



European Committee for Standardisation
Avenue Marnix 17
B-1000 Brussels

31 July 2015

Dear Sir or Madam,

The [European Network of Medical Competent Authorities](#) (ENMCA) brings together organisations in Europe responsible for recognising medical qualifications under the Directive on the recognition of professional qualifications. Many of the competent authorities represented by ENMCA are also responsible for regulating the competencies and training of health professionals.

At its November 2014 meeting in Malta, ENMCA discussed standardisation in European healthcare in the context of the recent adoption of a European Standard on aesthetic surgery services by the European Committee for Standardisation (CEN). As the bodies responsible for regulating the competencies and training of health professionals, many ENMCA participants are affected by standards drafted by CEN and implemented by its national member organisations. As competent authorities, we are concerned about European standards for healthcare services, specifically when they may infringe upon our competence to define the training content for the medical profession, our responsibilities regarding continuous medical education (CME), the professional duties in general or treatment procedures.

ENMCA has reservations about the adoption of standards for healthcare services for the following reasons:

- The organisation of healthcare services is a competence of the European Union's member states. CEN acknowledges that "*European standards shall not cover those subjects that clearly belong to the domain of regulation of the member states, under the principle of subsidiarity, unless this is explicitly supported by the national authority.*" However, the national competent authorities that regulate the medical profession were not consulted during the development of this standard. This lack of consultation is worrying.
- The regulation of medical practice must, in the interest of patient safety, be carried out with the best possible knowledge and expertise in technical clinical skills and medical ethics, regulatory coherence, and legislative legitimacy. The responsibility to regulate medical standards and practice including guidelines and recommendations is either given to the medical profession or handled by independent medical competent authorities or government ministries. The creation of alternative frameworks of reference risks infringing upon national competences and may create ambiguity, thus potentially endangering patient safety and quality of care.



- We doubt that this European Standard is consensus-based. Throughout the process of drafting the European Standard on aesthetic surgery services, a number of medical regulatory and professional bodies expressed concern regarding the initiative and called upon CEN to refrain from continuing or to consult with national bodies responsible for regulation in this field. These concerns were not taken into account. The European Standard is therefore not supported by the representative bodies of the medical profession at the European level. In addition to the lack of support from the medical profession itself, only one third of the national members of CEN have explicitly supported this European Standard.

Both EU and national policy must aim to ensure the best possible quality of care for every patient. Frameworks which threaten to undermine this must be rejected. We therefore call on CEN to promote the importance of respecting the principle of subsidiarity in healthcare and the need to ensure that any guidelines and recommendations are based on legitimacy and expertise for the benefit of patients in Europe and that a true process of consultation takes place.

We would be happy to discuss these issues further before work in this area continues.

We thank you in advance for considering these proposals.

Yours faithfully

European Network of Medical Competent Authorities (ENMCA)

contact@enmca.eu

Copy to:

European Commission DG Research and Innovation

European Commission DG Internal Market, Entrepreneurship and SMEs