

Brussels, 3 July 2015

Mr Jean-Claude Juncker President European Commission Rue de la Loi, 200 Bruxelles

CC: Commissioner Vytenis Andriukaitis - Health & Food Safety Commissioner Elżbieta Bieńkowska - Internal Market, Industry, Entrepreneurship and SMEs

Dear President,

We observe with great concern the efforts at European level on the subject of standardising medical treatments and other health care services.

The practice of the healthcare professions is shaped by evidence-based guidelines and recommendations developed by them. They are appropriate measures to enshrine good practice for optimal patient outcomes.

Recent initiatives in standardisation at EU level have gone beyond the products and facilities supporting healthcare and have interfered with the services delivered by healthcare professionals in patient care. The European Committee for Standardisation (CEN) as a private standard setting body is neither scientifically suited nor carries sufficient legitimacy to intervene in national competences.

In the interest of ensuring the quality and patient safety of care provided by guidelines and recommendations, we strongly oppose the involvement of standardisation institutes in regulating such healthcare services.



Guidelines and recommendations for professional practice developed on the basis of the national competences, as confirmed by the Treaty on the Functioning of the European, have a legitimate basis. They ensure best possible coherence with the other rules governing health services and professional rules, including ethics. Mechanisms which are not embedded in this expertise and legal framework do not provide an equivalent legitimacy.

While the practice of the healthcare professions is shaped by evidence-based guidelines and recommendations, an essential characteristic is the ability to divert from these guidelines when a healthcare professional believes it to be in the best interest for a patient's individual care. Such professional autonomy is fundamental to ensure both quality of treatment and patients' rights.

To ensure the quality of decision-making, professional autonomy is counterbalanced by professional liability. This balance is embedded in the regulatory framework of the profession, including monitoring and sanction mechanisms. Standards, such as those developed with the involvement of standardisation institutes, created outside of these structures cannot rely on these mechanisms, thus creating ambiguity as to their enforcement.

Recommendations and guidelines created within the legitimate regulatory framework are applicable to all professionals. They do not generate profits for the issuing bodies and their application is not subject to fees. This precludes selectivity and safeguards all patients' access to high quality healthcare.

We therefore call upon national and EU decision-makers to refrain from initiating or supporting any activities seeking the standardisation of healthcare services by standardisation institutes, both in the context of public policy and private standardisation bodies' initiatives.



We remain dedicated partners in promoting transparency and exchange relating to guidelines and recommendations on healthcare services and committed to informing the policy debate on the best approach.

Nina Bernot Head of Office Council of European Dentists

Birgit Beger Secretary General Standing Committee of the European Doctors

Pascal Garel Chief Executive European Hospital and Healthcare Federation

Pascal Garel



The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, to contribute to safeguarding the protection of public health and to promote the interests of dental profession, including through regular contacts with other European organisations and EU institutions. The CED is registered in the Transparency Register with the ID number 4885579968-84.

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The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

We believe the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice, the safe mobility of physicians and patients, lawful and supportive working conditions for physicians and the provision of evidence-based, ethical and equitable healthcare services. We offer support to those working towards these objectives whenever needed.

We see the patient-doctor relationship as fundamental in achieving these objectives and are committed to ensuring its trust and confidentiality are protected while the relationship evolves with healthcare systems. Patient safety and quality of care are central to our policies.

We strongly advocate a 'health in all policies' approach to encourage cross-sectoral awareness for and action on the determinants of health, to prevent disease and promote good health across society.

CPME's policies are shaped through the expertise provided by our membership of national medical associations, representing physicians across all medical specialties all over Europe and creating a dialogue between the national and European dimensions of health and healthcare.

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HOPE is the acronym of the European Hospital and Healthcare Federation, an international nonprofit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 37 organisations coming from the 28 Member States of the European Union, as well as from Switzerland and Serbia as observer members. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

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