Question for written answer E-005758/2015
to the Council
Rule 130
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Subject: Risk of cancer linked to breast implants and the state of play concerning the regulation on medical devices

Five years after the PIP implants scandal, breast implants have once again become a matter for concern. In a report published in mid-March, the French National Cancer Institute (Inca) announced that it had discovered a new illness called anaplastic large cell lymphoma. A total of 173 women around the world, all of whom have had breast implants, have reportedly been diagnosed with the disease.

Breast implants are covered by European rules on medical devices. Manufacturers are required to evaluate their devices before placing them on the market in order to ensure that they meet legal requirements and, above all, that they do not compromise the health of patients. In the case of high-risk devices such as breast implants, a third-party conformity assessment body, called the notified body, is involved in the conformity assessment process.

In 2012, the Commission put forward a regulation on medical devices which was intended to improve patient safety by guaranteeing compliance with rigorous quality and safety standards.

– What is the state of play in the discussions on the regulation?

– Does the Council advocate extending the scope of the regulation to cover certain implantable devices with an aesthetic purpose, as proposed by the Commission and supported by the European Parliament?