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## EU Medical Device Directive Revision - What's going on ?

The publication of the Commission's revision proposal to the Council and European Parliament should be done during this month of September 2012. However, It will be only the beginning of the Ordinary Legislative Procedure where the Council and European Parliament discuss the proposal and bring amendments in order to agree upon a common text which will be most likely published in early 2014 before the new European Parliamentary elections.
Since the text should be published as Regulations and not as Directives, it will be immediately applicable. However, a transition period should be given in order to allow the manufacturers, notified bodies and national competent authorities for implementation of some of the new rules.

### Background

In reaction to the PIP breast implant case, the EU Commission calls, last February, for a "joint action plan for immediate actions under the current legislations regarding Notified Bodies, market surveillance, vigilance and further actions including the preparation of the revision of the Medical Devices legislation scheduled for adoption in September 2012 which will take into account the results of a 'stress test' that is identifying the shortcomings come to light by the PIP case.
In April 2012, the European Parliament addressed a resolution to the Commission and the Council to seek ways to prevent a PIP-like event. The resolution included among other tools, a pre-market authorization for higher risk medical devices.

### What could be the main changes for manufacturers?

- Unannounced inspections: Under the current legislation, Notified Bodies (NB) may already use their power of unannounced inspections but this is not the case for most of the National Competent Authorities (NCAs) which have to inform 15 days before visiting manufacturers. It is expected that all NCAs will have this new right and probably will use it systematically to inspect the MD manufacturers located in their territory. NCAs will also put pressure on the NB they have designated to increase their numbers of unannounced inspections which was close to zero at the time of the PIP case.

- Notified Bodies: More in deep review by the NB during their conformity assessment, checking and inspecting that all the essential requirements relating to the product have been fulfilled. More prescriptive competence requirements will be probably requested for NB in order to better evaluate clinical data, post-market clinical follow-up and vigilance reports.

- Clinical investigations: Randomized clinical trials could be requested as a first choice when possible. If not, clinical studies for CE marking should be comparative trials.

- Pre-market authorization: High risk/innovative products could be put on the market after the review of the clinical data by the competent authority where is located the manufacturer/authorized representative or by a coordinating body such as a kind of European Heads of Medical Technologies and not by the European Medicines Agency (EMA) which will of course be involved as they are today in so-called drug-device combination products. It could be considered as a pre-market authorization only if this review occurred after the CE marking.

The text of the Commission's proposal should be available this September on the europa website: http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm however such as indicated in my introduction, European Parliament will bring amendments to this proposal which will be subject to discussion before the adoption of the new regulations for medical devices..

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