EU Regulation on in-vitro Diagnostic Medical Devices – *call for urgent action*.

The European Commission issued a proposal for a new Regulation on in vitro diagnostic devices in September 2012. At the committee stage in the European Parliament, the Rapporteur Peter Liese, MEP introduced an entirely new article into this proposed Regulation. The article is focused on the practice of genetic medicine, and seeks to regulate what happens in clinics and hospitals where patients may have a genetic test as part of their medical care.

In May 2013, the European Society of Human Genetics issued a position statement opposing this new article, stating that the provisions of the article were "unworkable in the daily practice of genetic medicine."

A version of the Regulation containing this new article was recently passed by the committee, and will be voted on at the European Parliament on October 21. It is very important that this article is removed at the European Parliament vote, or it may become European law.

This article tries to regulate medical practice via device regulation. The proposed IVD Regulation mostly covers actors (i.e. device manufacturers) that are at least two steps removed from the patients- it is not at all clear how the proposed IVD Regulation can be used to regulate the users of the devices (i.e. laboratory personnel), and even they are not the people practicing medicine and seeing the patients. This creates a burden on the users of the device to determine, in some unspecified way, that the requirements of this article have been met. These requirements include, for example "t*hat the rights, safety and well-being of the test subjects are protected*", that genetic counselling should be "*appropriate and comprehensible*" and should "*include medical, ethical, social, psychological and legal aspects*".

Medical practice, (including Genetic Medicine) is organized and delivered in many different ways in different Member States. This proposed article encroaches on this diversity and seeks to dictate in detail the arrangements for every clinic where a genetic test may be ordered. It insists on the direct involvement of a medical doctor in every patient interaction, where, in reality, it is common practice for genetic tests to be ordered by other healthcare professionals such as genetic counsellors under the supervision of a medical doctor. Marvellous advances in genetic science are bringing genetic testing into every area of medicine. The proposals set out here seek to impose a single restrictive template on all genetic tests; this is unworkable and can only impede the progress of medical practice in the EU.

These proposals are utterly impracticable. Furthermore, they are unenforceable, unless IVD regulatory bodies are going to start visiting genetics clinics to monitor what goes on between a doctor and patient before a genetic test is ordered.

We have set out the Rapporteur's proposed text in Appendix 1 below and provided responses alongside each paragraph, explaining why this law would be so damaging.

EuroGentest agrees with the European Society of Human Genetics position that these proposals are unworkable and would inevitably mean that "fewer, not more, patients would benefit from genetic testing".

ESHG and EuroGentest opposed this proposal at the committee stage, but the committee narrowly voted to retain it. We now feel that the best way to defeat this proposal is to support an alternative proposal from British MEP Rebecca Taylor. The text of this proposal is set out in Appendix 2 below.

EuroGentest also supports an alternative amendment (Amendment 40) which says that devices for genetic testing should be prescription-only; i.e. genetic tests should only be ordered by a doctor. In our opinion, this restriction will protect patients from abusive direct marketing of genetic tests, without restricting medical practice. This amendment, which addresses the marketing of IVDs, is clearly within the scope of the Regulation. The proposals on the practice of genetic medicine are clearly outside the scope of a Regulation on IVD Devices.

EuroGentest urges you to contact your MEPs urgently before October 21 and urge them to vote against Article 4a (Amendment 72) and in favour of Amendment 40. To ensure that Amendment 72 is removed, they should support MEP Rebecca Taylor's alternative text (see Appendix 2 below).

You can find details of your MEPs at http://www.europarl.europa.eu/meps/en/map.html

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About EuroGentest

EuroGentest is a Network of Excellence promoting harmonization and quality in genetic testing, established in 2005 under the EU 6th Framework and now funded as a Coordination Action in FP7. EuroGentest represents many hundreds of laboratories and genetics centres across all EU member states and beyond.

Quality is at the heart of EuroGentest's mission. EuroGentest maintains that only high quality, clinically and

analytically valid diagnostic tests should be performed in clinical laboratories. EuroGentest promotes accreditation to appropriate international standards such as EN ISO 15189:2007 “Medical laboratories — Particular requirements for quality and competence”. EuroGentest also maintains that accreditation, regular participation in external quality assessment schemes (which are themselves accredited) and adherence to professional guidelines such as those produced by the European Molecular Genetics Quality Network, ensures the availability of safe, effective, appropriate, and patient-oriented genetic testing. Furthermore, the OECD has issued Guidelines for Quality Assurance in Molecular Genetic Testing, which state “All molecular genetic testing results for clinical care purposes should be reported by competent laboratories, as established by accreditation or other equivalent recognition”.

EuroGentest has sought to explore how the EU’s IVD regulations can further our goal of a harmonised approach to improving the quality of genetic testing in the EU. Our approach has three main strands:

1. Clarifying requirements for clinical genetics labs, e.g. reference materials
2. Promoting more rigorous approach to regulation of the commercial genetic testing sector (kit manufacturers and commercial laboratories)
3. Exploring the potential of IVD regulation as a mechanism for mandatory laboratory accreditation for commercial and public sector laboratories

Information on EuroGentest’s previous work on the regulation of genetic testing and IVDs can be found at www.eurogentest.org/web/info/public/IVD.xhtml

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Appendix 1 – Text of proposed new law on genetic testing (Amendment 72)

Note: **Although amendments to the text are suggested below, our recommendation (on behalf of EuroGentest) is that this proposed article should be deleted entirely.**

Amendment 72

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*	**EuroGentest Analysis**
	Article 4a (new)	
<none>	***1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.***	The wording does not make it clear who should have a "personal consultation", or with whom. It can be read to mean that persons are admitted to the medical profession after a personal consultation. **This paragraph should be deleted**
	2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.	While laudable in its intentions, this provision goes well beyond the regulation of IVDs into the practice of medicine and areas of patient well-being which are beyond the control of the test manufacturer, the end-user of the device or even the clinician seeing the patient. **This paragraph should be deleted**
	3. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.	The meaning of this paragraph is unclear, as no specific person is mentioned in paragraph 1. If it means the clinician ordering the test, (s)he will not usually be "using a device", that is done by laboratory personnel. Genetic testing is organised in different ways in different Member States: information about the test will not always be given by a medical doctor. **This paragraph should be deleted**
	4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has	This text does not specify who should have genetic counselling; in fact it seems to suggest that the user of the device should receive the counselling. The meaning of "*has to be addressed by physicians qualified*

	been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians qualified in genetic counselling.	*in genetic counselling*" is not clear. Again, the users of IVDs have no control over what happens between the clinician and his/her patient. The suggestion that counselling should be given (to the patient) "after a genetic condition has been diagnosed" is all very well, but it has nothing to do with the IVD. **This paragraph should be deleted**
	The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.	
	5. 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.	The wording is hopelessly vague. It is unclear who the "person concerned" might be; it appears that this person must consent to the device, rather than the test. Even assuming that this paragraph is addressing informed consent for the test from the patient to be tested, this again mixes up laboratory diagnostics and the practice of medicine. The laboratory which carries out the test is not in a position to judge whether the consent obtained is "free and informed" Explicit consent in writing is not routinely obtained in newborn screening programmes and in many other areas of genomic medicine. A requirement for explicit written consent is excessively burdensome for low-risk genetic tests (e.g. FV Leiden). Consent cannot be revoked after a test is carried out and results released or, if it is, this revocation has no real meaning. **This paragraph should be deleted**
	6. Testing of minors and incapacitated subjects. In case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in	This paragraph has dropped even the pretence of being a regulation of IVD devices. Again, the users of IVDs have no control over what happens between the clinician and his/her patient. It is

	accordance with national laws; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated subjects not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will of the incapacitated subject and may be revoked at any time, without detriment to the person.	entirely unclear who will be policing these proposed regulations. Clinicians are already bound by national laws; this does not need to be re-stated in an EU Regulation. Consent cannot be revoked after a test is carried out and results released or, if it is, this revocation has no real meaning. **This paragraph should be deleted**
	7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation of Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.	This paragraph could (presumably inadvertently) outlaw large areas of current genetic testing practice. Gender-checking forms an important part of all prenatal karyotype analyses, even when no specific risk of a gender-specific hereditary disease exists. Increasingly, genomic tests which reveal the gender of the foetus are quite properly used in prenatal diagnosis. Derogations from the fundamental definitions of a medical device and an IVD medical device indicate either a deficiency in the definitions or a logical flaw in the proposed legislation. This derogation would be unnecessary if, as suggested by us and others, "lifestyle tests" and all predictive tests are included in the scope of the Regulation. **This paragraph should be deleted**
	8. The provisions of this Article on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.	

Appendix 2 – Text of amendment to be proposed by MEP Rebecca Taylor

Note: Recitals come at the beginning of a legal document and set out the motivation for the Articles that follow.

Recital 59(c) new

Motion for a resolution	*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 these on Member State prescription policies, are addressed in a suitable framework.

Motion for a resolution	*Amendment*
	Art 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.
	These 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.