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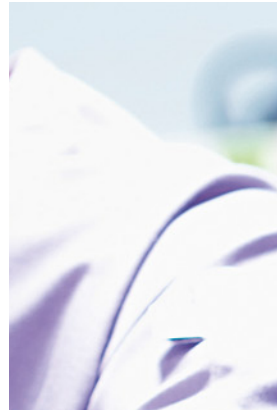


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Standardisation in social and health services:

Where do we stand today?



Dear Reader,

The trade in goods doesn't work without standards. There's a reason for this: an important prerequisite for the cross-border movement of goods is the removal of any technical barriers to trade. As technical specifications, standards stipulate a product's level of quality and they can contain normative specifications on its suitability in the interests of customer safety or the safety of others.

Standards can also be useful in healthcare, for example where they support the safety of products used in the health sector, because this contributes significantly to the safety of patients. They are also very important for the safety and health of doctors and nurses who use these products.

However, it's not that easy to take something useful for products and simply transfer that to other areas. For example, standardisation of medical treatment via standardisation bodies such as CEN and ISO is entirely unsuitable. This would unnecessarily restrict the scope and leeway for individual, needs-based treatment. There is also the danger of parallel structures being developed which ultimately lead to legal uncertainty and the undermining of national statutory requirements.

Therefore, the German Social Insurance has repeatedly highlighted this issue in recent years. And this is not an isolated position. Numerous interest groups from the German healthcare system, the Ministry of Health and the national standards institute (DIN) have all rejected the formal standardisation of medical treatment. The European associations for health care providers and social security are also against this.

The standardisation industry, with its commercial focus, does not appear to have been swayed by this. Private companies are convinced that the healthcare sector is a large, attractive and untapped market. Therefore, they will not tire of submitting proposals to the European Standardisation Institute (CEN) to develop European standards via national standardisation bodies. The problems that result from this can already be seen from standards developed for homoeopathy and aesthetic surgery.

In this issue of ed*, we want to give you a closer look at the status quo of efforts being made to develop European standards in healthcare.

We hope you enjoy reading this issue of ed*!



Ihre Ilka Wölfle

Different ways towards quality and standards

There are three parallel 'creation worlds' that contribute to the formation of uniform standards in the broadest sense. The first world is the most trusted: primary and secondary legislative standards, directives, etc. This world, however, is not the usual way, especially when it comes to the standardisation of material goods.

Instead, the legislature has shifted its steering function back to society and business, thus creating a secondary level of regulation. Private standardisation institutes that are officially recognised by the state, such as the German Institute for Standardisation (DIN), develop technical standards in a complex process on request, including requests from the business world. Use of these standards by companies is (at first) voluntary. However, they remain the intellectual property of the standardisation institutes. There are fees for accessing this work and for purchasing standards.

At this point, it is important to explain the different paths that are taken when standardising goods as opposed to standardising services. As will be seen, these have consequences for the positions and demands of the German social insurance system. Whether a tangible 'good' meets a certain standard is determined by accredited bodies using the 'conformity assessment procedure'; this is the case for most medical devices. In Germany, these are generally the TÜV inspection bodies. The focus here is on the result of the production process and less on the process itself. The situation is different for services. They cannot be observed in the same way as 'tangible' goods. In many cases, production and consumption occur at the same time, which is the case for healthcare services. The focus of quality control is then on inspecting the facility, its equipment, the qualifications of the people providing the service and internal processes. If these

comply with the descriptions in a standard then the facility meets 'certification' requirements. However, these types of certificates cannot hide the fact that the 'interchangeability' of services is for consumers far more questionable than the interchangeability of goods.

The third path is only mentioned here to complete the picture. On a case-by-case basis, the business community and other interested parties can agree on specifications in the form of codes of conduct or good practices, without going through the formal standardisation institutes such as DIN or CEN. These are often referred to as 'quality standards', although the word 'standard' here is not used in its strict sense.

Product standardisation plays an important role in healthcare.



In Europe, standardisation prepares the foundation for the Single Market.

Standardisation applications are also increasingly being submitted for healthcare services.



The globalisation of the flow of goods and services means that formal standardisation has shifted to a global level. In Europe, it is standardisation which prepares the foundation for the Single Market. The dualism of legal regulation and formal technical standardisation is also found here. It is generally well-known that the harmonised European legal framework does not leave any room for national rules to deviate. Less well-known is that European Standards from the European Committee for Standardisation (CEN), supersede conflicting national standards as far as these have been adopted by formal national standardisation institutes such as DIN. But compliance with these standards is voluntary. In addition, European Standards cannot displace national laws; these have precedence.

However, it is already clear at this point that Europe not only legally 'regulates' its Single Market but also steers self-organisation of the market towards European level. The two creation worlds – legislative and technical – completely overlap or complement each other when the European Commission publishes a European Standard. This is also referred to as a mandate to create 'harmonised European Standards'. These then displace national technical standards in the same area.

At first, the use of European Standards is voluntary; however, they can be made compulsory by means of contractual provisions or implementation into law. Within the framework of the European Single Market, pressure is being applied to use standardised

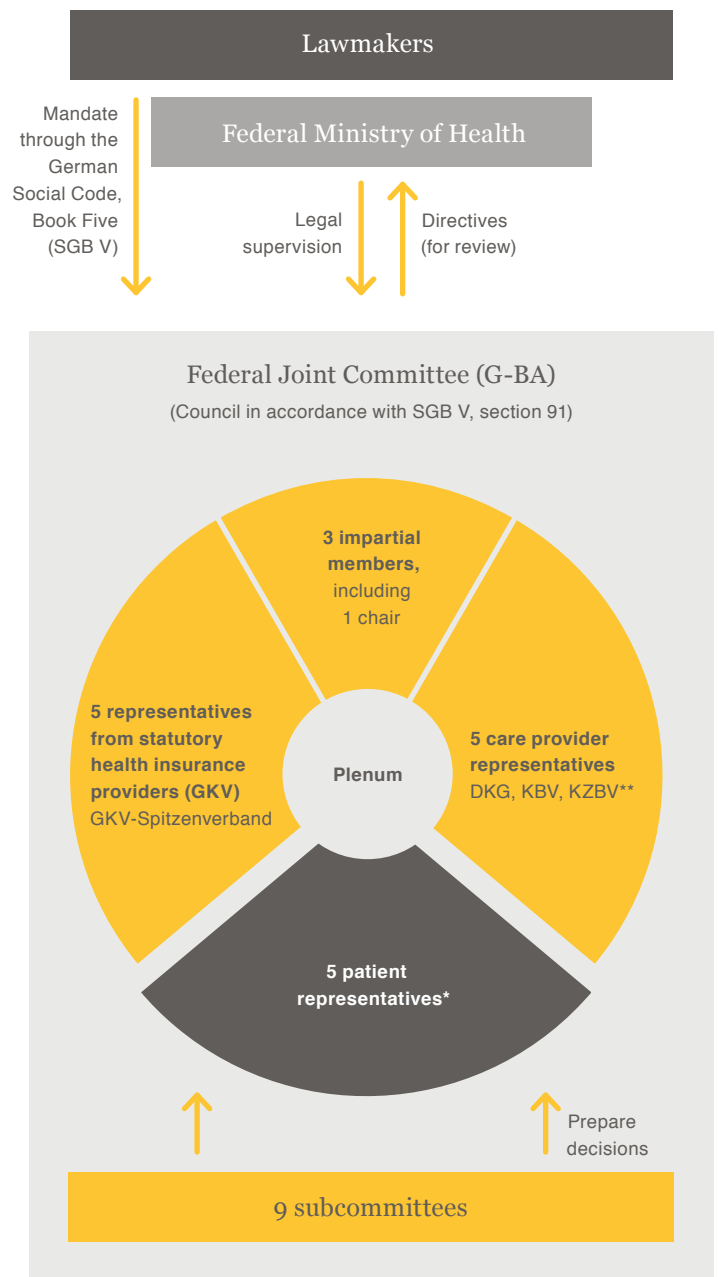
goods in public procurement procedures. In addition, national regulatory bodies are also encouraged to inspect goods at a level which complies with formal European Standards.

Quality definition and assurance in Germany: responsibility lies with the system of self-governance

In Germany, the quality of medical care and rehabilitation is controlled and assured by secondary legislative regulations and guidelines on a contractual basis in close cooperation between service providers and social insurance institutions. This is achieved through a wide range of instruments that are coordinated with one another. The system of self-governance plays a special role in this. For example, in the Federal Joint Committee, repre-

In Germany, the quality of medical care and rehabilitation is controlled and assured by secondary legislative regulations and guidelines on a contractual basis and in close cooperation between service providers and social insurance institutions.

Structure of the Federal Joint Committee (G-BA)



representatives from health insurance funds, physicians and hospitals issue directives on medical care and quality assurance. In addition, evidence-based guidelines are developed by self-governing committees from the medical profession, professional associations and expert associations in the field of medical science. The same applies to the setting of quality standards for outpatient, inpatient and rehabilitative care of patients injured in the workplace. The medical and occupational rehabilitation services provided by the German statutory pension insurance scheme are also subject to a sophisticated quality assurance system both internally and externally.

As such, the German social insurance system has developed numerous instruments to ensure the highest possible level of quality care without needing to involve standardisation institutes.

European standardisation of healthcare services

European Standards which are relevant to healthcare are still mostly found in industrial medical devices including

* Entitled to take part in discussions and submit petitions, but not to vote

** Care providers are entitled to vote only on issues affecting their area of expertise. Otherwise these votes are allocated proportionally in accordance with the bylaws, section 14a, paragraph 3

Current standards in aesthetic surgery breach German law in a number of areas.



Meanwhile, there is a clear tendency towards the core areas of healthcare being opened to the standardisation market.

digital applications (known collectively as ‘medical technologies’), as well as in IT systems for communication between the various contact points in the health system.

Compared with goods, the European standardisation of services has progressed far less. This particularly applies to the core of healthcare, namely healthcare services including their definition, technical specifications, quality standards, clinical directives and their implementation. It is no coincidence that the European Institutions have been rather reserved about this in the past. According to the European Treaties, health policy is essentially the domain of the Member States; the European level plays a supplementary and coordinating role.

However, there is now a clear tendency towards opening up the core area of health to the standardisation market. Although the European Commission has stated that it does not intend to give the European Standardisation Institute a mandate to standardise health services, the Commission does support standardisation projects initiated by other parties. Above all, the ‘sale’ of standards to potential users is a lucrative business model that the standardisation institutes are reluctant to miss out on. Incidentally, the health systems of the Member States could be harmonised as a result, thus opening them to global competition. In recent years, individual member organisations of CEN have successfully launched various horizontal and sector-specific standardisation initiatives. This is done with the backing and support of the Advisory Board on Healthcare Services (ABHS). The first of these are standards for homeopathy and aesthetic surgery. These have not only come under heavy criticism from experts but also violate German law in a number of areas. Other standards are in the pipeline.

At the end of 2014, the European Standardisation Institute (CEN), in conjunction with European stakeholders, began developing a strategy for the standardisation of health services. The work ended tentatively at the start of 2016 with the explicit conclusion that consensus could not be reached among the stakeholders. Nevertheless, CEN continued its work on the draft strategy. It addressed the concerns of critics in so far that it initially excluded clinical guidelines from standardisation. Towards the end of 2016, CEN’s Technical Board set up a new working group which included the European umbrella associations of the social insurance institutions, albeit with observer status only. The

European Social Insurance Platform, of which the German Social Insurance is a member, is also involved in the working group.

The following meetings of the CEN Healthcare Services Focus Group left little hope of an 'open-ended discourse'. The interests of the commercially-oriented standardisation and certification industry are often in sharp contrast to the positions taken by most of the other invited representatives from the insurance funds and service providers. Their respective European umbrella associations sent a joint letter to the Focus Group prior to its first meeting in March 2017 which included the following key points:

1. There is no room for European standardisation initiatives where primary or secondary legislation at

national level already exists, including collective agreements between service providers and social insurance institutions.

2. Standards are only beneficial when the relevant interest groups and business stakeholders have already reached an agreement (market relevance).

3. European standards must not interfere with the Member States' competence to define and organise their public healthcare systems.

Contrary to initial expectations, discussions have yet to be concluded and will continue through most of 2018. Nevertheless, the chair and secretariat of the focus group, which are in the hands of the standardisation industry (Norway and Austria

respectively), have left no doubt that they are not impartial moderators but rather are acting in the interests of the standardisation organisations. For this reason, the European umbrella associations of the healthcare service providers and social insurance institutions are going to send a second joint letter to reach a broader public audience. Essentially, it is about the national policy makers retaining the competencies that private standardisation institutes want to take over.

European standardisation of health services and social services – the wrong path to take

Ideally, compliance with a standard tells end users about the type of service and its quality. Certainly, in situations where patients can freely choose a doctor or facility across

There is no room for European standardisation initiatives where primary or secondary legislation already exists at national level.

National policy makers must safeguard their competences from being taken over by private standardisation institutes.



borders, they must be able to rely on information about the quality and price of the prospective treatment. However, there are serious doubts about the suitability of CEN standards to provide reliable help when making individual decisions on social and health services. In the worst case, a patient could be misled to believe that a facility that is certified according to a European standard is automatically 'better' than a facility that follows other quality assurance procedures. In reality, the patient must know and trust the health system of the country where he is receiving treatment. The European Directive on patients' rights requires the establishment of national contact points which provide patients with access to the necessary information. Even though this is complex in practice and could be improved, this system contributes significantly more to patients' understanding than simply fulfilling a technical standard.

If compliance with European Standards is of little help in making decisions, perhaps these standards would still be a suitable instrument for increasing the level of healthcare across Europe and improving patient safety, thus contributing to a more social and 'healthier' Europe. In fact, this argument is repeatedly put forward in the public debate, not least by representatives from 'poorer' Member States. However, this argument is quickly countered. The problematic level of healthcare in some Member States is not due to the lack of sophisticated formal technical standards and specifications, but to the lack of appropriate health budgets. In addition, it should be made clear: as far as patient safety is concerned, there is the danger that European Standards have only limited consen-

sus and thus exert 'pressure to adapt downwards'.

Position of the German Social Insurance: Where does it make sense to have standards and where not?

Standards can help make products safe. As such, product standards are also useful in the healthcare sector. Thus, the safety of medical devices is not only important for patient safety but also for the safety and health of the doctors and nurses who use these products.

Despite all of this, the German Social Insurance is critical of the European standardisation of social and healthcare services because, ultimately, this is an attempt to influence national social security systems via privately organised standardisation institutes and their members. This position was already stated in October 2015 with a detailed public statement. It called on standardisation institutes and the European Institutions to no longer pursue or support efforts to standardise healthcare services and social services. The latest developments confirm the criticism raised in the original position statement.

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