the expert panels. This has led to 18 scientific opinions on the clinical and performance evaluation assessments performed by notified bodies and, respectively, manufacturers.