



UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES EUROPEAN UNION OF MEDICAL SPECIALISTS

Association internationale sans but lucratif

International non-profit organisation

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Brussels, 18 November 2020

To: ...
Member of the European Parliament

Re: UEMS opinion regarding the Regulation EU 2017/746

Dear ...,

We write to you on behalf of Union Européenne des Médecins Spécialistes (UEMS) to express our concerns regarding the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices.

UEMS is registered in Brussels as an International Non-profit Association (AISBL) of national medical associations representing medical specialists from all 31 EU and EEA countries. With 5 associate and 5 observer organizations representing non-EU countries it represents almost 1.5 million medical specialists. Since its establishment 62 years ago UEMS has been developing voluntary European standards to ensure the quality of training of medical specialists and the quality of care provided to patients. As such, several medical specialties that we represent would be directly affected for the worse by this Regulation.

More particularly, the paragraph 5 of the article 5 of the Regulation on *Placing on the market and putting into service* states that “the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met”. Yet, several of these conditions, more specifically from d) to i), would increase healthcare costs and jeopardize doctors’ ability to design precise personalized laboratory tests, which are necessary for precision medicine, and to adapt to shifting test needs. Hence UEMS strongly recommends that Article 5-§5 conditions (d) to (i) for in-house exemptions are removed from the IVD directive

Please find attached our position statement with more detailed information on the matter.

We remain at your disposal should you require further information and, as representation of European Medical Specialists, we declare our willingness to join the planned EU4Health Steering Group.



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Best regards,

Prof. Vassilios Papalois
President of UEMS

Dr João Grenho
Secretary General of UEMS