

Proposed amendments to EU Regulation on Medical Devices are counter to patients' interests and unworkable, says ESHG

The new Regulation was proposed by the European Commission in order to bring the regulation of diagnostic kits or In Vitro Devices 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.

Dr David Barton, speaking on behalf of the ESHG 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. “

says Dr Barton

“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.”

New workshop format:

ESHG goes TEDEX Success stories from developing countries

Members from underprivileged countries can upload on ESHG website

2-minute stories about diagnosing, or treating , or otherwise encountering a “patient that changed my life“

The best 5 (or so) will be invited to tell these stories on stage in a special workshop with a moderator

Aim: Active participation in the meeting accross Europe

Organiser: Milan Macek