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EUROLAB Briefing

Strengthening Consumer safety: Improving the safety of medical devices

The European Commission adopted on 24th September, two measures to improve the safety of medical devices fulfilling its commitment to restore patient confidence in the medical devices sector following, amongst others, the Poly Implant Prothèse (PIP) breast implants scandal. The new rules are a Commission Implementation Regulation clarifying the criteria to be met by notified bodies[i], which are responsible for inspecting manufacturers of medical devices, and a Recommendation clarifying the tasks these bodies have to undertake when they perform audits and assessments in the medical devices sector, which covers some 10 000 types of products, from plasters to pacemakers.

Background:

EU Commissioner for Consumer Policy, Neven Mimica, said that *"with today's measures the European Commission further strengthens the safety of medical devices. We now have a clearer basis for unannounced audits, sample testing, or joint assessments by notified bodies. Full clarity can only be achieved through amending the basic legislation. I am committed to support the Parliament and the Council with a view to completing the on-going revision by early next year."*

The measures adopted on 24th September were announced in the **Joint Plan for immediate action** agreed between the Commission and the EU Member States. **The plan focusses on the functioning of notified bodies;** the surveillance by the Member States of the products on the market, EU coordinated investigations and responses to problems with specific devices as well as improved transparency and communication between Member States, industry, health professionals and notified bodies.

Most of the actions agreed upon have now been implemented or are under implementation. The overall progress will be presented in a Commission Staff Working Document to be published in October. In addition, a pilot project of joint audits of notified bodies undertaken by auditors from several Member States and the Commission was launched earlier this year. 11 such audits have taken place and 8 more are planned before the end of the year. These actions have already, before

the adoption of today's measures, resulted two notified bodies been obliged to temporarily stop issuing certificates until deficiencies have been corrected.

Examples of the strengthened requirements laid down in the measures adopted today:

- A Member State shall only designate a notified body after a 'joint assessment' conducted with experts from the European Commission and other Member States. The assessment reports shall be made available to all other Member States.
- Member States are required to carry out surveillance and monitoring of the notified bodies at certain intervals to ensure that they continuously live up to the requirements. If this is not the case, the Member State must withdraw the designation as notified body.
- Knowledge and experience requirements of the staff of the notified bodies to be required by Member States are clarified.
- It is now required that notified bodies shall randomly perform unannounced factory audits and, in this context, check adequate samples from the production. Failure to carry out random checks will result in the suspension or the withdrawal of the designation of the notified body.
- Where risks might be caused by the substitution or adulteration of raw-materials, such as in the PIP-case, a notified body shall also check that the quantity of finished products corresponds to the quantity of the crucial raw material purchased.

For more information please contact: info@eurolab.org or visit the following website where you can find the article in 22 European languages:

- http://europa.eu/rapid/press-release_IP-13-854_en.htm

[i] Notified bodies are independent public or private third party organisations or companies designated by the Member States to carry out control of manufacturers of medium and high risk medical devices. A control made in one Member State is valid for the whole EU. There are about 80 notified bodies for medical devices in the European Union.