COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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On 8 May 2014, the CPME Executive Committee adopted the ' CPME Position paper on standardisation of healthcare services' (CPME 2014/020 FINAL)

CPME Position paper on the standardisation of healthcare services

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.[1]

Standardisation by standardisation institutes has become increasingly present in healthcare systems. Traditionally, technical standardisation provided specifications ensuring the safety and universal applicability of products used in healthcare. It ensured that healthcare settings fulfilled physical requirements which constituted an appropriate framework for the delivery of healthcare.

In contrast to these activities, recent initiatives in standardisation, also at EU level, have focussed not on the products and facilities supporting healthcare, but on the services delivered by healthcare professionals in patient care. This development can be seen i.a. in Regulation (EU) 1025/2012 on European Standardisation, which applies not only to products, but also to services[2].

The practice of the medical profession is shaped by evidence-based guidelines and recommendations developed by the medical profession are an appropriate measure to enshrine good medical practice for best patient outcomes.

In the interest of safeguarding the quality of care these guidelines provide, CPME strongly opposes the involvement of standardisation institutes in regulating healthcare services in light of the following considerations:

- Healthcare services cannot be equated to services that are purely commercial in nature. Nor is the demand and supply of healthcare services subject to conventional market forces or competitiveness which are the purported drivers of standardisation. The specificity of healthcare services is acknowledged at EU level, e.g. in their exclusion from the Services Directive. CPME calls for this this specificity to be acknowledged and safeguarded.

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.
More information about CPME's activities can be found under www.cpme.eu
[2] Please find the CPME position on the legislative proposal for a Regulation on European Standardisation, as adopted in 2011, here.

- In accordance with Article 168 of the Treaty on the Functioning of the European Union, the national competence as regards the regulation of the healthcare system, including the professions as well as the services provided in the exercise of the profession, must be respected. This extends to the self-regulatory competence for the profession which may be established at national level.

- Guidelines and standards for professional practice developed on the basis of thenational competences as confirmed by the Treaty on the Functioning of the European Union, be they governmental or self-regulatory, have a legitimate basis and ensure best possible coherence with the other rules governing health services and professional rules, including ethics. Mechanisms which are not embedded in this expertise and legal framework cannot be considered to achieve the equivalent legitimacy. They may therefore create a misleading perception among patients and other users of healthcare services, thus compromising patient safety and quality of care.

- While the practice of the medical profession is shaped by evidence-based guidelines and recommendations , an essential characteristic is the ability to divert from these guidelines when a doctor believes it to be in the best interest for a patient's individual care. Such professional autonomy is fundamental to ensure both quality of treatment and patients' rights. To ensure the quality of decision-making, professional autonomy is counterbalanced by professional liability. This balance is embedded in the regulatory framework of the profession, including monitoring and sanction mechanisms. Standards, such as those developed with the involvement of standardisation institutes, created outside of these structures cannot rely on these mechanisms, thus creating ambiguity as to their enforcement.

- Recommendations and guidelines created within the legitimate regulatory framework are applicable to all professionals and may not create a profit for the issuing bodies, nor is their application subject to fees. This precludes selectivity and safeguards all patients' access to high quality healthcare.

CPME therefore calls upon national and EU decision-makers to refrain from initiating or supporting any activities seeking the standardisation of healthcare services by standardisation institutes, both in the context of public policy and private standardisation bodies' initiatives.

CPME remains a dedicated partner in promoting transparency and exchange relating to guidelines and recommendations on healthcare services and is committed to informing the policy debate on a future approach.