In vitro diagnostic medical devices

2012/0267(COD) - 05/04/2017 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution 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.

A proposal to reject the Council proposal, submitted by the EFDD group, was rejected in plenary by 59 votes to 635, with 9 abstentions.

In line with the recommendation for second reading by its Committee on the Environment, Public Health and Food Safety, Parliament approved the Council position at first reading without amendments.

The proposed Regulation seeks to harmonise the rules for the placing on the market and putting into service of in vitro diagnostic medical devices (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics) and their accessories on the Union market which may then benefit from the principle of free movement of goods.

Parliament took note of two Commission statements annexed to the legislative resolution. With these statements, the Commission:

- will present, no later than five years after the date of application of the Regulation, a report on the Member States' experience with the implementation of the obligations for information and counselling in the context of use of genetic tests;
- stipulated that, with respect to genetic tests intended for wellbeing or lifestyle purposes, devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered by the definitions of the Regulation. Nonetheless, the Commission intends to monitor specific safety issues which might be linked to the use of these devices.