

Petition on the proposed EU Regulation on In-Vitro Diagnostic Medical Devices

Recent amendments to the proposed Regulation on In Vitro Diagnostic Medical Devices (IVDs) passed by the European Parliament will restrict the rights of patients and doctors to carry out essential genetic testing. 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 oversight of diagnostic kits (or IVDs) up to date. The European Society of Human genetics (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 amendment 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.

We, the Presidents of the National Human Genetics Societies throughout Europe, welcome the European Commission's proposed new Regulation on IVD Medical Devices. However, we deplore the diversion of this important Regulation from its proper purpose by the European Parliament. For the benefit of patients and families affected by genetic disorders, we call on our Governments to take note of this new legal opinion and to reject Amendment 271 in all future negotiations on the proposed Regulation.

Signed,

Presidents, National Human Genetics Societies.
(full list below)