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European Society of Human Genetics

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Dear colleagues,

Proposed new EU Regulation on *in vitro* Diagnostic Devices

You will be aware that the EU regulations on *in vitro* diagnostic devices (IVDs) are currently being revised. In 2012, the Commission published a proposed new Regulation. The European Parliament considered the proposal and proposed over 700 amendments. One of these, Amendment 271, attempts to change the purpose of the regulation to dictate practice in Clinical Genetics. The ESHG has issued a position statement deploring this amendment. Last year at the ESHG conference, 35 presidents of National Human Genetics Societies signed a petition calling on EU governments to reject this amendment. Last month, the Council (representing the governments) published its proposals for the IVD Regulation. Amendment 271 is not included in the Council proposals, which is a welcome development. However, the Council, Commission and Parliament have now started "Trilogue" negotiations to establish an agreed text, and the Parliament will be trying to get Amendment 271 restored into the Regulation.

The ESHG has formed an alliance with the Wellcome Trust, the Public Health Genomics Foundation, the European Alliance of Genetics Networks and others to produce a position statement on Amendment 271 and another amendment (268) which addresses genetic tests being prescription-only.

It is very important that the negotiating teams are informed by professionals in the field of the possible consequences of the implementation of these amendments. The National Human Genetics Societies should contact their Departments of Health and their regulatory authorities immediately with the petition and the joint statement, to inform these negotiations.

In these contacts, please emphasise that the joint statement comes from bodies representing patients, professionals and policymakers in medical genetics - there is no support for Amendment 271 amongst those most affected by this regulation.

A list of national regulatory bodies ("Competent Authorities") is linked below.

The joint statement and signed petition are attached to this letter.

Please do not hesitate to contact me if you have any questions.

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The previous ESHG position statement, with links to the legal opinion, is at
https://www.eshg.org/566.0.html
The European Parliament's page on the revision of the IVD Regulations is at
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2013-0427&language=EN&ring=A7-2013-0327 (with links to other relevant documents)

A list of national regulatory bodies and contact points is at
http://ec.europa.eu/health/medical-devices/files/list-of-vigilance-contact-points-within-the-national_en.pdf