KAN Kommission Arbeitsschutz und Normung

Position of the Commission for Occupational Health and Safety and Standardization (KAN) on the standardization of health services

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KAN's position on the standardization of health services

Both within Germany and internationally, general willingness and the efforts of policymakers to promote the standardization of health services are growing. The European Commission for example has referred to the relevance of the standardization of health services in its annual work programmes since 2013. It regards standards as an instrument for enhancing the quality of services in the health sector. It takes the view that medical practitioners, regulatory bodies and representatives of the research and development community and of accreditation and standards organizations should also be involved in developing the standards in this area; and that standardization mandates issued by the European Commission to CEN, the European standards organization, should promote the process in the future. The desire to improve the quality of health services in Europe and to make these services more comparable and transparent overall is a legitimate objective of the European Commission. This is however conditional upon the relevant measures being taken within the framework of competencies defined by the EU treaties[1].

1 Standards for product safety in the health sector

As in other sectors, product-related standards can "boost the competitiveness of enterprises by facilitating in particular the free movement of goods [...], network interoperability, means of communication, technological development and innovation[2]" in the health sector. Such standards enhance the safety of products that are used in the health sector. This also increases the safety of workers, for example when working with hospital beds or medical equipment, or when using safe hypodermic needles. Products complying with high-quality standards can consequently have a positive influence upon the delivery of health services.

[1] Refer here also to Recital 12 of the European Standardisation Regulation 1025/2012 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF

[2] Refer here also to Recital 3 of the European Standardisation Regulation 1025/2012 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF

2 Interfaces between health services and occupational safety and health

The first interface concerns health services for workers and insured individuals[3], which in Germany derive from statutory obligations, benefits provided by the statutory accident insurance institutions and agreements with them, and additional, voluntary benefits provided by companies:

- Preventive measures in occupational medicine (for example the involvement of the company physician in risk assessments, general consulting on occupational medicine and preventive occupational medical care)
- Workplace health promotion and prevention of work-related health hazards
- Education and training of persons in the conducting of preventive measures in occupational safety and medicine and in workplace health promotion
- Curative treatment (particularly medical rehabilitation and special diagnostics) in the area falling within the responsibility of the statutory accident insurance institutions
- Rehabilitation, e.g. for the reintegration of persons into working life

These services may be delivered in the different Member States for example by the statutory accident insurance institutions or other social insurance institutions. The distribution of responsibilities for the health services in the Member States is governed by the respective national legislation, rules, regulations, guidelines, and agreements between the social partners.

The second interface arises when workers[3] providing a service, for example as nursing, medical or physiotherapy staff, must be protected against hazards. The provisions governing the protection of patients (recipients of the service) and of workers (the party delivering it) may have a reciprocal influence. Requirements for the wearing of protective gloves, the provision of instruction in matters of safety, or

[3] Workers in the sense of the German occupational safety and health act and DGUV Regulation 1 concerning the principles of prevention: workers in the sense of DGUV Regulation 1 in the health services include, for example, volunteers, individuals undergoing work experience, family members and other persons.

measures for working with medicines may have an influence upon the safety of patients and the safety of workers.

Employers bear responsibility for protecting workers in their companies based upon directives under Article 153 of the TFEU and the corresponding national legislation. An employer is not able to determine which protective measures are relevant to the worker until a risk assessment has been performed. This cannot be determined by standards developers without knowledge of the specific work situation concerned.

That not every service lends itself to standardization is shown clearly by the commitment by CEN itself as laid down in CEN Guide 15[4] concerning the standardization of services. The guide expressly excludes the safety and health of workers at work from the scope of standardization with reference to the existing European and national arrangements. KAN's position paper[5] on services also supports this rejection of standards governing health services that interface with occupational safety and health.

The two interfaces described above are governed by legal systems that cannot be replaced or governed uniformly by a standard. Should standards nevertheless be created for health services that are regulated at national level, problems may arise for example as a result of duplicate but divergent provisions or a lack of compatibility with existing systems of rules and regulations.

The aim must be to retain and improve the standard of health services that has already been attained for workers, derived in Germany from the high quality of the social insurance system and the interaction between the state, the statutory accident insurance institutions and the social partners, and likewise to retain and improve the existing standard of safety and health for workers at work. The social security systems of other Member States should likewise not be influenced negatively by standards: duplicate provisions, contradictions or uncertainty should for example be avoided at European level and in particular in cross-border scenarios. For workers, too, health services necessitate customized services to a particular degree; this is not compatible with the standardization of services.

[4] CEN Guide 15:2012, Point 7.2.3, Page 18/19; http://boss.cen.eu/ref/CEN15.pdf

[5] www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/Hinweise_der_KAN_-_e.pdf

3 Limits to the standardization of health services

These needs cannot therefore be met by standards[6], which are rejected by KAN in principle as a supporting instrument:

- When they impact upon requirements concerning health services for workers and insured individuals deriving from statutory obligations, benefits provided by the statutory accident insurance institutions and additional, voluntary benefits provided by the companies.

- When they impact upon requirements concerning the safety and health at work of the persons delivering the health services concerned.[7]
  In specific cases however, the safety and health of workers at work may be made the subject of standardization when this yields advantages for protection of the workers involved in delivering health services, when the remaining requirements of the Policy paper on the role of standardization in the safety and health of workers at work[8] are met, and when all stakeholders in OSH[9] in Germany agree to it.

[6] The principles described also apply to specifications: unlike standards, these are developed without the same requirements for a consensus and are also unsuitable for governing occupational safety and health (refer also to the KAN position paper on the inclusion of safety and health aspects in "new deliverables": www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/KAN-Positionspapier-Spezifikationen-neu2013-en.pdf).

[7] Requirements concerning the protection of patients may in some cases overlap those for the protection of workers.

[8] Notice by the German Federal Ministry of Labour and Social Affairs (BMAS) of 24 November 2014 published in the Joint Ministerial Gazette 2015 No 1 pp. 2 ff

[9] An example are the committees for occupational medicine of the German government and the German Social Accident Insurance.