New Medical Devices and In Vitro Diagnostic Regulations - Status of the Ongoing Discussions

The approval of the new EU **Regulations on Medical Devices and In-Vitro Diagnostics Devices** will be **postponed** to 2016.

The Luxembourg Rotating Presidency has presented during the Employment, Social Policy, Health and Consumer Affairs Council of the European Union of December 7th, 2015 an information report concerning the status of the ongoing discussions between the **Council**, the **European Parliament** and the **European Commission** (so called trialogues).

Status of the negotiations

So far, 5 informal meetings and 7 technical meetings have tried to reach a **consensus** in view of developing a common text. Nonetheless a consensus is not yet reached among the involved parties.

Even though the negotiations will be extended through 2016, marking a 4th year of discussions since the original **Commission's proposals** in 2012, the **agreement** between the institutions is being finalized and progresses are scored on some sections of the text. For instance, Chapter I (**Scope**), II (**Obligations of economic operators**) and III (**Identification and Traceability**) are now fundamentally agreed among the European Parliament and the Member States.

Consequences for manufacturers

It is expected that in 2016 a fundamental **progress** in the definition of the final text will be achieved.

This will imply that the new Regulations will be soon enforced and become the **new regulatory framework** for medical and in-vitro diagnostics devices in the European Union. Manufacturers will clearly have an added value in relying on the support of professionals in order to **safeguard their operations** in Europe.

Obelis, with its more than 27 years of experience, can offer a full range of **solutions** for the compliance of manufacturers with the **new requirements** of the European legislation and the **CE marking** of their products.

If you want to know more about the **New Medical Devices and In Vitro Diagnostics regulations**, please contact us.