# In vitro diagnostic medical devices

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The Council took note of a presidency progress report on two draft regulations on medical devices and on in vitro diagnostic medical devices.

Ministers provided guidance for future work on these files as regards the three following elements:

(1) The designation of conformity assessment bodies as notified bodies and the monitoring of these bodies: most Member States supported the idea of further clarifying the procedures for designating notified bodies and strengthening cooperation between Member States to ensure that notified bodies meet similar standards throughout the EU. But they also warned against increasing the administrative burden unnecessarily.

(2) The reporting of incidents, market surveillance and corrective measures: all Member States supported strengthened requirements on post-market surveillance and responsibility for follow-up by manufacturers, e.g. by collecting and analysing data on the performance of medical devices, in particular on adverse reactions in which they are involved.

However, as regards the balance between controls before and after placing devices on the market there were diverging views.

(3) The role and tasks of the medical device coordination group (MDCG): all delegations support the establishment of the MDCG. Most delegations support the idea to unify co-operation between Member States regarding medical devices and in vitro diagnostic medical devices by appointing one representative per Member State in the Medical Device Coordination Group (MDCG) rather than separate representatives for medical devices and in vitro diagnostic medical devices. There is broad agreement that the establishment of a network of reference laboratories is important for the proper evaluation of in vitro diagnostic medical devices.

As regards the evaluation of medical devices, however, many delegations have expressed an interest in either complementing the reference laboratories with device panels or replacing them entirely with device panels in order to provide relevant expertise input for regulatory measures.

Overall, many Member States stressed the need to develop a consistent legislative package that guarantees patient safety and facilitates innovation in order to improve treatments, decrease costs for patients and taxpayers, and preserve the competitiveness of the EU industry.

The Council instructed its preparatory bodies to continue examining the two files with a view to agreeing a Council position in the autumn.