

## **Call for action on the proposed EU Regulation on In-Vitro Diagnostic Medical Devices**

Recent amendments to the proposed Regulation on In Vitro Diagnostic Medical Devices (IVDs) currently before the European Parliament will restrict the rights of patients and doctors to carry out essential genetic testing, says the European Society of Human Genetics (ESHG). Furthermore, an independent legal opinion now shows that the European Union (EU) has no competence to enact the Regulation as amended by the Parliament.

The new Regulation was proposed by the European Commission in order to bring the regulation of diagnostic kits or IVDs up to date. The ESHG has welcomed the Commission's proposal as it will 'improve the quality, safety availability and oversight of IVDs marketed and used in the European Union.'

However an amendment (known as Amendment 271) proposed by German MEP Peter Liese at the EU Parliament's ENVI Committee, calls for mandatory detailed genetic counselling to accompany every genetic test and holds the person carrying out a genetic test responsible for the rights, safety and well-being of the test subjects. The amendments say that genetic counselling should be appropriate and comprehensible and that it should include medical, ethical, social, psychological and legal aspects. These are praiseworthy objectives with which no-one would disagree, but they are well beyond the scope of a regulation on the safety of IVDs.

Medical practice, including genetic medicine, is organised 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 in the Liese amendment 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

The new legal opinion, from the respected life science law firms Lawford Davies Denoon and Axon Lawyers, says that because the proposed amendments are outside the competence of the EU, if a Regulation were to be enacted incorporating the new articles, it could be challenged on the grounds of 'infringement of the principle of subsidiarity by a legislative act.'

The European Parliament has passed this amendment (along with many contradictory amendments). It now falls to the EU Member State Governments to agree a position on the proposed Regulation and to enter negotiations with the Parliament on a final text.

The ESHG now calls on each National Human Genetics Society to contact their own Department of Health to urge them not to accept Mr Liese's proposed Amendment 271 on "Genetic Counselling". Societies should also contact the Competent Authority for Medical Devices in their country, as officials from the Competent Authorities are involved in the day-to-day negotiations. A list of national competent authorities can be found at [http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national_en.pdf)

National Societies should also lobby their newly-elected MEPs once they take office. A full list of MEPs can be found at <http://www.europarl.europa.eu/meps/en/full-list.html>

The Executive Summary of the new legal opinion is attached as Annex 1.

The full text of amendments approved by the European Parliament is at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2014-0267&language=EN&ring=A7-2013-0327>

## Annex 1 – Executive summary of the new Legal Opinion

### New legal opinion finds EU does not have the power to enact radical genetic counselling laws

On 2 April, 2014, the European Parliament adopted a radical new article to a proposed Regulation on *in vitro* diagnostic devices<sup>1</sup>. The European Commission had intended the IVD Regulation to ensure the safety of IVDs, but Parliament's amendments took the proposed legislation into an entirely new realm. The new article aimed to regulate *how (and by whom) patients are counselled before a genetic test is even ordered*. If adopted by the EU Council, the legislation will mark an unprecedented interference by the European Union in clinical practice and the rights of patients. The European Society of Human Genetics has previously stated that the proposed article would be "*unworkable in the daily practice of genetic medicine*". An independent legal Opinion by members of the Alliance of European Life Science Law Firms (the "ESHG/Alliance Opinion"), produced after Parliament's endorsement of these amendments, now shows that the European Union lacks any power to put them into law.

#### The nature of the amendments

EuroGentest (a European Commission-funded project to harmonize the process of genetic testing in Europe to ensure high quality and accurate and reliable results), has summarised the proposed article as follows:

'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 would create 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 "*that 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*". All laudable objectives, surely, but well beyond the scope of a Regulation on the safety of IVDs.

'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 restrict legitimate, ethically-acceptable genetic testing activities such as newborn screening and foetal sex determination, and they infringe on accepted and acceptable clinical practice when they should be regulating IVDs, effectively highjacking a sound and important directive to interfere with carefully regulated clinical practice and infringing on patients' autonomy.'

'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.'

<sup>1</sup>The proposed Article is Amendment 271 at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2014-0267&language=EN&ring=A7-2013-0327>

## **The EU lacks the power to enact the article**

The amendments adopted by the European Parliament in October first appeared in an Opinion (the “Passau Opinion”) written on behalf of the European People’s Party Group at the request of its MEP, Peter Liese. Dr Liese, who was Rapporteur of the committee with primary responsibility for reviewing the proposed IVD Regulation, copied the Passau wording into his Report to Parliament, with an assurance, also founded on the Passau Opinion, that the Union had the competence to enact it. However, as the ESHG/Alliance Opinion now explains in comprehensive detail, the European Union has no such power.

Among the reasons for the EU’s lack of legislative competence, the Alliance authors cite the following:

### Principles of proportionality and subsidiarity

Under the principle of conferral, the European Union competences are restricted to those conferred on it by Member States in the Treaties. Those not conferred remain with the Member States.

Outside the realm of its exclusive competence, the principles of proportionality and subsidiarity forbid the Union to act unless, and only to the extent that, the objectives of its proposed action cannot be sufficiently achieved by Member States, but can be better achieved at the Union level by reason of the scale or effects of its proposed action.

The Alliance authors found no evidence that the Liese amendments reflect these principles. If a Regulation were to be enacted incorporating the proposed article, those directly affected could institute proceedings against the European Union in the Courts of Justice of the European Union “*on grounds of infringement of the principle of subsidiarity by a legislative act.*”

### Harmonisation of the practice of medicine

The Passau Opinion relies specifically on Articles 114 & 168 of the Treaty of the Functioning of the EU to state that it has the competence to harmonise the practice of medicine with respect to the IVDs, by obliging Member States to change practices, if they have not adopted these already, and prescribing a detailed and mandatory process for the practice of medicine involving IVDs for genetic testing. However, the Alliance authors observe that earlier case law specifically prohibits the Union from taking such an action using Articles 114 and 168 in the manner advocated in the Passau Opinion.

### Competence to legislate on bioethical matters

The Passau Opinion asserts that the jurisprudence of the Court of Justice of the European Union in the field of bioethics has expanded significantly in cases such as *Bristle v Greenpeace* and that this validates a general extension of Union competence to legislate on bioethical matters.

The Alliance authors explain that the European Union’s competence to produce bioethical legislation remains restricted in a way that prevents it from enacting the Liese amendments. Not only is the Passau Opinion incorrect in applying the concept of “human dignity” to non-persons, but the Charter of Fundamental Rights, the Convention on Human Rights and the

case law of the European Court of Human Rights prevent any such extension of competence. Despite the rhetoric of the *Brüstle* judgment, for example, the Court is powerless to force Member States to breach the World Trade Organisation Agreement, which they would do by following it. Judgments of the Court are therefore inherently restricted and can do nothing to expand Union legislative competence.

The ESHG/Alliance Opinion also notes an inconsistency in the Passau authors' attempt to use OECD Guidelines on best practice to support their radical proposals; The OECD Guidelines say:

*“Pre and post test counselling should be available. It should be proportionate and appropriate to the characteristics of the test, the test limitations, the potential for harm, and the relevance of test results to individuals and their relatives.”*

The inflexible compulsion of the Passau Opinion (and Peter Liese's proposal) supplants the OECD requirement of proportionality and appropriateness. In effect, it removes the clinical discretion that the OECD Guidelines seek to inform, replacing best practice with a blunt, EU-level intervention.

The Alliance authors, Erik Vollebregt and Julian Hitchcock, conclude that

*“...the European Parliament's amendments to the draft legislative act are not within the scope of the European Union's legislative competence. It is regrettable that the European Parliament has been misled and, as a matter of procedure, it now falls to the Council of the European Union to consider the proposals in the light of its true competence.”*