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EUROPÄISCHE VEREINIGUNG DER LEITENDEN KRANKENHAUSÄRZTE
EUROPESE VERENIGING VAN STAFARTSEN
DEN EUROPÆISKE OVERLÆGEFORENING
ΕΥΡΩΠΑΪΚΟΣ ΣΥΛΛΟΓΟΣ ΝΟΣΟΚΟΜΕΙΑΚΩΝ ΙΑΤΡΩΝ ΔΙΕΥΘΥΝΤΩΝ
ASSOCIAZIONE EUROPEA DEI MEDICI OSPEDALIERI
DEN EUROPEISKE OVERLEGEFORENING
ASSOCIAÇÃO EUROPEIA DOS MÉDICOS HOSPITALARES
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ΕΒΡΟΠΕΪΣΚΑ ΑΣΟΪΙΑΪΙΑ ΗΑ ΣΤΑΡΣΗΤΕ ΒΟΛΗΙΧΝΗ ΛΕΚΑΡΗ
ASOCIATIA EUROPEANA A MEDICILOR DIN SPITALE**

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Standards of medical practice

Open Letter

The undersigned European Medical Organisations are committed to the achievement of high standards in healthcare because they recognise the importance of these for the safety and quality of care for patients.

These Medical Organisations strongly support the considerable work that has been, and continues to be performed by medical experts in healthcare in developing medical standards and guidelines for practice based on their clinical experience and research findings.

These Medical Organisations recognise that medical standards and guidelines are best implemented when the doctors who will be implementing them are engaged in their development and in their application in local healthcare services.

Accordingly, these Medical Organisations have profound concerns about the attempts by the European Committee on Standardisation (CEN - Centre Européen de Normalisation) to introduce standards based on quality management systems that do not have a solid evidence-base within the clinical environment of healthcare systems.

These Medical Organisations further question the rationale for CEN to extend its remit into this area as this would appear to be in breach of core elements of European legislation as applied to healthcare which is subject to the principle of subsidiarity.

These Medical Organisations consider that the CEN initiative to develop standards derived from the ISO 9000 series and apply them top down in healthcare systems conflicts with:

- The Treaty of Lisbon, Article 168 (update of Treaty of Amsterdam, Article 152)
- The European Directive on the mutual recognition of professional qualifications (2005/36/EC) and in particular the recognition of the right of individual Member States to determine their own training structure while ensuring compliance with criteria set out in the Directive.
- National laws and regulations on healthcare systems and professional practice that are specific to the different healthcare systems in Europe.

These Medical Organisations have attempted to engage in a constructive dialogue with CEN but finds that there is a lack of reciprocation for a meaningful dialogue.

These Medical Organisations have concluded that CEN does not wish to engage in partnership working with representatives of the medical profession.

These Medical Organisations therefore call on the European Commission and Parliament, the EU Member States and other relevant institutions or bodies to challenge the approach being taken by CEN and to question the rationale of its initiative in healthcare.

Dr João de Deus

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

Dr Roland Kerzmann

President of the European Council of Medical Orders (CEOM)

Dr Konstanty Radziwiłł

President of the Standing Committee of European Doctors (CPME)

Dr Jörg Pruckner

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)

Dr Borislav Manev

President of the European Medical Students Association (EMSA)

Dr Enrico Reginato

President of the European Federation of Salaried Doctors (FEMS)

Dr Ferenc Hajnal

President of the European Union of General Practitioners/Family Specialists (UEMO)

Dr Romuald Krajewski

President of the European Union of Medical Specialists (UEMS)



The Director General

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15 Rue Guimard
1040 Brussels

Brussels, 20 December 2012

Ref: 14463

Subject: Open letter from nine European Medical Organisations regarding standards for medical practice

Dear Dr Radziwill,

I refer to your message of 4 December 2012, drawing my attention to the 'open letter' signed by the Presidents of European Medical Organisations. I noted the concerns expressed therein about European Standards developed by CEN based on quality management systems. It is my assumption that you refer to EN 15224:2012 'Health care services - Quality management systems - Requirements based on EN ISO 9001:2008', a standard prepared by CEN/TC 362 'Project Committee - Healthcare services - Quality management systems'.

In a first instance, I would like to clarify that the use of European Standards is not mandatory. European standardization follows a bottom-up approach and, as such, responds to market needs and is therefore a legitimate option for relevant stakeholders who can benefit from a technical standard. Through the CEN system, composed of its 33 national standardization bodies, stakeholders can propose to initiate standards work on a wide range of topics. The decision on whether or not to accept a proposal to develop one or more European Standards is based wholly on the inputs and reactions from stakeholders, through the national standardization bodies, based on whether or not the resulting standard will meet their individual and (often) differing needs. If, based on a formal decision of our members, the proposal is pursued and when a consensus is found (after a multi-stakeholder enquiry and voting process) the resulting European Standard is then implemented by our members as the national standard in their country.

To put it in other words: There is no direct link between CEN standards and European or national laws and regulations. Nevertheless, our standards could be referred to in European regulatory context but only if and when the legislator would decide to do so. Therefore, the reasoning that CEN, as a standardization organisation, would put top-down requirements on the European regulatory framework is not correct. I believe this principle was already explained by me to representatives of CPME during a bilateral meeting in July 2011.



CENELEC

The letter states that the medical organisations '*attempted to engage in a constructive dialogue with CEN only to find a lack of reciprocation for a meaningful dialogue.*' This came as a surprise to us. As a matter of fact, any organisation can request a technical liaison with a CEN/TC (giving it the right to attend TC meetings and participate in the development of standards). However, to my knowledge neither my office nor the CEN/TC 362 secretariat have been approached by any of the 9 signatory organisations to establish such a liaison with CEN/TC 362.

Likewise, any draft standard is submitted by our national Members to a public enquiry during which any interested party is entitled to introduce comments. A quick check with the CEN/TC 362 secretariat revealed that no adverse comments in the sense of the concerns raised in the open letter were voiced at national level. As a matter of fact, from the feedback received, it was clear that the large majority of stakeholders welcomed the standard and its provisions.

Finally, as CEN and its Membership adhere to the WTO/TBT Code of Conduct, openness, consensus and transparency form the very basis of all our activities. Therefore, and referring to the elements mentioned earlier, I cannot accept the criticism in the open letter stating '*that CEN does not wish to engage in partnership working with representatives of the medical profession*'.

Having clarified the context of our standardization work, I would like to invite you to further discuss any additional clarification you may need with me and for any further practical questions about the process itself, you may contact our Unit Manager, Cinzia Missiroli at cmissiroli@cencenelec.eu who will be glad to provide the necessary support.

Yours sincerely,

Elena SANTIAGO CID

C.c.: Mr Smaxwil, CEN president
Mr Dossett, CENELEC President
Mr Trondvold, CENELEC President Elect
Mr Holsters, President of the Conseil national de l'Ordre des Médecins
Mr Haelterman, NBN President of the Management Committee

11th May 2013

Draft Joint response letter of the European Medical Organisations

Dear Ms Santiago Cid,

We would like to thank you for your response dating 20 December 2012 to the Joint Open Letter of the European Medical Organisations on Standards of Medical Practice.

The undersigned European Medical Organisations would like to reaffirm the position elaborated in the Open Letter.

Firstly, we would like to clarify that it is the drafting of a standard on aesthetic surgery services by the CEN/TC 403, that is an example of the type of initiative which we regard with great concern as regards its implications for quality of healthcare and patient safety.

As set out in previous exchanges, the competence for the development of standards and guidelines as regards healthcare services delivered in medical practice is a matter of subsidiarity, and furthermore subject to self-regulatory competences of the profession.

This division of competences characterises the regulatory and legislative framework in which doctors exercise their profession since it has been found to be the most beneficial to the quality of professional practice and thus clinical outcomes for patients.

Standards, guidelines and recommendations for medical practice must adhere to the highest possible ethical, professional and scientific values and must be characterised by the greatest possible legitimacy. They have to reflect current medical knowledge and practice and therefore, have to remain an exclusive competence of medical professional bodies.

We have serious reservations to your statements on support of TC/403 initiative from medical community. In fact, this community has almost unanimously negative opinion on this initiative and we are concerned that CEN relies on opinions of isolated and unsupported groups and ignores opposing opinions of vast majority.