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# EUROLAB Special Briefing

## Restoring confidence in medical devices. Action Plan after the PIP scandal tightened control in Europe

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council has discussed the joint actions taken by the European Commission and the Member States to restore confidence following the scandal of defective breast implants produced by the French Poly Implant Prothèse (PIP) company. These measures were included in the Joint Plan for Immediate Actions under the existing Medical Devices legislation (the so-called PIP Joint Action Plan) agreed in 2012 (See IP/12/119).

*"Consumers are safer today than they were when the PIP scandal was discovered", said Neven Mimica, Commissioner for Consumer Policy. "Thanks to close cooperation between Member States and the European Commission, today's rules on medical devices are better enforced. We succeeded in particular to tighten the control of notified bodies. Some key improvements, however, require a reinforced legal basis. This is why I called on the Member States to reach a political agreement before the end of this year in order to allow rapid adoption of this vital dossier."*

The PIP scandal made it clear that immediate improvements in the oversight of medical devices were needed. **This is why the European Commission and Member States agreed on an Action Plan aiming at improving the control on the basis of existing legislation. It focusses on four key areas: the functioning of notified bodies; market surveillance; coordination in the fields of vigilance; communication and transparency.**

The Commission Staff Working Document discussed in the EPSCO Council on 20th June 2014 contains a detailed analysis of the main elements as well as additional work arising from the action plan such as a Commission Recommendation on the use of a specific system for traceability of medical devices adopted in April 2013, ongoing discussion on improving product registers, Member States reports on their market surveillance activities as basis for further improvement, or discussions on incident reporting from medical practitioners and patients.

The analysis shows that on certain aspects of the Joint Action Plan progress has been limited and continued work is necessary until the new legislation comes into force. These aspects concern in particular:

- the organisation of unannounced audits and their effectiveness
- development of a common understanding of market surveillance and better co-ordination and communication on surveillance data
- assessment of how to make best use of registers for providing data and identifying problems on the long term with devices
- identification of mechanisms to detect signals, trends and increased incident frequency more effectively based on a JRC project to be presented mid 2014
- assessment with Member States of the need for, and possibilities of, organising peer training programmes

Further steps have been taken in the implementation of the Joint Plan. However, it is a series of short term measures designed to maximise the potential of existing legislation. A long term solution requires a thorough revision of the legal framework. The adoption of the proposed new Regulations is necessary to solve a number of outstanding issues which are pivotal towards ensuring patient and consumer safety:

- the scope of the legislation
- the governance of the system and its transparency
- certain obligations of notified bodies, in particular in relation to mandatory unannounced audits
- clinical evaluation
- the risk classification of devices and the safety and performance requirements
- the obligations of economic operators
- the reporting of incidents by users and patients to the Competent Authorities
- certain aspects relating to vigilance system and market surveillance
- the role and the functioning of the database Eudamed and the access of notified bodies to Eudamed
- the traceability of devices

*Source and further information:*

http://ec.europa.eu/health/medical-devices/regulatory-framework/pip-action-plan/index_en.htm