ETUC comments on the "Business Plan of CEN CT 449" (BT N 10512, ref BT C146/2016).

Following consultation of the main European Trade Union Federation active in the field of healthcare services, the European Federation Public Service Unions (EPSU), the ETUC provides the following comments on the business plan of TC 449:

- In the executive summary of the Business Plan, the following change is proposed in the **scope**, last sentence: "The scope does not include standardization of products (medical devices and associated software), clinical and professional qualifications and the built environment." The underlying rationale is that "professional qualifications" is the broader term and closer linked to aspects that are regulated (access to profession; titles; duration of training).
- In the **executive summary** of the Business Plan, the following changes are proposed on the last paragraph of the "**business environment**" subsection: "While in the end all older persons have similar needs, the area is complex and all European countries has national legislation and in some cases standards. The aim is to look to the older person's interest and the standard aims to support and complement the national legislative framework, without jeopardizing or undermining existing national regulatory framework and the right of MS to independently organise and deliver health services and medical care".
- In addition, the **section 1.1 on "business environment"** should reflect the current business environment, i.e. the fact that major stakeholders have shared their opposition to CEN entering in this field. This could be done either by attaching the received joint letters (from ETUC, ESPU, HOPE, CPME, CED as well as from AIM and ESIP, in annex to this document) or by referring to ETUC/EPSU input during the consultation on the creation of the CEN TC/449.
- In this connection, further reference to the existing business environment shall be added in **section 5 "factors affecting completion and implementation of the CEN TC work programme"**; without reference to the positions shared by main stakeholders from employees and employers side, the business plan gives the impression that the TC is working in a vacuum.
- ETUC proposes to add a **new section "4.3 Regulatory environment"** and call for the TC to make a first evaluation of the situation in some countries, so as to be

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able to deliver "standard aims to support and complement the national legislative framework" -without concrete knowledge about this dimension, it will be hard to achieve the proposed objective.

To the Member States' competent authorities,
To the Council of the European Union,
To the European Commission,
To the European standardisation organisations,
To the national standardisation bodies,

Brussels, 6 July 2016

Dear Madam,
Dear Sir,

We observe with great concern the initiatives at European level on the subject of standardising medical treatments, other healthcare services and elderly care. In the following we wish to explain why we consider these initiatives to be unacceptable and superfluous.

Guidelines and recommendations for professional practice developed on the basis of the national competences, as confirmed by the Treaty on the Functioning of the European Union (TFEU), have a legitimate basis. They ensure best possible coherence with the other professional regulation governing health services, including ethics. Mechanisms which are not embedded in this expertise and legal framework do not provide an equivalent legitimacy.

While the practice of the healthcare professions is shaped by evidence-based guidelines and recommendations, an essential characteristic is the ability to divert from these guidelines when a healthcare professional believes it to be in the best interest for a patient's individual care. Such professional autonomy is fundamental to ensure both quality of treatment and patients' rights.

To ensure the quality of decision-making, professional autonomy is counterbalanced by professional liability. This balance is embedded in professional regulation, including monitoring and sanction mechanisms. Standards, such as those developed with the involvement of standardisation institutes, created outside of these structures cannot rely on these mechanisms, thus creating ambiguity as to their enforcement.

The development of European standards for healthcare services is incompatible with national social security systems. Healthcare is to a very large extent collectively funded (by taxes and/or social contributions) and regulated to guarantee the realisation of public services principles and objectives underpinned by fundamental social and human rights.

The so-called voluntary and market-driven nature of European standardisation is not an appropriate mechanism for ensuring the realisation of public services principles and objectives which are better achieved through democratic decision-making processes, consultation and social dialogue. Moreover, the market-driven and "pay to play" principles governing European standards' development process fall short of ensuring transparency, representativeness and accountability towards the general public.

Rules created within the legitimate regulatory framework, be it established in law, self-regulation or collective agreements, are applicable to all professionals. They do not generate profits for the issuing bodies and their application is not subject to fees. This precludes selectivity and safeguards all patients' access to high quality healthcare.

Recent initiatives in standardisation at EU level go beyond the products and facilities supporting healthcare and are interfering with patient care and treatment delivered by healthcare professionals. The European Committee for Standardisation (CEN) as a private standard setting body is neither scientifically suited nor carries sufficient legitimacy to intervene in national competences. Its latest challenges to the right of Member States to independently organise and deliver health services and medical care as guaranteed by the TFEU, include the development of a "European strategy on standardization on healthcare services" and the creation of a standardisation committee addressing "Quality of care for elderly people in ordinary or residential care facilities". The strategy in preparation recommends the development of healthcare services standards which address topics such as professional competences, clinical processes, billing and payment fees, governance, patient communication and risk management.

Call to action

We therefore call upon national and EU decision-makers to refrain from initiating or supporting any activities seeking the standardisation of healthcare services by standardisation institutes, both in the context of public policy and private standardisation bodies' initiatives. More precisely, we strongly urge public authorities, national and European standardisation bodies to explicitly limit the scope of standardisation in the field of healthcare. In this context, we also fully support the recent information note of the Polish delegation to the Council on the standardisation of healthcare services.

We remain dedicated partners in promoting transparency and exchange relating to guidelines and recommendations on healthcare and committed to informing the policy debate on the best approach to be taken to improve the quality of care.

Sincerely yours,

Pascal Garel
Chief Executive
HOPE

Jan Willem Goudriaan
General Secretary
EPSU

Peter Scherrer,
Deputy General Secretary
ETUC

Annabel Seebohm
Secretary General
CPME

Nina Bernot
Secretary General
CED

HOPE *is the acronym of the European Hospital and Healthcare Federation, an international nonprofit 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 37 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.*

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 250 trade unions across Europe. EPSU organises workers in the energy, water and waste sectors, health and social services and local, regional and central government, in all European countries including the EU's Eastern Neighbourhood. It is the recognised regional organisation of Public Services International (PSI). EPSU represents health and social services workers across Europe, including nurses, health care assistants, midwives, doctors, elderly and child care workers, social workers, laboratory staff, hospital cleaners and medical secretaries. We organise in public, non-for-profit and private services. EPSU is the recognised European social partner organisation for workers in the hospital and health care sector throughout the European Union.*

ETUC *is the voice of workers and represents 45 million members from 89 trade union organisations in 39 European countries, plus 10 European Trade Union Federations. The ETUC aims to ensure that the EU is not just a single market for goods and services, but is also a Social Europe, where improving the wellbeing of workers and their families is an equally important priority. The ETUC believes that this social dimension, incorporating the principles of democracy, social justice and human rights, should be an example to inspire other countries. The European social model – until the onset of the crisis – helped Europe to become a prosperous, competitive region with high living standards.*

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.

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.

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EUROPEAN SOCIAL INSURANCE PLATFORM
The Social Insurers of Europe

AIM
Healthcare and social benefits for all

OPEN LETTER

Brussels, 14 September 2016

Standardisation of Health and Social Services

Dear Sir or Madam,

The members of ESIP and AIM, social security organisations, mutuals and health insurance funds, are following with great concern increasing efforts at European level for standardisation in the field of health and social services. In particular, recent requests for standardisation in quality of care for elderly people and patient involvement in person-centered care, as well as deliberations on standardisation in the field of healthcare within a CEN working group, represent a fundamental interference with existing national rules and medical guidelines developed by the competent institutions.

Whilst the work of the European standardisation institutions (CEN/CENELEC) can be genuinely valuable resources for the safety of products used in health or nursing care, medical devices or the design of hospital beds, **there is no added value in developing standards for the quality of health and social services.**

European standards in the field of health and social services developed by privately-organised standardisation institutions such as CEN/CENELEC will not necessarily improve the quality of services but could rather endanger patient safety. **Evidence-based guidelines to ensure the quality of health and social services already exist at national level**; they are developed and coordinated by experts from the health/social care sector based on the latest scientific evidence in a transparent manner which avoids conflicts of interests. If European standards were to contradict these existing guidelines they would reduce the quality of services rather than improve them and lead to legal uncertainty.

In the field of social security, guidelines are aimed at providing high quality services focusing on the insured person and taking into account the diversity and complexity of health systems in the Member States. **European standards are market driven** with the aim of facilitating the trade in services in the single market.

Social security institutions, health insurance funds and health mutuals, believe that **consideration should be given to existing standards first, instead of developing additional new standards**.

EUROPEAN SOCIAL INSURANCE PLATFORM
The Social Insurers of Europe

AIM
Healthcare and social benefits for all

ESIP and AIM call upon the governments of the Member States and Standardisation Bodies to take the above arguments into consideration and to stop the discussions on standardisation of health and social services provided and paid for by social security institutions, health insurance funds and health mutuals. Issues related to clinical processes, professional qualifications and training, quality of care, requirements for healthcare provision and management as well as occupational safety and health must be excluded from the scope of standardisation.

Kind regards

Dr. Franz Terwey
President ESIP

Christian Zahn
President AIM

About the *European Social Insurance Platform* (ESIP)

The European Social Insurance Platform (ESIP) represents over 40 national statutory social insurance organisations (covering approximately 240 million citizens) in 15 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

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About AIM

The Association Internationale de la Mutualité (AIM) is an international umbrella organisation of not-for-profit healthcare mutuals and health insurance funds in Europe and in the world which operate on the basis of solidarity. Currently, AIM's membership consists of 63 member organisation in 30 countries. In Europe alone they provide coverage of healthcare to around 200 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone.

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