

**Statement by the
AWMF - Association of the Scientific Medical Societies
in Germany**

**on the plans for standards governing health care services in the
European Committee for Standardization
(Comité Européen de Normalisation - CEN)**

15 May 2014

The AWMF takes firm and justified opposition to the standardization of medical health care services and treatment processes proposed by the European Committee for Standardization (CEN). The main reasons are

1. Standardization in this sector stands in contradiction to the patient's right to appropriate health care on an individualized basis
2. The transferability of standards to other countries such as Germany is unproven.
3. Methodology and verifiability on how the standards are developed are lacking.

For more than 50 years, the AWMF has been supporting its member societies, meanwhile totaling 168, in the pursuit of medical and scientific missions and objectives, while linking scientific medicine with medical practice. As early as March 2012, the AWMF made clear in a statement that the scientific medical societies reject every standardization and norming of medical services on both the national and European level¹. The standardization of medical health care services and of the treatment process on the European level breaches European treaties and contradicts nationally established professional and legal codes and regulations². Today, the AWMF continues to stand by the opinions it expressed in 2012 opposing the present plans for common standards of treatment processes proposed by the European Committee for Standardization (CEN).

After critical analysis of the initial drafts and of the completed plans for common standards in the European Committee for Standardization, there are fundamental objections to the suitability, transferability, quality and systematic development of the standards.

The main criticisms of all plans for common standards in the medical services sector are the following:

- The initially voluntary standards in the health care services sector may intentionally become directives in several EU countries following their recognition and reference in corresponding regulations or laws. As a result, both the treatment-related freedom of physicians as well as the patients' rights to health care adapted to their individual needs is undermined.

¹ Statement by the AWMF on the plans for common standards in the European Committee for Standardization (CEN) and at the German Institute for Standardization (DIN).

Available at: <http://www.awmf.org/die-awmf/awmf-stellungnahmen.html>

² Consolidated Version of the Treaty on the Functioning of the European Union. Part three, Article 168 para. 7. Official Journal of the European Union 26.10.2012

- European Standards are binding for National Standardisation Bodies in the EU member countries. This now obviates the possibility to adapt to country-specific healthcare systems, cultures and medical care rules.
- Current plans for common standards of the European Committee for Standardization ignore all aspects of quality and systematic development such as:
 - **Transparency** over the development process and the persons and institutions involved.
 - **Free access to collaboration** in the development process which is not dependent on intransparent appointment procedures, cost sharing or compensation payments, but rather must be aimed at involving all relevant groups participating in the later treatment process.
 - **Expert selection criteria** to ensure that expertise is traceable.
 - **Transparency regarding the conflicts of interest** on the part of individual participants, the development group overall but also regarding project funding.
 - **Evidence for all statements** (systematic search, selection and appraisal of the literature or group consensus) and traceability of decision-making mechanisms (information on sources and criteria).
 - Description of the **methodology for determining** the current status of the science and technology as a basis for statements and transparent implementation of rules for **adapting changes** whenever the current state of science and technology changes over time.
 - **Rules and standards on methodology** and the corresponding transparent, description of the development process of each product that is rendered verifiable for independent inspection bodies.

In general, the AWMF does not believe that the plans for common standards will achieve any quality improvements in the provision of medical services. Rather, the process of a European standardization of medical services, which is primarily organized by private business may jeopardize the improvement objectives whenever plans for common standards are influenced by financial considerations. There is also a danger that the current state of science and technology in the complex medical services sector is not reflected and that a consensus oriented to the lowest achievable common denominator will lead to a deterioration of quality in the member states where the existing quality of care is already high.

The AWMF and its member societies will take an emphatic stance to ensure that the quality development of medical care will remain to be founded on current, systematically developed, scientifically sound clinical practice guidelines as decision-making aids for the care of individual patients and that the content and legal principles governing competence in practice of medicine in the individual disciplines in Germany will be upheld on the highest level. The AWMF will protest against the standardization of rules governing the practice of medicine on a European level as proposed by the European Committee for Standardization. It will also defend the established control mechanisms governing the medical profession in continuing medical education in Germany against redundant and interest-driven influences, while further developing them mutually with the responsible medical associations.

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