

Conference on Standardisation and Health

12.10.2017, 09:30–13:00h

Permanent Representation of Germany, Rue Jacques de Lalaing 14, 1000 Brussels

Speech given by Dr. Doris Pfeiffer, Chair of the Board National Association of Statutory Health Insurance Funds

Ambassador,

Ladies and Gentleman,

I am happy to be here at this conference on such an important topic. Let me first of all thank the German Permanent Representation for organising this event.

The debate about standardisation at European level has been ongoing for years. We have raised our voices against endeavours by European standardisation bodies to intervene with the way healthcare, long-term care, and certain social services are being provided.

We as the German Statutory Health Insurance Funds have voiced our concerns together with our colleagues from the German Pension Funds and the German Statutory Accident Insurance, together with health insurance funds from Austria, France and other EU countries, and



together with our cooperation partners in the German healthcare system, represented today by Mr. Baum and Dr. Jonitz.

Despite this broad opposition, standardisation activities at European level continue and the European Commission has not taken a stand. Thus it is our task today to once again address this issue and demand a policy change at European level.

Why are we so concerned?

We are observing the growing willingness of standardisation bodies, private entities, but also national authorities and the European Commission to standardise healthcare services, long-term care services and other social services that are delivered or financed by social insurers.

The European Committee for Standardisation – the CEN – has already published standards in the field of healthcare. You may be aware of the standards on homeopathy and plastic surgery. There are also initiatives to standardise “care, services, nursing, and rehabilitation for elderly people” and to set “minimum requirements for person-centred delivery of care”. These are only a few examples, where standardisation

initiatives directly interfere with the core tasks of the statutory social insurance in Germany.

New initiatives are often pushed by national standardisation organisations and private entities. Both have strong economic interests in creating new standards.

These attempts seem to match the European Commission's paradigm of completing a European single market for services, but only at a first glance. There is a clear and coherent distribution of competence between the EU and the Member States in the field of health. However, we sometimes get the impression that the further "marketization" and Europe wide "trade" with healthcare and long-term care services still has supporters within the European Commission.

That might be the reason, why the European Commission has to date not unambiguously rejected CEN's standardisation activities in the field of health and long-term care. The Polish ministry for health expressed its concerns during the EPSCO meeting in June 2016. They were supported by the German health minister and other delegations. The European Commission however referred to CEN's private entity status and the lack of formal influence of the Commission on their agenda.

CEN has continued its activities and recently has set up a working group, the so called “CEN Healthcare Service Focus Group”. The social insurance organisations participate with an observer status. And what my colleagues in Brussels report from the first sessions is purely and simply alarming:

There is a sharp contrast between the positions of the mainly commercially-oriented standardisation industry on the one hand and of most other stakeholders on the other hand. And unsatisfyingly, the chair of the focus group and the secretariat have left no doubt, that they are not impartial moderators but rather advocates of standardisation.

What would we like to see instead?

For the German social insurers comprehensive and high quality provision of healthcare and patient safety are crucial. Standardisation by CEN will not help us to further pursue these goals!

We rely on a solid legal framework requiring transparent and evidence-based decision-making. A major asset is consent between those players that are directly involved in the treatment of patients and the management of the healthcare system. Germany has chosen the way of

subsidiarity: the legislator sets the necessary political goals and legal framework and the joint self-government of the social insurance – the “Gemeinsame Selbstverwaltung” – fills this framework in detail.

There is a comprehensive system of rules and instruments of quality assurance and quality assessment in Germany. And we invest considerable resources to achieve the highest level of quality and safety. We focus on further developing this very system together with our cooperation partners, the physicians, the hospitals and the caregivers. In the field of product markets actually, we do see room for standardisation, for example when it comes to medical devices or products used by health professionals – for example implants or syringes.

Apart from that, there is no room for European standardisation of healthcare and long-term care services. And there is no need to further push the single market for these services. Most patients seek treatment close to their homes and communities. When people travel or live abroad, they should also be able to rely on their host country's health system. The recent problems of healthcare systems in some Member States are, however, not due to a lack of sophisticated technical standards, but due to a lack of appropriate capacities, structures and

health budgets. Any standardisation will not help to overcome this issue.

As social insurers we do see potential for closer cooperation between the Member States in the field of healthcare and long-term care.

Thus we welcome and support the closer cooperation between Member States in the field of health technology assessment at European level – a field with a lot of potential for quality and efficiency for the treatment with drugs and medical devices. We have also advocated a continuation of the European Network for Patient Safety and Quality of Care. The Commission unfortunately has neglected to support the network's continuous activity in 2016.

I call on the European Commission to support the Member States' cooperation in these fields with a clear focus on positive outcomes for quality and efficiency of healthcare and long-term care provision. Furthermore, the European Commission needs to unambiguously reject any CEN standardisation activity that interferes with the competences of the Member States and the statutory social insurance systems.

I call on CEN to no longer pursue or support efforts to standardise healthcare and social services.

Finally, I hope there are a lot of representatives from many different Member States in the audience today. I appeal to you to be alert to the repercussions the European standardisation may have on your systems. And I ask you to bring this discussion into your national arenas and to further our common cause.

Thank you for your kind attention.