



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS  
STANDING COMMITTEE OF EUROPEAN DOCTORS



PURPOSE: Adopted  
CONCERNING: Standardisation  
AUTHOR: European Medical Organisations – co-signed by CPME

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**Exchange of letters: Joint letter of the European Medical Organisations to European Commission on  
standardisation of healthcare services – co-signed by CPME**

**December 2015/February 2016**

Please find below an exchange of letter between the European Medical Organisations and  
Commissioner for Health Vytenis Andriukaitis on the standardisation of healthcare services.

Please find the CPME policy papers on standardisation [here](#).



Commissioner Dr Vytenis P. Andriukaitis  
 Commissioner for Health and Food Safety  
[Vytenis.ANDRIUKAITIS@ec.europa.eu](mailto:Vytenis.ANDRIUKAITIS@ec.europa.eu)

Brussels, 16 December 2015

Dear Commissioner,

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 levels for procedures.

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

- 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.
- 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 CEN European Standard on aesthetic surgery services. We see it as a clear breach of competence.

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.

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.

For the benefit of patients in Europe any standards, guidelines and recommendations have to be based on legitimate method and expertise. We also underline the importance of respecting the principle of subsidiarity in relation to the organisation of healthcare services.

To this end, we appeal to you to permanently exclude healthcare services from the CEN proposals submitted to the Commission’s work programme on standardisation and to oppose any proposals submitted by other Commission services. The medical profession has elaborated the sophisticated methods to develop standards, guidelines and recommendations. Such documents have been published and peer reviewed for vast majority of medical conditions and procedures.

Therefore, we remain at your disposal for the continued communication and exchange of good practices in adoption of guidelines and recommendations for medical practice.

We thank you in advance for considering these proposals and would be delighted to give further details in a meeting with you. To this end, we invite you to indicate availabilities at your earliest convenience.

Sincerely,

Dr João de Deus

President of the European Association of Senior Hospital Doctors (AEMH)

Dr Nicolino D'Autilia

President of the European Council of Medical Orders (CEOM)

Dr Katrín Fjeldsted

President of the Standing Committee of European Doctors (CPME)

Dr Claude Schummer

President of the European Working Group of Practitioners and Specialists in Free Practice (EANA)

Dr Carsten Mohrhardt

President of the European Junior Doctors Permanent Working Group (EJD)

Mr Jannis Papazoglou

President of the European Medical Students Association (EMSA)

Dr Enrico Reginato

President of the European Federation of Salaried Doctors (FEMS)

Dr Aldo Lupo

President of the European Union of General Practitioners (UEMO)

Dr Romuald Krajewski

President of the European Union of Medical Specialists (UEMS)





**Vytenis ANDRIUKAITIS**

Membre de la Commission européenne

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Brussels, 03 February 2016  
Ares (2016)

Dear Dr João de Deus,

Dr Nicolino D'Autilia,  
Dr Katrín Fjeldsted,  
Dr Claude Schummer,  
Dr Carsten Mohrhardt,  
Mr Jannis Papazoglou,  
Dr Enrico Reginato,  
Dr Aldo Lupo,  
Dr Romuald Krajewski

**Subject: CEN standards for healthcare services**

Thank you for your letter of 16 December regarding CEN standards for healthcare services, in particular the CEN standards for aesthetic surgery.

I am fully aware of the opposition of the medical organisations to European standardisation in the area of healthcare services and can confirm that the European Commission does not have the intention to request the European standardisation bodies to draft standards in the area of healthcare services.

As you will note in the Annual Union work programme on standardisation for 2016, the Commission is setting priorities for the standardisation for the coming year(s) directly linked to the Commission's priorities for e-health set out in the Digital Single Market Strategy and the Internal Market Strategy - but not in relation to healthcare services.

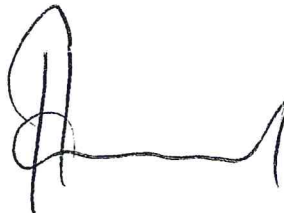
For further information, see [http://ec.europa.eu/growth/single-market/european-standards/policy/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/policy/index_en.htm)

With regard to CEN standard for aesthetic surgery services, it is outside the Commission's competence to prevent the European Committee for Standardisation from working on European standards that have been initiated by national standardisation bodies. The Commission's competence is limited to ensuring that European standards are developed in line with the principles of the Standardisation Regulation (1025/2012) and the Commission's Communication "More standards for Europe and faster" of 2011. This means, *inter alia*, that standards are voluntary, demand-driven and developed in an inclusive process.

I would like to stress that European standards supersede any relevant national standards in the particular area but remain purely voluntary so service providers are not obliged to adopt them unless they want to. To be applicable in practice, European standards cannot contradict legislation and do not aim at replacing it where it exists. Such standards therefore would not create an obligation for doctors to comply with them.

I would be pleased to meet with the representatives of the European medical organisations to discuss more broadly your work in the area of healthcare.

Yours sincerely,

A handwritten signature in black ink, consisting of a large, stylized capital 'A' followed by a horizontal line and a small upward stroke at the end.