In vitro diagnostic medical devices

2012/0267(COD) - 23/03/2017 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Peter LIESE (EPP, DE) on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The committee recommended the European Parliament to approve the Council position at first reading without amendments. It also took note of two Commission statements annexed to the draft legislative resolution.

The Commission:

- undertakes to present, no later than five years after the date of application of the Regulation, a report on Member States experience with the implementation of the obligations concerning the provision of information and counselling in the context of genetic testing;
- specifies that genetic testing intended for wellbeing or lifestyle purposes is not covered by the definitions in the Regulation. Nevertheless, the Commission will monitor specific safety issues which might be linked to the use of these devices.

Councils first reading position is in conformity with the agreement reached during the interinstitutional negotiations. The report is accompanied by a short justification which focuses on the following elements of the approved text:

- obligation for notified bodies to carry out unannounced inspections on the production site;
- strengthening of the provisions on the designation, organisation, monitoring and expertise of the notified bodies conducting the conformity assessment and certification for all devices on the Union market. These bodies shall have permanent availability of sufficient administrative, technical and scientific personnel of notified bodies for them to successfully conduct their conformity assessment activities;
- obligation to submit extra conformity checks on class D devices from a European reference laboratory;
- obligation of the manufacturer to put in place measures to provide sufficient financial coverage in respect of their potential liability concerning defective devices;
- inclusion of clear provisions on informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency as regards clinical trials of medical devices;
- individuals being tested with a genetic test should be provided with all relevant information on the nature, the significance and the implications of the genetic test, including appropriate access to counselling in the case where the test provides information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable;
- strengthening the authorisation procedures and the overall system for traceability of devices, vigilance and post-market surveillance, to ensure constant monitoring and swift reaction should problems arise.