



## 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.

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