

2012/0267(COD) - 22/10/2013 Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted amendments to the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

The issue has been referred back to the committee responsible. The vote has been postponed.

The main amendments adopted in plenary were as follows:

Relationship to the proposal on a regulation for medical devices: a large part of this proposal on IVD (such as provisions on diabetes, HIV and DNA) is the same as the [Commission proposal for a regulation on medical devices](#).

As for the abovementioned proposal, the amendments cover, for example, the role, the structure and the necessary improvement of the notified bodies, the surveillance system, the setting up of a Medical Device Advisory Committee, the obligation of manufacturers to take liability insurance with sufficient minimum coverage, the joint assessment, the scrutiny, identification and traceability, improved access to information for the general public and healthcare professionals and the role of the Medical Device Coordination Group (MDCG).

Members proposed, in particular, to improve the system of notified bodies. The personnel of the national authority responsible for auditing the work of personnel of notified bodies must have proven qualifications to do their work. Notified bodies shall have permanent "in house" competent personnel and expertise. The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices.

The transparency of fees charged by notified bodies for conformity assessment activities must be ensured.

Parliament also made improvements to the Commission proposal on the following points:

- Ethics committee: the clinical performance study should be positively assessed by an independent ethics committee before it starts. The time limits are slightly extended to give the ethics committee and the authorities the time necessary to assess the proposal.
- Genetic test: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The person concerned must receive appropriate information on the nature, the significance and the implications of the genetic test before the device is used.
- Genetic counselling: appropriate genetic counselling shall be mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. Such counselling shall include medical, ethical, social, psychological and legal aspects and shall be carried out by physicians qualified in genetic counselling.
- Consent: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

Testing of minors and incapacitated subjects: in the case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent shall represent the minors presumed will and may be revoked at any time, without detriment to the minor. In the case of incapacitated subjects who are unable to give informed legal consent, the informed consent of the legal representative shall be obtained.

Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC on clinical trials.

No incentives or financial inducements are given except compensation for participation in the clinical performance study.

Non-discrimination: the text should reflect the UN Convention on non-discrimination on disabled people. Regarding definitions, for example, the term 'congenital abnormality' is viewed by persons with disabilities and their representatives as discrimination, and it is proposed to replace it.

Taking account of the needs of SMEs: in the area of in vitro diagnostic medical devices many companies offering these devices are SMEs, and amendments are proposed in the report to alleviate the burden. For example it must be possible to provide some information electronically and it is also specified that the information accompanied the product shall be provided in an official union language and not in any other language.

Advisory Committee: Parliament called for a multidisciplinary Medical Device Advisory Committee (MDAC) to be set up which should be composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.

Scope: the amended text stated that certain devices may only be supplied on a medical prescription, particularly Class D devices (high risk) and Class C devices in the following categories: (a) devices for genetic testing; (b) companion diagnostics.

Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.

Delegated acts: basic aspects elements of the Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.

Application of the Regulation: Members proposed that the Regulation should be applicable three years after its entry into force, whereas the Commission had proposed five years.

