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# EU Rules on Medical Device Approval System Strengthened

Vital measures aiming at improving current approval method and patient safety are endorsed in plenary session, setting a solid discussion base with Member Sates for further improvements, though safety standards of device re-processing still questionable.

Most of the measures aiming to revise the EU Medical Devices Directive (MDD) were adopted this week in a plenary vote by the European Parliament and welcomed by Eucomed, the European medical technology industry association. The vote by Members of the European Parliament (MEPs) for much needed steps to enhance Europe's notified body system contribute to the enhanced traceability and transparency currently applied to medical devices. Furthermore, they introduce unscheduled site visitation and offer increased involvement of stakeholders.

Eucomed is particularly partial to the fact that the entire approach has been directed to a more manageable process by Parliament, all the while maintaining the shared target of enhancing patient safety. The method followed for revised rules on the reprocessing of single-use medical devices however still leaves important patient security concerns and legal inconsistencies. As an example, not subjecting reprocessors to any conformity assessment seems contrary to the European Parliament's aim of introducing a maximum pan-European safety level.
Overall though, Eucomed is convinced that the vote will signal Parliament's interest in achieving an implementable, balanced solution which will ensure improved safety for patients as well as an innovative, vibrant MedTech sector.

The association believes that Parliament and Council will now be in a position to focus even further on these issues and also adopt a scientific and sensible approach to hazardous substances. They are of the opinion that several majorly vital elements of the approval system were improved, i.e. the clarification of various authorities' responsibilities and roles and the introduction of an independent scientific expert task force aimed at supporting the decision making process of the clinical experts and Medical Device Co-ordination Group (MDCG).

In order to avoid augmenting the bureaucracy level further Eucomed would like to see the scrutiny process integrated into the current notified body approval system, thus upgrading it opposed to adding an additional level to it. In Plenary, the industry body was interested to hear Commissioner Mimica's view. He considers potentially moving from product scrutiny in the pre-market stage to a control process taking place post market, once trust has been established in the competence and quality in Notified Bodies.

By not agreeing to the full ENVI proposal that suggests the reusability of syringes by default, MEPs signaled their opposition, though they did not revert to the balanced Commission proposal either. As an alternative they chose a hybrid approach, which in turn displays elements of patient safety deficiencies coupled with legal inconsistencies within the actual definition of 'single-use devices'.

These inconsistencies should be addressed in the upcoming phase of the legislative process in order to ensure that all adopted measures are workable for stakeholders and authorities alike.
Serge Bernasconi, Eucomed Chief Executive Officer, stated "The Parliament has voted for many improvements that will effectively improve patient safety. We believe that this paves the way for further needed improvements to be discussed with the Council". Bernasconi congratulated Parliament on achieving a clearer and more positive approach on a very technical and complex dossier, and concluded that he is looking forward to witnessing further evolution on a tightened EU framework for the approval of medical devices.

Source: Eucomed

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