

CED Resolution

STANDARDISATION

May 2015

INTRODUCTION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 32 national dental associations and chambers in 30 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centred professional practice.

STANDARDISATION OF HEALTHCARE SERVICES

European standardisation in the healthcare sector has traditionally been used for developing technical specifications for medical devices and e-health applications to ensure their safety and universal applicability.

However, the adoption of [Regulation \(EU\) 1025/2012 on European Standardisation](#) has opened the way towards the establishment of standards for services. This has resulted in initiatives at EU level aimed at developing standards for services delivered by healthcare professionals. Sources of increasing concern are the recent publication of a new European standard on [Aesthetic Surgery services \(EN 16372\)](#), the project for a European standard on [non-surgical medical procedures \(prEN 16844\)](#) and creation of the CEN SAGS-ABHS Ad-hoc group which is to develop a strategy on standardisation of healthcare services.

CED POSITION

European dentists oppose standardisation of 'healthcare services' especially treatment at EU level for the following reasons:

- ✦ Developing standards on delivery of healthcare would infringe on professional and national competences as established in existing EU and national legislation, and ethical codes.
- ✦ Dental practice relies on evidence-based clinical guidelines and recommendations developed by healthcare professionals, as well as the direct relationship between dentists and their patients. Standardising delivery of dental treatments would limit dentists' professional autonomy and their ability to adapt treatment to patients' individual needs and requirements thus ensuring the highest possible level of quality and patient safety and the best outcomes for patients.
- ✦ EU standardisation of delivery of healthcare services would infringe on the rights of Member States to independently organise and deliver health services and medical care as guaranteed by Article 168(7) TFEU). This could seriously affect public funding and the sustainability of national health systems, already burdened by the effects of the economic crisis and demographic challenges. It would also make it impossible to organise healthcare in such a way as to reflect local and national needs, resources, professional regulation and ethical codes, compromising the efficiency of healthcare systems
- ✦ [Directive EU/2011/24 on the application of patients' rights in cross-border healthcare](#) requires cross-border healthcare to be provided in accordance with legislation, standards and guidelines in the Member State of treatment (Article 4) and cannot be regarded as justification for developing European standards on delivery of healthcare.
- ✦ European standards on delivery of healthcare containing provisions on education for health professionals conflict not only with national competences in education as enshrined in the Treaty but also with [Directive 2005/36/EC on the recognition of professional qualifications](#).
- ✦ Because of the unique features of healthcare, healthcare services cannot be regulated at EU level in the same way as purely economic services. The special nature of healthcare services was acknowledged by all actors in the EU when healthcare was explicitly excluded from the scope of the [Directive 2006/123/EC on services in the internal market \(the Services Directive\)](#).

Therefore, the CED appeals to EU and national decision-makers to carefully consider the serious concerns expressed by the dental profession and to abstain from supporting any initiatives by standardisation bodies aiming to standardise the delivery of healthcare services. European dentists are convinced that the safety and quality of dental care are best ensured by a highly educated dentist workforce through a combination of national laws, professional regulation and ethical codes, which cannot and should not be replaced or undermined by European standards.

Adopted by the CED General Meeting on 29 May 2015