



## Report on meeting of CEN healthcare services focus group

21-22 March 2017

Following the meeting of the CEN healthcare services focus group in November 2016 (please find the meeting report at [CPME Info 221-2016](#)) it was decided to create two working groups (WGs), which should look at the terminology used in the context of standardisation in the healthcare sector and criteria used to delineate the scope of standardisation (please find the meeting report at [CPME Info 016-2017](#)). To process the outcomes of these meetings, the CEN healthcare services focus group was convened for a second meeting in Vienna on 21-22 March 2017. The meeting was dedicated to the elaboration of the draft CEN strategy on standards for healthcare services, taking into account the outcomes of the WGs and comments delivered by participants.

The following points are to be highlighted:

- In preparation of the meeting, CPME co-signed a letter ([CPME 2017/011](#)) together with the International Association of Mutual Benefit Societies (AIM), the Council of European Dentists (CED), the European Hospital and Healthcare Federation (HOPE), European Federation of Public Service Unions (EPSU), the European Social Insurance Platform (ESIP), and the European Trade Union Confederation (ETUC). The letter highlighted crucial criteria for the assessment of the value added of standardisation/standards on healthcare services, and the scope for CEN activities resulting from the application of the criteria. This was submitted to CEN as proposals for amendments to the draft CEN strategy.
- The meeting was opened by a discussion on procedure and on the general dynamics around the process. One example of the critical points raised was the recommendation to CEN offered by Dr Romuald Krajewski, attending on behalf of the Polish Committee for Standardization (PKN). In relation to launching standardisation activities on healthcare services, his advice in first instance was “don’t do it” and if that could not be achieved “be very careful of the scope”. He concluded that CEN seemed decided to go ahead regardless. The majority of participants however underlined their conviction on the usefulness of standards for healthcare services, presenting examples of national level activity, the use of standards in laboratory medicine and accreditation.
- The discussion proceeded to examine the proposals for amendments to the strategy. All meeting participants, including CPME, were given a ‘vote’ on the items.
- The proposals for amendments to the scope of the strategy submitted in the joint letter CPME co-signed were rejected by a majority vote. The requests relating to the exclusion of publicly and privately financed healthcare service were rejected categorically. The proposal to exclude professional practice from the scope, as submitted by CPME also at previous meetings, was met with less opposition, with a general agreement that access to the profession should not be subject to standardisation. It was proposed that the French Standardization Association (AFNOR) and CPME try to find a compromise text. In this exercise, AFNOR presented CPME with a sentence based on the AFNOR text, excluding access to the profession and “general rules on

individual competency” from the scope of standards. AFNOR stated that no other wording, in particular any references to excluding professional practice, would be accepted by them. In light of the limited scope of the AFNOR proposal, CPME declined the text and went on to present the original wording which was rejected; AFNOR’s text was accepted.

- European Co-operation for Accreditation (EA) proposed to amend the sentence “The diagnosis and treatment of individual patients is not within the scope of standards” by deleting ‘diagnosis’, referring to the use of standards in laboratory medicine in the context of diagnosis. This amendment was put to debate, including the proposal to delete the entire sentence. CPME put strong emphasis on the fact that if CEN states that clinical guidelines are excluded from the scope of standards, the deletion of the sentence above gives rise to the question what CEN’s understanding of clinical guidelines is. If it was indeed so that this sentence does not reflect CEN policy, CPME requested for this to be explicitly recorded and underlined all future references to the clinical guidelines exemption. The decision whether or not to retain the sentence was heavily contested. Several stakeholders, in particular AFNOR, argued that diagnosis and treatment of individual patients should not be exempted from the scope of standardisation, as this was a key element assessed in accreditation which in turn is based on standards. There were several votes on how to proceed, in each case a majority was in favour of keeping the sentence. In light of this result AFNOR announced its deep concerns as regards the decision, stating that it effectively puts an end to their activities and it was necessary to rethink AFNOR’s future relationship with CEN.
- As to next steps, the CEN planning foresees the consolidation of the draft strategy and the development of a CEN guide to present the outcomes of the process. As regards the draft strategy, CPME remarked that following the meeting’s discussion, CPME felt negative about continuing with the discussion of the document (NB: at the beginning of the meeting, CPME abstained from a vote on whether or not to use the draft strategy as a basis for the meeting’s discussions, based on a proposal from the DIN). As there was no majority for this position, the draft strategy will continue to feature in future meetings. In terms of producing a CEN guide, ETUC made the proposal to abandon the idea for the time being, due to the lack of consensus and to instead prepare a report on the meeting outcomes. AFNOR underlined that there is no consensus and supported the idea of postponing the drafting of a CEN guide. This was accepted. It was also agreed that at the next meeting, scheduled for 25-26 September 2017, different participants should present the system in which they work and the role standards play or do not play within that system. This is intended to foster better understanding.

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**ADDENDUM:** On 24 March 2017, CPME met AIM, CED, HOPE, ESIP and ETUC to share first impressions of the focus group meeting. CPME presented its view that the dynamics of the discussion do not seem to shift, that there is no sign on the part of CEN to accept any of the concerns presented and that it is not clear how reliable statements relating to CEN’s position are. Pending a discussion and decision by the CPME membership, CPME was rather negative about continuing in the process. Feedback from the majority of other stakeholders was more varied. Some see the benefits of staying involved in the process to outweigh the risk of legitimising or being associated with the work. In support of this view it was suggested that there is an opportunity to engage with and influence CEN, while there is currently no contact with its competitors, such as the Joint Commission International or Den norske veritas. It was also reported that there is interest in and call for standards and it was

preferable to have a European system which maintains the division between standards and accreditation, in comparison to the US system in which both are managed by the same organisations. It was agreed that:

- all stakeholders must report to their membership and await a decision on how to continue
- all stakeholders should continue to coordinate their action to maintain a strong joint position
- there is currently no majority in favour of leaving the process
- action to promote awareness at national level for CEN's activities and the stakeholders' position should continue
- the stakeholders will cooperate on a briefing note which can be distributed at national level