

Joint statement on the potential impacts of the proposed In Vitro Diagnostic Medical Devices Regulation 2012/0267(COD) and amendments on genetic testing provision

The regulatory framework governing medical devices in the European Union is currently being revised in order to account for scientific developments and provide a regulatory framework for in vitro diagnostic medical devices that is fit for purpose.

We broadly support the Commission's proposals, although **we have a number of significant concerns with the amendments adopted by the European Parliament to the proposed In Vitro Diagnostic Medical Devices Regulation, which could have damaging effects on the provision of genetic tests for patient benefit and could potentially limit the uptake of new healthcare innovations.** In April 2014 the European Parliament adopted as its position the text agreed at the plenary meeting of the Parliament in October 2013.¹

Amendments of most concern to us are set out below. Overall, we recommend that EU institutions and Member States oppose amendment 271, as detailed below, and that the European Parliament and Council work to ensure that the updated regulatory framework is fit for purpose and proportionate, while reflecting current scientific developments and clinical practice.

Amendment relating to genetic testing:

Amendment 271 as adopted by the European Parliament proposes to **establish very specific requirements for the use of genetic tests**, including: provisions requiring medically qualified personnel to conduct tests; specific information to be provided prior to testing; mandatory genetic counselling to be provided prior to testing; and explicit consent to be required for every test.

We believe that amendment 271 risks restricting access to genetic testing, and ongoing diagnosis, targeted interventions and treatment. It also risks hindering the uptake of beneficial technologies across different clinical areas. This is significant given that genetic and genomic technologies are increasingly becoming part of mainstream care for a number of conditions such as cancer, heart disease and dementia. Requirements for consent and counselling need to be proportionate, taking into account the nature of the test and the likely implications of the information for the patient and their family.

We also draw your attention to the legal opinion by the Alliance of European Life Science Law Firms, backed by the European Society for Human Genetics.² This highlights concerns that the European Parliament lacks the statutory power to legislate in this area on the basis that these proposals are outside the scope of the European Union's legislative competence: the principles of subsidiarity and proportionality prevent imposing medical-ethical requirements for the practice of medicine.

Action: oppose amendment 271.

¹ <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2013-0427&language=EN>

² https://www.eshg.org/fileadmin/eshg/documents/IVD/ESHG_Opinion_19_February_2014_final.pdf

Amendment relating to the scope of the Regulation:

Amendment 42 proposes to widen the scope of the Regulation to encompass devices intended to be used for “direct or indirect medical purposes” including “providing information concerning direct or indirect impacts on health”. This would extend the regulatory reach to products having an ‘indirect’ effect on health through information provision, such as health and lifestyle ‘apps.’ Expanding the scope of the Regulation in this way without appropriate guidance could lead to lack of clarity regarding what devices are within scope. This may lead to delays in access to innovative products with the potential to enhance the quality and efficiency of healthcare and the health of individuals, without a corresponding contribution to improving patient safety. App and other software development is a dynamic area of innovation which should be regulated proportionately, and without additional clarity this amendment could unduly impact on the competitiveness of the EU in this sector.

Action: review amendment 42.

Amendment relating to the requirement for medical prescription:

Amendment 268 provides some scope for derogation from the requirement that certain class D tests can only be supplied on a medical prescription, on the basis of the need for public health protection. However, Amendment 268 also proposes that this derogation is not available for class C devices such as genetic tests and companion diagnostics even if this can be justified on the basis of public health need. A blanket requirement for medical prescriptions for genetic and genomic tests and companion diagnostics is disproportionate and could limit their potential for improved health care as these tests become an increasingly mainstream part of generalised healthcare. If the principle of a derogation on grounds of high public health protection is accepted, consideration should be given to extend this to applicable class C tests provided that appropriate justification can be demonstrated, and appropriate safeguards are in place: this is necessary in order to maintain a flexible and proportionate regulatory approach.

Action: review amendment 268.

Overall, the Regulation must aim for an appropriate and proportionate framework that favours and facilitates devices with proven clinical utility, while discouraging the direct marketing of devices of little or unproven clinical utility.

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Signatories to the statement



Further information and background

Genetic counselling:

The requirement for genetic counselling to be delivered by medical professionals is **not consistent with current practice in some Member States, including the UK**, where genetic counsellors are widely used to deliver genetic counselling, supported by guidance from medical practitioners. A narrow interpretation of this amendment, that medical practitioners should 'conduct' the test, would **restrict the delivery of genetic counselling to members of the medical profession and exclude this highly trained group of health care professionals from the legitimate delivery of healthcare**. Other examples include the delivery of routine prenatal screening tests by midwives, which would fall under the definition of genetic tests under these amendments. Moreover, as novel genomic tests are developed, their scale and complexity will mean that clinical bioinformaticians rather than medical professionals will be best equipped to interpret test significance.

Requirements for consent:

We are concerned that the requirement for informed consent for individual genetic tests, and for mandatory genetic counselling, might be interpreted in a way that **places disproportionate burdens on health services; especially as the use of genetic tests becomes increasingly routine in a range of clinical contexts**. Both these requirements assume that genetic tests are used solely for the prediction or diagnosis of serious inherited genetic disorders. However, genetic tests are increasingly being used in other clinical areas, such as the testing of cancer genomes to predict progression or sensitivity to specific treatments. In addition, the testing of risk factors, including genomic biomarkers, predisposing to common complex disorders such as heart disease is likely to become increasingly widespread. Here the information will usually be risk-based rather than biologically causative.

While such tests will create a critical need for healthcare professionals to be able to communicate this information effectively to patients, additional specialist genetic counselling may not always be required, although this will be the case for certain conditions where testing can have significant consequences (such as Huntington's disease). **Hence, care should be taken to ensure that requirements for consent and counselling are proportionate, reflecting the nature of the test, and the condition being tested for.**

In short, the proposals within amendment 271 are at odds with scientific and clinical developments, and ensuring compliance with these requirements would become increasingly limiting and unworkable.

These proposals could also **unnecessarily restrict the uptake of novel genomic technologies**; particularly as whole genome sequencing becomes an increasingly widespread part of front line care. The form of consent that should be used when a single test is used across multiple conditions has yet to be resolved. The requirement for explicit and written consent therefore has the potential to hinder future professional development and technological uptake in this area by introducing restrictions on the circumstances and practices around the provision of such tests, and we believe it is premature to attempt to regulate in this manner in the absence of agreed best practice.

Overall, regulation of this area must be flexible and proportionate to ensure the development of high quality products, while encouraging appropriate information provision for their use and taking account of current and future technological developments and clinical practice.