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On 26 November 2011, the CPME Board adopted the "CPME position on the legislative proposal for a Regulation on European Standardisation (COM (2011) 315 final)" (CPME 2011/147 FINAL EN)

CPME position on the legislative proposal for a Regulation on European Standardisation (COM (2011) 315 final)

The Standing Committee of European Doctors (CPME) represents medical doctors across Europe and is composed of the most representative National Medical Associations of 27 European countries. CPME aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of healthcare for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors, and the free movement of doctors within the EU. CPME also cooperates closely with national medical associations from associated and observer countries, as well as with specialised European medical organisations and international medical associations.

On 1 June 2011, the European Commission published a legislative proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council (COM (2011) 315 final).

In the following, CPME would like to comment on the proposal's provisions.

Extension of the scope of application

One of the main innovations which is to be introduced to the legislative framework of European standardisation through this Regulation is the extension of the scope of application to include 'services'. The rationale for this extension of scope is set out in Recital 7 as a response to the provision in Art. 26 Para. 5 of the Directive 2006/123/EC on services in the internal market, stating that "[...] it is not always possible to clearly distinguish standards on products from standards on services." Recital 8 goes on to explain that "[t]he development of voluntary standards on services should be market-

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driven whereby the needs of the economic operators and stakeholders directly or indirectly affected by the standard prevail and should take into account the public interest and be based on consensus. They should primarily focus on services linked to products and processes."

In the operative definitions identified for the purposes of the Regulation in Art. 2 Para. 6, a 'service' is defined as "any self-employed economic activity normally provided for remuneration, as referred to in Article 57 of the Treaty [.]"

CPME has noted the extension of scope of application to and definition of 'services' in the Regulation with great concern as to its implications on healthcare services.

As stated by CPME repeatedly[1], healthcare services cannot be equated with services delivered in a purely economic context. It is in the direct public interest to guarantee that quality and practice of the medical profession are regulated by professional bodies which can ensure that technical qualifications, ethical requirements, professional regulations, treatment procedures and quality assurance are defined and implemented with the necessary expertise.
This distinction is acknowledged in national laws and is also in the context of EU legislation, as exemplified by the exemption of "healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided [,]" from the scope of application of Directive 2006/123/EC on services in the internal market.
Furthermore, CPME considers that setting out European standards for technical qualifications, ethical requirements and professional regulations, as well as for professional duties, infringes on the rights of Member States to independently organise and deliver health services and medical care as guaranteed by Article 168 TFEU, paragraph 7.

[1] "CPME Answers to the health services consultation Sec (2006) 1195/4", adopted on 26 January 2007 (link to document); "Commission proposal for a directive on services in the internal market: Reaction of CPME", adopted on 3 September 2005 (link to document); "Commission proposal for a directive on services in the internal market: Reaction of CPME", adopted 12 November 2004 (link to document)

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In order to thus uphold the integrity and quality of healthcare services and maintain legal clarity and coherence for the benefit of patient safety and quality of care, CPME therefore calls for an exemption to be introduced to the Regulation, excluding healthcare services from its scope of application.

CPME calls for the following amendments to the legislative proposal:

Amendment 1
Recital 7

Text proposed by the Commission	*Amendment*
Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market establishes general provisions facilitating the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services. It obliges the Member States, in cooperation with the Commission, to encourage the development of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, information to the recipient and the quality of service provision. However, Directive 98/34/EC only applies to standards for products while standards for services are not expressly covered by it. However, the delineation between services and goods is becoming less relevant in the reality of the internal market. In practice, it is not always possible to clearly distinguish standards on	Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market establishes general provisions facilitating the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services***, with the exception of healthcare and pharmaceutical services provided by health professionals.*** It obliges the Member States, in cooperation with the Commission, to encourage the development of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, information to the recipient and the quality of service provision. However, Directive 98/34/EC only applies to standards for products while standards for services are not expressly covered by it. However, the delineation between services

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products from standards on services. Many product standards have a service component while standards on services often also partly relate to products. Thus, it is necessary to adapt the legal framework to these new circumstances by extending its scope to standards on services.

and goods is becoming less relevant in the reality of the internal market. In practice, it is not always possible to clearly distinguish standards on products from standards on services. Many product standards have a service component while standards on services often also partly relate to products. Thus, it is necessary to adapt the legal framework to these new circumstances by extending its scope to standards on services.

Justification

The amendment is intended to ensure cohesion within the European Union's legislation on healthcare services and ensure that the quality of healthcare and patient safety is adequately protected. Furthermore the amendment is necessary to reflect the Member States' competence in the organisation and delivery of healthcare and to respect the principle of subsidiarity.

Amendment 2
Article 1

Text proposed by the Commission	*Amendment*
This Regulation establishes rules with regard to the cooperation between European standardisation bodies, national standardisation bodies and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union	***1.*** This Regulation establishes rules with regard to the cooperation between European standardisation bodies, national standardisation bodies and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of

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legislation and policies, the recognition of technical specifications in the field of information and communication technologies (hereinafter "ICT") and financing of European standardisation.	Union legislation and policies, the recognition of technical specifications in the field of information and communication technologies (hereinafter "ICT") and financing of European standardisation.
	2. This Regulation shall not apply to any healthcare services, which are provided by health professionals to patients in the exercise of their profession, in particular to assess, maintain or restore patients' state of health, where those activities are reserved to a regulated health profession in the Member State in which the services are provided, whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private.

Justification

The amendment is intended to ensure legal clarity as to the exemption of healthcare services from the scope of application of the Regulation in the interests of cohesion of the European Union's legislative framework and the quality of care and patient safety.

Standards in the field of ICT

While CPME strongly opposes the application of this Regulation to healthcare services, benefits of standardisation at European level in the field of ICT are acknowledged. CPME very much supports efforts to promote the interoperability of eHealth applications across Europe, the aim however being not only technical interoperability, but also the

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maintenance of the highest possible standards of usability and, most crucially, data protection and confidentiality.

CPME welcomes the opportunity for advancing interoperability in eHealth and calls for any action taken under this Regulation in relation to eHealth to be bound maintaining the highest standards of data protection and confidentiality.

CPME furthermore calls for activities under Arts. 9 and 10 to be effectively integrated into existing initiatives at EU level and for outcomes of these initiatives to be taken into account during the development of standards.

Stakeholder participation in European Standardisation

Art. 5 Para. 1 provides that "European standardisation bodies shall ensure an appropriate representation of small and medium-sized enterprises (hereinafter 'SME'), consumer organisations and environmental and social stakeholders, in particular through the organisations referred to in Annex III [...]".

CPME welcomes this provision and its commitment to involving stakeholder expertise in the development of standards.

As to the process of selecting and consulting the representative stakeholders, CPME would favour a clarification of these procedures to be enshrined in Art. 5, so as to facilitate the implementation of the provision.

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