EU reaches deal over medical devices regulation

By DTI

BRUSSELS, Belgium: The European Parliament and the Council of the European Union have announced a breakthrough in negotiations concerning the overhaul of medical device legislation. After almost four years, the EU bodies have agreed on a new system of quality and safety regulations affecting all medical device manufacturers. The rules are expected to be adopted by early 2017.

Essentially, all devices will have to undergo more thorough assessment of safety and performance before they can be sold on the European market. Control processes are to be radically reinforced, aimed at giving European patients and consumers rapid access to innovative, cost-effective devices. According to the European Commission, manufacturers shall benefit from clearer rules, easier trading between EU countries and an equal competitive environment that excludes those who do not comply with the legislation. The new regulations take particular account of the specific needs of the many small and medium-sized manufacturers in this segment.

The main elements of the law include wider and clearer scope for EU legislation. Software, instruments, apparatus, appliances and implants will all qualify as medical devices and be subject to the new safety and performance requirements. According to the press release, the regulations will help manufacturers to improve their devices continuously based on the latest clinical data and thereby maintain a high standard of quality. A central database will give manufacturers and patients all relevant information, such as certificates and clinical investigations.

Other elements include stronger supervision of independent assessment bodies by national authorities, as well as greater power and obligations for these assessment bodies, to ensure thorough testing and regular checks. Manufacturers should expect unannounced factory inspections and sample testing of devices that are already on the market. In addition, the regulations are intended to establish clearer rights and responsibilities for manufacturers, importers and distributors, which will apply also to diagnostic services and Internet sales, as well as better traceability of devices throughout the supply chain owing to a unique identification number. Finally, patients participating in clinical investigations will be better protected.

According to the Council of the EU press release, the new rules are aimed at ensuring that medical devices and in vitro-diagnostic medical devices are safe in two ways: strengthening the rules on releasing devices to the market and tightening surveillance once they are available. Furthermore, the agreement seeks to ensure that patients have timely access to innovative health care solutions.

For dental dealers, the regulations might jeopardise existing agreements if manufacturers are unable to achieve the level of quality that the new body requires. Furthermore, dental organisations will be forced to cancel preferred supplier arrangements and look elsewhere for partners.

The next steps

In mid-June, the Council of the EU’s Permanent Representatives Committee is expected to endorse the agreement, while the European Council and the parliament will probably follow by the end of the year after a thorough review process. The new regulations will apply three years after entry into force.