Session 1: Challenges facing health professional regulation

Panelist: Annabel Seebohm

The Impact of Standardisation Initiatives in Europe and Global Lessons for Health Professional Regulation

Session 1: Challenges facing health professional regulation

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Outline

Standardisation in Europe

- Propositions
- Players
- Projects
- Problems

International Dimension

Global Lessons

Standardisation in Europe

Propositions

- 'Standard' means a **technical specification**, adopted by a recognised standardisation body, for continuous application, with which compliance is **not compulsory**.

- Standards must not violate laws at the national level.

- Standards can become **legally binding**, e. g. by contract or by reference within a legislative text.

- This is also a stated aim: "(…) a more effective means of ensuring that **products** meet the essential health and safety requirements of legislation than the writing of detailed laws."

Standardisation i
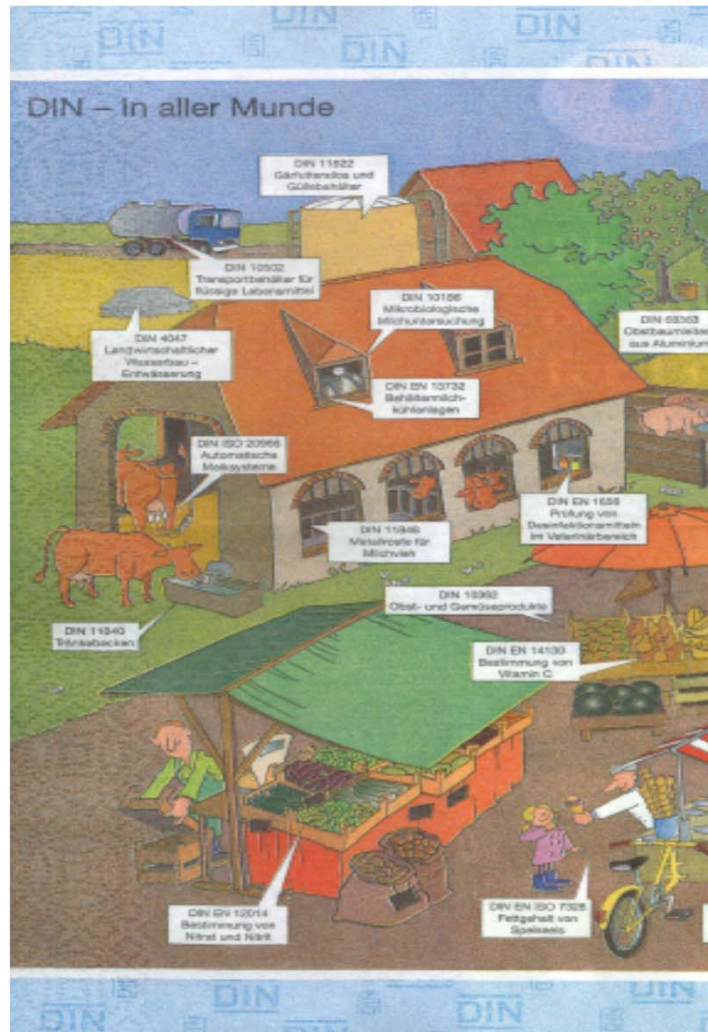
The introduction of European Standards in the services sector brings many advantages and opportunities for both businesses and consumers. Businesses can use standards as a tool for improving the quality and performance of their services, while consumers can benefit from greater transparency regarding the offers of different service providers.

Having common standards for services at European level is also necessary to support the development of a single market for services within Europe. Within CEN, the Strategic Advisory Group on Services (CEN/BT/WG 214 - 'SAGS') acts as an advisory and coordination body on policy and strategic matters in relation to the standardization of services.

In 2013, CEN accepted a request from the European Commission (EC mandate M/517) for the programming and development of horizontal service standards. Any new standards developed in this framework should cover issues that are common to many different kinds of services, such as information to customers, complaints and redress procedures, etc.

CEN will:

• undertake a mapping of horizontal service standards (at national, international and European levels) and work with interested stakeholders to identify priorities for the possible development of horizontal service standards (in accordance with EC mandate M/517 - phase I);

• finalize a mapping of existing national standards in the area of services, which will also help in identifying potential areas for standardization work at European level;

• cooperate with ISO on the development of standards regarding facilities and equipment for interpretation services (in accordance with EC mandate M/516);

• initiate new standardization activities relating to the service chain for social care alarms, as well as the competences of customs representatives.

Healthcare services

European standardization in the healthcare sector has traditionally been limited to medical devices and 'health informatics' (or e-health) applications (see Chapter 13). Nevertheless, in recent years there has been an increasing level of demand from stakeholders for the development of standards in relation to various kinds of healthcare services.

CEN will:

• publish a new European Standard on aesthetic surgery services (EN 16372);

• continue work on the development of a European Standard for aesthetic non-surgical medical services and a Technical Report on care services for persons born with a cleft lip and/or a cleft palate (Project Committee CEN/TC 424);

• launch a new standardization activity regarding the services of Medical Doctors with additional qualification in Homeopathy (Project Committee CEN/TC 427).

Standardisation in Europe
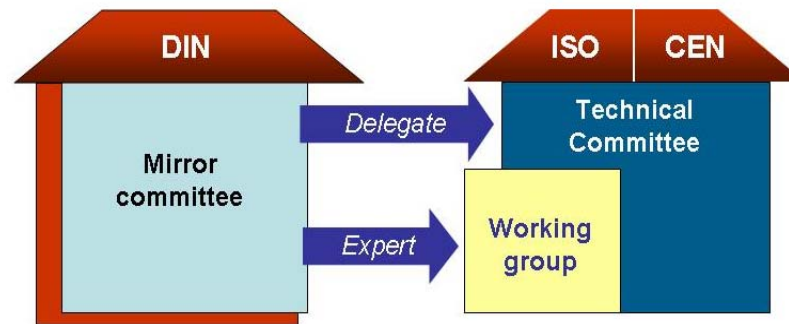
Aesthetic surgery services

Dienstleistungen in der ästhetischen Chirurgie

Services en chirurgie esthétique

ICS:

Descriptors:

Document type: European Standard
Document subtype:
Document stage: Formal Vote
Document language: E

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Legal problems

- Conflict with professi
- Conflict with evidence
- Conflict with EU mand

Fundamental problem

- Legitimacy and Comp
- Procedure and Finan
- Benefit and Evaluatio

WMA Resolution on Standardisation in Medical Practice and Patient Safety

Adopted as a Council Resolution by the 194th WMA Council Session, Bali, Indonesia, April 2013
and adopted by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Ensuring patient safety and quality of care is at the core of medical practice. For patients, a high level of performance can be a matter of life or death. Therefore, guidance and standardisation in healthcare must be based on solid medical evidence and has to take ethical considerations into account.

Currently, trends in the European Union can be observed to introduce standards in clinical, medical care developed by non-medical standardisation bodies, which neither have the necessary professional ethical and technical competencies nor a public mandate.

The WMA has major concerns about such tendencies which are likely to reduce the quality of care offered, and calls upon governments and other institutions not to leave standardisation of medical care up to non-medical self selected bodies.

International Dimension

The transatlantic trade and investment partnership **(TTIP)**

TTIP is a free trade agreement being negotiated between the European Union and the United States.

The aim is to create jobs by removing trade barriers in order to facilitate the buying and selling of goods and **services**. The agreement has three main elements:

- Market access: removing restrictions on **services**
- Improved regulatory cooperation by dismantling unnecessary regulatory barriers
- Improved cooperation when it comes to **setting international standards**

Global Lessons

Are you willing to accept „quasi" professional regulation in healthcare created by non-professional self selected bodies?

Caring
Ethics
Science

WMA