

Joint Letter by the Healthcare Stakeholder Group On the CEN Healthcare Services Focus Group

The undersigned healthcare stakeholder organisations (AIM, CED, CPME, EPSU, ESIP and HOPE¹) are concerned about the developments of the Healthcare Services Focus Group (HSFG) organised by the European Committee for Standardization (CEN) and invite national health ministries to join our political action to protect national health systems.

Problem statement

The undersigning organisations wish to trigger discussions at national level as to whether healthcare systems are prepared to accept “quasi regulation” on healthcare services developed by self-selected groups through technical standards. In this letter, we outline conclusions we drew from attending a strategic working group on standardising healthcare services led by CEN, the European Committee for Standardization². Please find our concerns elaborated in more detail below.

We believe that the structures in which standards are developed are not compatible with the demands and objectives that regulation affecting healthcare services must observe given its impact on patient safety and quality of care.

- In contrast to the legitimate structures in which guidelines and recommendations on healthcare services are adopted, European standards can be motivated by a variety of interests, including those of the private/commercial sector, and need not fully comply with national systems’ regulatory frameworks.
- This stems from the fact that European standardisation bodies are private membership-based organisations, which only provide a platform for the development of standards and, by their own rules, cannot be held accountable for standards’ content nor do they systematically enforce requirements as to the representativeness, expertise and quality commitment of the parties developing standards.

¹ See Annex for more information on each organisation.

² CEN is a private association under Belgian law that brings together the National Standardization Bodies of 34 European countries. The purpose of CEN consists amongst others in the development of European standards in relation to products, materials, services and processes, and, in using standardisation to promote the removal of trade barriers. CEN is member-led, independent in its decision making of any individual stakeholder (public or private) and market driven. It provides a platform for various sectors including e. g. air, space, chemicals, construction and consumer products. A standard (French: Norme, German: Norm) is a technical document designed to be used as a rule, guideline or definition. It may become legally binding by way of reference in laws or contracts. It is a consensus-built, repeatable way of doing something. Standards are created by bringing together all interested parties such as manufacturers, consumers and regulators of a particular material, product, process or service. A European Standard (EN) automatically becomes a national standard and therefore is included in the standards catalogue of CEN's Members, the National Standardisation Organisations in 34 countries.

- In essence, standards are developed by parties which pro-actively ask to be involved and are willing to pay participation fees. There are no sine qua non requirements which need to be fulfilled beyond this.

The undersigned organisations fear that this approach falls significantly short of providing sufficient safeguards as to the quality of process and outcomes and can therefore not be applied to healthcare services.

Developments until today

In 2014, the CEN Technical Board Strategic Advisory Group on Services (SAGS) and the Advisory Board for Healthcare Standards (ABHS) created an ad-hoc joint group that met four times to develop a draft strategy on standardisation of healthcare services. As a result of this work, the HSG was established in June 2016, met for the first time in November 2016 and for a second time in March 2017. Two sub-groups were created after the first meeting, to discuss terminology and criteria for applying standards and met in February.

Involvement of the Healthcare Stakeholders in the process

Organisations representing a number of healthcare stakeholders, including doctors, hospitals, dentists, insurers, trade unions, and others, have been involved in the discussions as observers. We have attended the above-mentioned meetings, trying to work constructively with CEN while voicing our concerns through a series of letters sent to the secretariat of the group, through numerous oral contributions in these meetings as well as written comments to the minutes of the meetings. However, we want to stress again that broad stakeholder representation cannot get around having started with the wrong approach.

Concerns of the Healthcare Stakeholders

There are a number of developments and approaches that are of concern to us:

Lack of governance:

- There is no clear governance of the CEN Focus Group and related predecessor meetings on healthcare standardisation, nor is it clear what impact the opinions presented by the stakeholder group, or contributions in meetings and written input prior to and after meetings, have on the further process. The meeting minutes have in the past often misrepresented the discussions and omitted important arguments that were presented, often with the incorrect justification “out of scope”. Such a lack of governance is of great concern to us, as our contributions are not reflected the way they should be.

Lack of health systems knowledge:

- The lack of understanding of healthcare and healthcare services (e.g. their functioning, their funding, the relevant legal and regulatory frameworks at different levels, but also to guiding principles of health care services as services of general interest, such as accessibility, affordability, continuity, etc.), as shown by CEN, is disconcerting and has made it difficult to find common ground on many occasions.

- The exclusion of clinical guidelines from the scope of CEN activities is essential for the healthcare stakeholders group as these are based on sound scientific evidence and should not be subject to a standardisation body like CEN that does not have the scientific expertise in this field. At the same time, we are facing strong interests from some of the national standardisation bodies that would like to write standards touching upon diagnosis and treatment of individual patients (including e.g. on clinical pathways).

Stakeholder representation:

- Unfortunately, it has become evident that the concept of representativeness of key stakeholders in health care is neither applied nor appreciated by CEN. Stakeholders that do not represent major groups affected by the envisioned action have the same voting rights and representation as groups that represent all or the majority of healthcare professionals, hospitals or insurers as well as the national and EU-level social partners (trade unions and employers' organisations) in the field of hospital/health care.
- This leads to a situation where a small number of people interested in a standard can set up a standard that may go against the interests of the majority of affected stakeholders.

Conflicts between national legislation and standards:

In addition to the above-mentioned concerns, we are also worried about conflicts between standards and national legislation and the burden that unsuitable standards can bring to the work of national ministries as well as other affected bodies (e. g. professional organisations). Generally, CEN members can ask for a derogation from the application of a standard (A-deviation) if it is not in compliance with the national legislation. Such a request then leads to a lengthy administrative process where the burden of proof rests with the member organisations together with the ministries and/or the other affected bodies – depending on who is part of the national delegation. They need to provide CEN with the applicable national legislation together with a comprehensive table highlighting each sentence of the standard in question and explaining how this conflicts with or is less demanding than the applicable law. Once provided with all the documents, CEN decides whether the A-deviation is plausible or not. We would like to highlight that CEN is usually not familiar with the intricacies of national health systems and its applicable legislation. Therefore, its capacity to provide well-founded objections to the legal arguments put forward by the CEN member requesting the A-deviation, can be questioned.

The abovementioned process shows that even though CEN states that national regulation prevails over standards, it is ultimately up to CEN to decide if its standards conflict with the national legislation or not. The signatories of this letter fully share the concerns expressed in a letter from the Polish delegation on “standardisation of healthcare services” (9487/16 SAN 221) addressed to the EPSCO Meeting on 17 June 2016.³

³ See <http://data.consilium.europa.eu/doc/document/ST-9487-2016-INIT/en/pdf>

We believe that you will share our concerns and we urge national health ministries to get involved in this matter before inappropriate standards are developed that undermine the national health systems. Therefore, we would like to ask you to contact your national standardisation body and voice our shared concerns. We will continue to monitor the CEN activities and inform you when the CEN Technical Board is due to vote to approve the strategy. If possible, we would appreciate it if national ministries could also approach the CEN Technical Board at that stage to voice their opposition.

We are at your disposal if you would like more information or are interested to discuss this topic with us in person.

Sincerely,

The undersigning healthcare organisations



ANNEX

AIM

AIM is the umbrella organisation of health mutuals and health insurance funds in Europe and in the world. Through its 64 members from 31 countries, AIM provides health coverage to 240 million people in the world and 209 million in Europe through compulsory and/or complementary health insurance and managing health and social facilities. AIM strives to defend the access to healthcare for all through solidarity-based and non-for profit health insurance. Its mission is to provide a platform for members to exchange on common issues and to represent their interests and value in the European and international Institutions.

CED

The Council of European Dentists (CED) is a European not-for-profit association representing 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 aims to promote high standards on oral healthcare and dentistry with effective patient-safety centred professional practice, and to contribute to safeguarding the protection of public health. The CED is registered in the Transparency Register with the ID number 4885579968-84.

CPME

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 institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

- *We believe the best possible quality of health and access to healthcare should be a reality for everyone.*
- *We see the patient-doctor relationship as fundamental in achieving these objectives.*
- *We are committed to interdisciplinary cooperation among doctors and with other health professions.*
- *We strongly advocate a 'health in all policies' approach to encourage cross-sectorial awareness for and action on the determinants of health.*

EPSU

EPSU is the European Federation of Public Service Unions. It is the largest federation of the ETUC and comprises 8 million public service workers from over 260 trade unions across Europe. EPSU organises workers in health and social services, local, regional and central government, and in the energy, water and waste sectors, in all European countries including the EU's Eastern Neighbourhood. It is the recognised regional organisation of Public Services International (PSI). For more information please go to: <http://www.epsu.org>.

ESIP

ESIP (European Social Insurance Platform) represents a strategic alliance of over 40 national statutory social security organisations in 15 EU Member States and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality.

Maison Européenne de la Protection Sociale, rue d'Arlon 50, 1000 Brussels

Tel.: +32 2 282 05 60 Fax: +32 2 282 05 98

Email: esip@esip.eu Web: <http://www.esip.eu>

**ESIP members support this position in so far as the subject matter lies within their field of competence.*

HOPE

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966 representing national public and private hospital associations and hospital owners. With 37 organisations from the 28 Member States of the European Union, Switzerland and the Republic of Serbia, HOPE covers almost the 80% of hospital and social care activity.

HOPE mission is to promote improvements in the health of citizens and a uniformly high standard of hospital care by the European Union, fostering efficiency, effectiveness and humanity in the organisation and operations of hospital and health services.