



Council of the  
European Union

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**NOTE**

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From: General Secretariat of the Council  
To: Council

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Subject: **Employment, Social Policy, Health and Consumer Affairs Council**  
meeting on 17 June 2016  
Standardisation of healthcare services  
– *Information from the Polish delegation*  
(Any Other Business item)

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Delegations will find attached an information note from the Polish delegation on the above mentioned subject.

## **Standardisation in healthcare services**

Polish delegation would like to draw your attention to the ongoing activities on the European level in the field of healthcare services.

The European Committee for Standardisation (CEN) Work Programme for 2016 mentions healthcare services as potential field for standardisation:

*European standardization in the healthcare sector has traditionally been mostly limited to medical devices and e-health applications. (...)*

*Recent years have seen an increasing level of demand from stakeholders in relation to the standardization of healthcare services. The increasing mobility of patients and healthcare professionals means that there is a greater need for transparency, in order to make it possible to measure quality and compare services, ensure patient safety and facilitate the mobility of healthcare professionals.<sup>1</sup>*

Bearing in mind regulation No 1025/2012 on European Standardisation Polish delegation is deeply concerned by the document published by CEN and planned actions which might be against member states national competences to organise and deliver their health systems.

The process initiated by CEN in the field of healthcare services might create regulatory system which will impact healthcare professionals' ability to exercise their judgement under domestic regulatory system what is contradictory to the Article 168 of the TFEU and complementing role of the European Union. Exclusions in the field of healthcare services is not the matter of tradition as stated in CEN Programme but the legislation.

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<sup>1</sup> CENELEC Work Programme 2016

Medical professionals are very well trained and highly skilled. Standards can be issued as far as they concern technical and engineering issues, but not activities within medical professionals. Medicine should be personalised and cannot fall into narrow standards created in an one size fits all manner. Patient-oriented and individualized health care needs rather guidelines and recommendations than standards. In order to safeguard patients safety and best quality of care all these principles of good practice should be left in the hands of the health care professional organisations concerned and technical bodies like CEN should restrict their activities to technical standards only.

Member States and the Commission should act together to prevent further actions initiated by CEN aimed at undermining member states competences in the field of healthcare, protected by the Article 168 of the TFUE and brought out in the regulation No 1025/2012. Actions both on national and on the European level are necessary to prevent doctors from being bound by technical standards issued by CEN.

There are at least two reasons why we should talk about this issue. First of all, only medical professionals shall determine what is right and what is wrong in their professions. Secondly, we should remember about the subsidiarity rule of the Treaty. Standards made by CEN are indeed only guidance recommendations, but in practice, they become applicable rules throughout the EU very quickly.

Poland is holding a dialogue with European Commission in this matter. We are grateful for the answer to our letter. But we would like to receive a feedback on this matter from the Member States and we would like to ask Member States to be more active as it comes to national policies in the area of standardisation.