



The Royal College of Pathologists

Pathology: the science behind the cure

Dr Peter Liese MEP
Europäisches Parlament
Rue Wiertz
Altiero Spinelli 10E158
B-1047 Brüssel

26 June 2013

Dear Dr Liese,

Proposal for a Regulation on *in vitro* diagnostic devices: 'in house' exemption

I am writing on behalf of The Royal College of Pathologists. The College is a professional membership organisation with charitable status, concerned with all matters relating to the science and practice of pathology. The College's objectives are to advance the science and practice of pathology; to further public education in the field of pathology and to promote research in pathology and disseminate the results.

Thank you for your attention to the proposals for the IVDD Regulations. I am liaising on behalf of the College with other professional bodies and the Medicines and Health Regulatory Authority here in the UK, and you will recall that I have been in touch with you earlier this year.

Our position is that the Health Institution exemption from the requirement for CE-marking should be extended from Classes A to D, not restricted to Classes A to C. We fully support the condition that such Health Institution laboratories should be accredited, and that accreditation should be based upon ISO15189 and other standards as appropriate.

However, while we share your concerns that genetic tests, in particular, should be ordered only by medical practitioners, within the setting of appropriate counselling and performed in the laboratory by similarly regulated professionals, we are equally concerned that the proposed amendments 143 and 144 risk bringing regulation of the medical practice of clinical genetics into in-vitro diagnostic device legislation. We would take the view that medical professionals should decide, and should themselves regulate, the appropriate standards in this area of clinical practice.

We therefore strongly urge you to reconsider these amendments, so that medical practice remains within the realm of the medical profession.

Please do not hesitate to contact me for further details.



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Yours sincerely,



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Laboratory Medicine**

Consultant in Genetic Pathology

Laboratory Director, All-Wales Medical Genetics Service

On behalf of The Royal College of Pathologists' Specialty Advisory Committee on
Genetics and Clinical Embryology

cc. Ms Rebecca Taylor, Shadow Rapporteur

cc. Dr Rachael Liebmann, Registrar