



Mr Hermann Gröhe
Federal Minister of Health
11055 Berlin
Germany

16 December 2015

Dear Minister,

On behalf of European and national medical associations across Europe, please allow us to contact you in the context of the activities of the European Committee for Standardisation (CEN) on standards for healthcare services, in particular the adoption of a European Standard on aesthetic surgery services.

The CEN European Standard on aesthetic surgery services seeks to establish “a set of requirements, which are deemed to be essential for the provision of aesthetic surgery services.” It addresses *i.a.* competencies and training of health professionals involved, ethics, medications, and defines anaesthesia and risk level for procedures.

We strongly oppose the European Standard. We recall in particular that

- 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.” Moreover the professional bodies were not consulted in a consistent manner as to their explicit support of the CEN process and this CEN European Standard on aesthetic surgery services. We see it as a clear breach of competence.
- 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 medical profession itself is therefore given the competence to regulate its practice, including standards, guidelines and recommendations. The creation of alternative frameworks of reference outside the medical profession infringes national competences and creates ambiguity, thus endangering patient safety and quality of care.
- Throughout the process of drafting the CEN European Standard, the undersigned organisations, as well as a number of their members at national level, expressed their concerns regarding the initiative and called upon CEN to refrain from continuing it. This was not taken into account, nor

was the position of the World Medical Association 'Resolution on Standardisation in Medical Practice and Patient Safety' respected. The CEN European Standard is therefore not supported by the representative bodies of the medical profession at either European or international level.

- Of the 33 national members of CEN, 20 abstained from casting a vote on the European Standard, many citing as a reason the lack of expertise or consensus on the content of the standard. Only the remaining 13 votes were taken into account, of which 11 approved the European Standard. Only a third of the national members of CEN can therefore be deemed to have explicitly supported this European Standard. Seen in context with the lack of support from the medical profession itself, we cannot accept that this European Standard is consensus-based. In fact, the CEN voting procedures might allow a "standard" to be adopted even if a majority of individual voters opposed it. Such an approach is completely unacceptable when applied to medical standards. Any document that is given the level of evidence called "medical standard" has to be based on solid evidence and a wide consensus of competent experts.

We therefore appeal to you to advise against any national application of this European Standard.

With a view to CEN's broader activities on standards in healthcare services, we are also much aware of the impact of national standardisation bodies' recommendations with regard to pursuing activities. In light of the other initiatives on the standardisation of healthcare services currently on-going at CEN, we would be most interested in meeting you to discuss potential cooperation on this issue, including the role of national standardisation bodies.

We thank you in advance for considering these proposals.

Sincerely,

Dr João de Deus
President
European Association of Senior
Hospital Doctors (AEMH)

Dr Nicolino D'Autilia
President
European Council of Medical
Orders (CEOM)

Dr Katrín Fjeldsted
President
Standing Committee of
European Doctors (CPME)

Dr Claude Schummer
President
European Working Group of
Practitioners and Specialists in
Free Practice (EANA)

Dr Carsten Mohrhardt
President
European Junior Doctors
Permanent Working Group (EJD)

Mr Jannis Papazoglou
President
European Medical Students
Association (EMSA)

Dr Enrico Reginato
President
European Federation of
Salaried Doctors (FEMS)

Dr Aldo Lupo
President
European Union of General
Practitioners (UEMO)

Dr Romuald Krajewski
President of the European
Union of Medical Specialists
(UEMS)