EU Parliament adopts new diagnostics and medical device regulations, focus now shifts towards implementation

4 April 2017 - MedTech Europe welcomes the final vote of the European Parliament endorsing the new Regulation on *In vitro* Diagnostic Medical Devices (IVDR) and the new Regulation on Medical Devices (MDR). Governing two different types of essential health technologies for citizens, for example blood screening tests (in vitro diagnostics) and pacemakers (medical devices), this vote is the last step in a near eight-year process to update legislation first written in the 90's.

"The new Regulations are welcomed by our industry as these will strengthen patient safety and facilitate access to new and innovative technologies. Medical technologies save lives, improve health and contribute to sustainable healthcare. The Commission, the Council and the European Parliament have recognised the specific and differing nature of the two types of technologies when building these two new regulations and we welcome this vote that allows industry to begin the work needed to transition the two sectors to the new rules within the set timeframes", says Serge Bernasconi, CEO of MedTech Europe.

The official timings for transition start 20 days after the new laws are published in the Official Journal. This is expected in early May, which means an official transition starting date around the 1st of June. The Regulations will be fully applicable in three years for medical devices and in five years for *in vitro* diagnostics medical devices.

Going forward, a successful implementation of the Regulations will be a key priority for MedTech Europe. We welcome the European Commission and national Competent Authorities' initiative to consult stakeholders in developing an official implementation roadmap. A clear roadmap is important to ensure that all players - authorities, notified bodies and economic operators - can successfully transition to the new Regulations

"*A lot of work has gone into these regulations and there is still a lot to do to make them a reality. The amount of effort needed from all parties to implement these revised rules cannot be underestimated. Essential elements, like notified body availability to handle the new requirements, should be dealt with outmost urgency." says Serge. "We hope to continue the collaboration with the Commission, the national Competent Authorities for both in vitro diagnostics and medical devices, the European Parliament and other stakeholders in ensuring that there is minimum disruption for patients, health care professionals and health systems access to needed medical technologies.*"

For the in vitro diagnostics sector, this is a major overhaul of the rules. Whilst, in the large part, the new text brings Europe in line with international regulatory norms in this area, there is still the need for all parties to work together on the needed secondary legislation and European best practice guidance in order to meet the transition deadline. Industry has already pointed to several priority areas including classification, conformity assessment, clinical evidence and the early availability of notified bodies.

For the medical device sector, this new regulation is a modernisation of the original rules, bringing together best practices from existing Commission guidance. With a tight three-year transition period, the areas

where industry has highlighted as priority for agreed harmonised approaches and clarity are the transition provisions, the updated clinical evaluation requirements, the new 'scrutiny' process and the early availability of notified bodies.

MedTech Europe will continue to seek clarity and early stakeholder involvement in the new governance structure development. It is critical that in vitro diagnostics and medical devices are given equivalent level of attention and investment during the development of necessary secondary legislations and European Commission guidance and that pragmatic solutions be found to address the notified bodies' capacity to handle the enormous flow of new and renewal dossiers that these regulations trigger.

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide**.**

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