Medical Xpress

EU Regulation on Medical Devices still poses dangers to patients' interests

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The proposed Regulation on In Vitro Diagnostic Medical Devices (IVDs) negotiations, currently at the stage of tripartite negotiations between the Council (representing Member State governments), the European Parliament, and the European Commission, still risks restricting the rights of patients and doctors to carry out essential genetic testing, says the European Society of Human Genetics (ESHG) today (20 October 2015) in a statement issued by a range of organisations representing geneticists and patients.

Although amendments trying to limit the use of genetic testing are not included in the Council proposals, the ESHG, together with the Wellcome Trust, the Public Health Genomics Foundation, the European Alliance of Genetics Networks, is concerned that the Parliament may try to reinstate their amendment 271, whichcalls for mandatory detailed genetic counselling, including medical, ethical, social, psychological and legal aspects, 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. Another Parliamentary amendment, number 268, says that all genetic tests should be prescription-only, which would limit the application of genetic testing in screening programmes and hinder the work of qualified genetic counsellors.

Last year, ESHG commissioned a legal opinion which asserts that Amendment 271 goes beyond the legal powers of the EU to regulate medical practice.

Speaking for ESHG, Dr David Barton, from the Department of Clinical Genetics, Our Lady's Children's Hospital, Dublin, Ireland, said:

"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.

"We are gravely concerned that these proposals, as they stand, restrict legitimate, ethically-acceptable genetic testing activities such as the screening of new-born babies. They infringe on accepted and acceptable clinical practice when they should simply be regulating IVDs, effectively hijacking a sound and important Regulation to interfere with carefully regulated clinical practice, and infringing on patients' autonomy. We speak on behalf of bodies representing patients, professionals, and policymakers in medical genetics when we say that there is no support for these amendments among those who will be most affected by the Regulation."

The joint statement uses case examples to illustrate how the Parliament's proposals would unintentionally impede the daily work of clinical geneticists, genetic counsellors and other healthcare professionals, to the detriment of patient care.

Provided by European Society of Human Genetics

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