In vitro diagnostic medical devices

2012/0267(COD) - 10/10/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Peter LIESE (EPP, DE) the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

The committee recommends that the position of Parliament adopted in first reading following the ordinary legislative procedure should amend the Commission proposal 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. These parts have been assessed together in the two reports. The amendments cover, for example, the role, the structure and the necessary improvement of the notified bodies, the surveillance system, the joint assessment, the scrutiny, identification and traceability 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.

The report also made improvements to the Commission proposal on the following point :

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 minor’s 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.

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.

Scope: the amended text states 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.

‘Companion diagnostic’ means a device specifically intended for and essential to the selection of patients with a previously diagnosed condition or predisposition as suitable or unsuitable for a specific therapy with a medicinal product or a range of medicinal products.

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 propose that the Regulation should be applicable **three years** after its entry into force, whereas the Commission had proposed five years.