Medical devices

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

The report noted that considerable progress has been achieved on these files under the Italian presidency. However, further discussions are needed for the Council to agree its position.

Outstanding issues include:

- **aesthetics devices**: the report noted that 15 delegations favoured inclusion of aesthetic devices under the scope of the Medical device Regulation. Five delegations opposed this, mainly on the grounds that this would increased the financial and administrative burden on competent authorities;
- **ingested products**: the proposal on medical devices provides for inclusion of certain substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally ("Ingested products") into the scope of the Regulation. It further provides that all these devices be classified as high risk devices ("Class III"). A compromise has been made in this area given that several delegations expressed concerns on the suitability of the proposal, especially in relation to the delimitation between medical devices and medicinal products. It was however generally recognised that such products could not fall outside the scope of both medicinal products and medical device legislation;
- **reprocessing of single-use devices**: the Commission proposal provides rules for reprocessing of single-use devices to make them suitable for further use within the Union. The Presidency believes that a compromise proposal that allows Member States to prohibit re-processing under national law but provides that if not prohibited re-processing should follow minimum harmonised rules could find support from a broad majority;
- **the unique device identification system**: the Commission proposal contains a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows for traceability. Important issues include the functionality of the system, and the nature and scope of requirements;
- **mechanisms for surveillance and appointment of the Notified Bodies responsible for conformity assessment of medical devices and In vitro diagnostic medical devices**: the main subject of controversy is the level of detail laid down in the legislative provisions and, consequently, what had better be left for guidelines;
- **scrutiny mechanism for certain high-risk devices**: almost all delegations state that the scrutiny procedure as proposed by the Commission is not possible to apply. Many delegations argue that a scrutiny mechanism before devices are placed on the market is not necessary. On the other hand, some delegations would wish to include a "pre-market scrutiny mechanism" for implantable devices in the highest risk class "Class III devices". There is scope for a possible compromise on this issue;
- **clinical investigation**: the discussion of the Working Party is currently going in the direction of further aligning the provisions on ethical and methodological principles to those for clinical trials of medicinal products;
- **tasks of the proposed medical device coordination group (MDCG)**: the progress report noted the discussions of the tasks of the MDCG is closely related to many of the other issues still subject to discussion. A central question is the legal status of the opinions from MDCG, where most delegations hold that this cannot be of a binding nature, as this would make it a decision-making body;
- **role of expert panels and reference laboratories**: while most delegations agree that there is a need for such laboratories for in vitro diagnostic medical devices in order to compare predicting powers

of tests, few delegations see the same need as regards other medical devices. Instead, they favour the establishment of expert panels with competence for certain groups of devices.

The Presidency is satisfied to have contributed to the progress of the work and intends to **compile complete texts for both proposals** by the end of its tenancy.