Amendment 255
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Recital 59 c (new)

Text proposed by the Commission	*Amendment*
	(59 c) Genetic testing can present risks to patients if not performed within an appropriate framework of healthcare. The implications of the result of a predictive genetic test may present psychosocial risks to the patient, and therefore, such testing should be undertaken with due regard to these implications, providing appropriate information and counselling by persons qualified to provide such counselling where necessary. Member States should ensure that applicable legal, ethical, and professional standards are respected. The Commission and Member States should ensure that the risks presented by over-the-counter and online sales, as well as the impact of those sales on Member State prescription policies, are addressed in a suitable framework.

Or. en

Amendment 256
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 4 b (new)

Text proposed by the Commission	*Amendment*
	Article 4b
	Genetic testing
	1. Within one year after the entry into force of the present Regulation, the Commission, in consultation with Member States and stakeholders, shall develop guidelines on the safe use of genetic testing within a framework of healthcare, taking into account the OECD Guidelines for Quality Assurance in Genetic Testing, as well as the need to ensure patient safety and confidentiality through appropriate information and counselling.
	Those guidelines shall take into account market developments such as direct-to-consumer sales, including online sales, and the impact of these sales on domestic prescription policies.
	2. The provisions of this Article on the use of devices for the purpose of genetic tests shall not prevent the Member States from maintaining or introducing, for reasons of public health protection, more stringent national legislation in this field.

Or. en

Amendment 258
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 41 c (new)

Text proposed by the Commission	*Amendment*
	Article 41c
	Network of special notified bodies
	1. The Commission and the MDCG shall establish, host, coordinate and manage the network of special notified bodies.
	2. The network shall have the following objectives:
	(a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of in vitro diagnostic medical devices;
	(b) to contribute to the pooling of knowledge regarding in vitro diagnostic medical devices;
	(c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;
	(d) to help identify the experts in innovative fields;
	(e) to develop and update rules on conflicts of interest; and

(f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies;

(g) to identify and notify significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices and to communicate these to the MDCG;

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall meet at least twice a year.

Or. en

Amendment 259
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 44 a (new)

Text proposed by the Commission	*Amendment*
	Article 44a (new)
	Additional assessment procedure in extraordinary cases
	1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76b.
	2. Within 20 days of receipt of the information referred to in paragraph 1,

the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evidence report and the clinical performance study report as referred to in Annex XII,

- data obtained from the post market follow-up referred to in Annex XII, and

- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries.

The members of the MDCG shall decide on making such a notably on the basis of the following criteria:

(a) the novelty of the device with possible major clinical or health impact;

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of a request from the

MDCG within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assesment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall inform the Commission, the Special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the Special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the Special notified body shall forward to the MDCG the detailed grounds for the request within 30

days after receipt of the opinion. The MDCG shall immediately transmit this information to the Commission

Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MDCG shall send its final opinion to the Commission, the Special notified body and the manufacturer.

8. In case of a favourable MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device or group of devices concerned and adopt them where possible.

In case of an unfavourable MDCG opinion, the special notified body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted, the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing

allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the Special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13 The company concerned shall not be charged for the additional costs due to

this assessment.

Or. en

Amendment 260
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 76 b (new)

Text proposed by the Commission	*Amendment*
	Article 76b
	Assessment Committee for Medical Devices
	1. An ACMD is hereby established, under the principles of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest.
	2. When undertaking a clinical assessment for a specific device, the ACMD shall be composed of:
	- a minimum of 5 clinical experts in the field of which a clinical assessment and recommendation have been requested;
	- one representative of the EMA;
	- one representative of the Commission;
	- one representative of patients' organisations appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed.
	The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its clinical assessment and recommendation.

The Commission shall be responsible for providing the secretariat of this Committee.

3. The Commission shall establish a pool of clinical experts in the medical fields relevant to in vitro diagnostic medical devices being assessed by the ACMD.

In order to undertake the clinical assessment and recommendation procedure, each Member State may propose one expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year term which may be renewed.

The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the fields referred to in the first subparagraph of this paragraph.

4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation,

the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. Any diverging opinion shall be annexed to the ACMD opinion.

5. The ACMD shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

- the adoption of opinions, including in case of urgency;

- the delegation of tasks to reporting and co-reporting members.

Or. en

Amendment 261
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 77

Text proposed by the Commission	*Amendment*
Tasks of the MDCG	
The MDCG shall have the following tasks:	The MDCG shall have the following tasks:
	(-a) to provide regulatory opinions on the basis of a scientific assessment on certain types of in vitro diagnostic medical devices pursuant to Article 44a;
(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;	(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;
	(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;
	(ab) to review and approve the criteria of the competent authorities of Member

	States in respect of point (aa);
	(ac) to oversee the coordination group of Notified Bodies as specified in Article 37;
	(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 25;
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;	
(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;	(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;
(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;	(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;
(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;	(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;
(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.	(f) to contribute to harmonised administrative practice with regard to in vitro diagnostic medical devices in the Member States.

Or. en

Amendment 262
Rebecca Taylor
on behalf of the ALDE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40a) Clinical expertise and specialist product knowledge within notified bodies, Special notified bodies and the Medical Device Coordination Group should be appropriate for the specifications of in vitro diagnostic medical devices. Clinical experts should have expertise in clinical interpretation of in vitro diagnostic results, metrology and Good Laboratory Practice. Clinical experts and product specialists should have expertise in fields such as virology, haematology, clinical analysis, genetics.

Or. en