STANDARDIZATION IN HEALTHCARE

HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 35 organisations coming from the 28 Member States of the European Union, as well as from Switzerland and Serbia as observer members.

HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

What is the issue?

HOPE is concerned by the temptation at EU level to develop standardization in healthcare under the authority of the CEN (European Committee for Normalization).

Expanding the work of CEN outside its usual work on technologies is not only against the interest of individual patient treatment but also against the good quality of care in general.

What is the standardization?

The European Regulation on standardization states that: "the primary objective of standardization is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardization can cover various issues, such as standardization of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential."

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Standards are developed at national level by various institutions, at European level by the European Committee for Standardization (*Comité européen de normalisation*, CEN), and at international level by the International Organization for Standardization (ISO).

CEN is a private standards-setting body. Standards are based on expert opinion in which the circle of persons and institutions involved should insofar as possible reflect the entire available spectrum of opinions.

The standardization of products has been developed by CEN in the healthcare field for many years in particular on uniform safety standards and specifications for medical products and devices, concerning the ergonomic design of equipment and the technical equipment of laboratories.

Why it is not adapted to the provision of care to patients?

While this might be useful for products the approach is wrong as far as the provision of care is concerned. For CEN, standards in the service sector, like those of products, serve the economy through the development of national and international markets, thus facilitating liberalization of trade in services. Healthcare quality and safety are not the core basis of this work. The approach would therefore be inappropriate.

Determining unified specifications is increasingly difficult for a service and its associated processes become more and more complex. The desire to standardize, harmonize and simplify on the basis of standard specifications is not adapted to the needs of individual patients and limits the possibilities for medical care. Additionally standardized processes in forms of norms would generate potential for conflict with doctors' decisions in execution of their free profession. There are also reasons to fear that European standards would not be as extensive as existing and established medical standards, and would thus jeopardize the quality of healthcare.

The approach would be inefficient. While European standardization in the product realm might in fact be helpful and desirable, it is completely unsuitable in the context of medical treatment for individual patients. CEN as a private standards-setting body is neither scientifically suited nor carries sufficient legitimacy to intervene in decisions reserved to self- administrating bodies in this area.

The method is questionable. Standards are based on expert opinion (so-called interested parties), in which the circle of persons and institutions involved should insofar as possible reflect the entire available spectrum of opinions. However, the

persons involved are not named in public documents and their interests or potential conflicts of interests are not disclosed. Doubts about the representativeness and legitimacy are enforced by the fact that participation in the decision processes are depending from a fee an interested party would have to pay for.

Standardization by CEN therefore raises serious concerns with regard to legitimacy and the preparation process. It has become apparent that in practice, "only" interested parties active in the preparation of pertinent standards participate in the CEN processes. However, these interests are not exclusively oriented towards the common good, and can pursue other motives as well. "Standardization is also extremely relevant for the individual participants in economic processes, since whoever makes the standards controls the market." As standards are additionally subject to a fee, there is conceivably an economic interest associated with the production of further such "products".

European standard specifications with rigid provisions would not only interfere in an unacceptable manner in the medical profession's therapeutic freedom, they would also be obstacles to patients' claims to individualized medical treatment and rehabilitation.

Finally, this goes beyond the competence of the European Union. The desire to improve the quality of healthcare services in Europe, as well as to make such services more generally comparable and transparent, represents a legitimate goal for the European Union, insofar as it is carried out within the context of the competences allowed to it by the European treaties. CEN is encouraged to adhere to the self-imposed obligation that "European standards shall not cover those subjects that clearly belong to the domain of regulation of the member States, under the principle of subsidiarity, unless this is explicitly supported by the national authority".

What do we already have?

National and regional accreditation systems already exist in many European Union member states and have been adopted for several years. They were developed considering the different policies, priorities and organizations in each member state. In the health sector, the comparison needs to consider also major differences, in particular as the roles and duties of healthcare professionals are not the same.

These accreditation systems developed professional norms in the medical sector – directives, guidelines versus standard specifications, which take in account the different aspects of health quality: structure, process, and outcome.

To improve the quality of medical care, there are – in addition to programmes of thorough and stringent basic, advanced and continuing education training – proven instruments such as scientifically based (evidence-based) clinical guidelines, which are significantly better adapted to the specific features of medical or healthcare services than would be a set of standards. There is no need for parallel standardisation by private, non-scientific standardisation bodies, because there are already specific instruments established within the healthcare sector that support appropriate and high-quality healthcare, while at the same time doing justice to the field's complexity and the needs of patients.

The basis of legitimation for guidelines is that all parties involved in writing a guideline shall disclose their conflicts of interest at an early stage and a procedure for managing conflicts of interest shall be put in place: ensuring transparency in collecting and recording conflicts of interest builds trust and protects the group from any charges of bias or impartiality.