UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS

Multidisciplinary Joint Committee on Clinical Genetics

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Revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Public consultation

This is the response of the Multidisciplinary Joint Committee (MJC) Clinical Genetics of the European Union of Medical Specialist (UEMS).

Introduction

We are grateful to the Commission for providing this opportunity to contribute to the revision of Directive 98/79/EC on in vitro diagnostic medical devices.

The UEMS represents national associations of medical specialists in the European Union and associated countries to promote the free movement of European medical specialists while ensuring the highest quality of medical care for European citizens. For this purpose it has developed standards and policies in the areas of postgraduate training, continuing medical education, and professional development. The UEMS commits itself to ensuring that the highest quality standards of medical practice are applied throughout Europe for the benefit of European citizens.

The Multidisciplinary Joint Committee on Clinical Genetics was formed in 2008 to ensure appropriate training and education for specialists in clinical genetics as this discipline, although existing in all but 4 of the Member States, is currently not a formally recognised speciality according to the European Community Directive 2005/36. Specialists in clinical genetics are closely involved in genetic testing, both as medical laboratory professionals and as experts on genetic counselling.

Response

Our response mainly relates mainly to Questions 7-9 and Question 11, but is also valid for all aspects if the use of IVDs is developed for genetic testing. The revised Directive should be flexible enough to cover all types of test equitably, to protect the best interest of patients. Laboratory professionals, medical doctors and laboratory genetic scientists, who perform such tests have, and must continue to have, vital roles in working with clinicians outside the genetic

testing environment to improve patient management. The development of in-house tests has contributed to major advancement in the diagnosis and management of inherited diseases, as well as a wide range of cancers. Taking away the exemption would severely hamper the future development of new diagnostic and therapeutic products within the Member States.

In general, the UEMS MJC Clinical Genetics endorses the response to this public consultation provided by the EuroGentest network of excellence and the Public and Professional Policy Committee of the European Society of Human Genetics, PPPC-ESHG.

As the main area of interest of this UEMS committee is training and education of medical doctors in clinical genetics, we must stress the importance of accredited education for medical supervisors of laboratories performing genetic tests. All tests developed in-house need both clinical and technical validation before being introduced into the market, in order to benefit the health care systems of the Member States and the patients. Therefore, properly regulated education of the clinical genetic scientist and medical doctors harmonised between the Member States is crucial. We recommend this to be highlighted in the new directive.

We believe that qualified genetic testing laboratory staff, which will include both medical doctors as well as clinical genetic scientists, with proper education in laboratory and clinical genetics is necessary for those departments that have an exemption to use in-house tests. In the best interest of the patients, departments offering in-house tests, especially if they offer direct-to-consumer tests must have the necessary expertise to provide genetic counselling, either by themselves, or through contracts with an accredited genetic counselling unit. These issues should be properly advertised and included in reports.

On behalf of the steering group of UEMS MJC Clinical Genetics

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chair