CEN-CENELEC Advisory Board for Healthcare Standards (ABHS)

Strategy to 2020

In view of the new Medical Devices (MDR) and In Vitro Diagnostic Medical Devices Regulations (IVDR), the next few years will be very challenging. ABHS commits to help the CEN and CENELEC BTs take adapted decisions and shape appropriate technical policies in the healthcare sector. The following areas will be a key focus for ABHS:

1. Support standardization work towards advancing patient and user benefit and safety.

2. To actively support the transition to the new landscape under the MDR and IVDR, including the future standardization requests.

3. To actively encourage timely Official Journal of the European Union (OJEU) citation of up to date and internationally recognized medical devices standards providing presumption of conformity, which is essential to avoid fragmentation of the medical devices market, and other work to support these objectives such as the work of the Medical Devices BT Task Group.

4. To strive to increase ABHS representation and actively encourage the sharing of knowledge across all stakeholder groups, particularly Technical Committees (TCs), manufacturers, healthcare professionals, competent authorities, conformity assessment bodies and the EC.

5. To keep conversant with developments in the CEN Healthcare Services Focus Group.

6. To identify areas that are not sufficiently covered by standardization.

7. To cooperate with ISO and IEC.

1. Background

The original strategy was presented at the CEN and CENELEC BT meeting of April 2014, where its content was welcomed by the BT Members. The strategy was updated at the start of 2017, to take into account the focus of ABHS for 2017-2020 as agreed at the October 2016 plenary.

2. Trends in medical technology

The medical device sector is highly innovative and leads among all sectors in the number of patent applications submitted to the European Patent Office.

However, a number of trends have emerged and some areas are developing more rapidly than others. Standardization will be key in ensuring that future trends can be accommodated to ensure patient and user safety in a rapidly changing environment.

2.1 Personalized Care

With a more dispersed care pattern comes a more personalized care with active patient involvement, and practices. In this regard, medical devices will need to be tailored more to individual patients. This will also inevitably require enhanced CEN-CENELEC Advisory Board for Healthcare Standards (ABHS) training of clinical staff and closer cooperation between providers of medical devices, the clinicians and patients who use them.

2.2 Ambient assisted living

The objective of Ambient Assisted Living is to extend the time people can live in their preferred environment by increasing their autonomy, self-confidence and mobility. Health technology and health services, therefore, have a role in supporting and maintaining the health and functional capability of the elderly to help them achieve this.

2.3 Software and IT networks

Software, IT networks and more specifically, 'mobile' Apps are becoming a significant aspect of healthcare delivery. The level of regulatory clarity and – thus – oversight has been poor, resulting in many Apps of dubious quality and performance manage their health, appropriate regulation and standardization is necessary to ensure that Apps are 'fit for purpose'. IT security is among others one of the key factors that need to be addressed.

2.4 Automated devices

Since reliance is placed on assisted living, diagnosis will sometimes need to be automated to enable the patient to carry out self-testing without clinical intervention. Self-testing devices so employed must be easy to use, reliable and be validated for the intended user. Robotics will also play a (therapeutic) role in the near future, both in (tele)surgery and in revalidation. Some standardization work is on-going in this area, but only in the early stages at the moment.

3. Trends in regulations for medical technology

3.1 International standards

Most standards used in Europe are drafted at the international level and are consequently the result of contributions from the global arena. This brings the benefit of using the global knowledge on safety and performance. Consequently, global standards reflect the demands of all the national standards bodies that contributed. The EU has expressed a desire to use global standards where possible in order to reduce technical barriers to trade. Since global standards are not written specifically for the European environment, they may not fully cover all the relevant EU requirements. This needs to be addressed so that regulatory requirements in the EU are fully compatible with global standards.

3.2 Citation of standards in the Official Journal of the European Union

Since 2011, the number of standards not cited in the OJEU has increased substantially. To date, over 200 standards developed by CEN-CENELEC are

awaiting citation in the OJEU: 209 under MDD, 14 under IVDD and 22 under AIMD. The issue of non-citation of standards is not exclusive to medical devices and spreads into sectors including construction, LVD, RED and others. Consequently, it is an issue that is being addressed in different forums, including but not limited to the recently created CEN-CENELEC BT WG 12, the European Commission's Joint Initiative on Standardization Action 8, and the European Commission's Regulatory Fitness and Performance (REFIT) programme Platform. While finding solutions on a horizontal level that would cover all affected sectors is important, the focus of the ABHS will be specifically on the healthcare sector. In this respect, ABHS will closely liaise with the Medical Devices Task Group to find a well-defined and sustainable solution. This task is vital now that the revised regulatory framework for medical devices is coming in force in Europe.

3.3 EN harmonization / Regulation 1025/2012

Regulation 1025/2012 sets out the future for standardization in the European Union and the ABHS fully supports the aims and objectives of this Regulation, welcoming it as a very positive step forward. In particular, ABHS is concerned that the requirements, aims and objectives of Regulation 1025/2012 seem to be overlooked by the European Commission, not least that both the European Commission and the European standards organizations (ESOs) are responsible for assessing the compliance of standards drafted under a standardization request with the requirements of the request (Art. 10.5), and that such documents 'shall be market driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus' (Art. 10.1).

4. Trends in standards development

4.1 Regulators' participation

One of the weaknesses in the drafting of standards is the lack of participation by regulators. This is in contrast to the Food and Drug Administration (FDA), which not only gets involved in standardization but actively leads some standardization projects. Regulators provide an invaluable and unique insight into where standards could be of benefit and their participation is very strongly encouraged. Regulators possess an extensive and invaluable amount of information contained in adverse event reporting. This information is of great value in the drafting and maintenance (or periodic update) of standards. Although Regulation 1025/2012 (Article 7) encourages regulators to participate, not much impact of this encouragement is visible. It appears that some Member State Authorities are in favour of establishing a pool of EU Competent Authorities experts who would participate in the development of important standards. This is warmly encouraged by ABHS.

4.2 Use of international standards for compliance

Today, medical devices are developed for global use and this is to the benefit of all stakeholders, in terms of expertise, cost and resources among others. The industry is typified by being moderate volume and high technology, making it almost inevitable to operate globally if economies of scale are to be realized. International standards form the bedrock of eliminating technical barriers to trade and it is therefore imperative that regulations and standardization at EU level are fully consistent with international standardization.

4.3 Industry experts' participation

The current economic adversities, among other factors, have resulted in a difficulty to maintain a sufficient number of industry experts in Technical Committees. Regulation 1025/2012 states that European standardization is driven by the NSBs and ESOs to attract suitable representatives to attend Technical Committees. While the participation in Technical Committees is not, and should not, be a primarily industry responsibility, the work in these Committees may suffer from a lack of expertise from industry representatives. The current difficulty in harmonizing standards and the increasing emphasis on the use of Common Technical Specifications create further challenges.

4.4 Participation of healthcare professionals

The participation of healthcare professionals in European standardization work is crucial for the success of the standardization of products and processes. In this context, patients crossing borders and movement of healthcare professionals should be mentioned.

4.5 ESOs' TCs as mirror committees for International Standards

Special efforts are required to take European concerns into consideration within international standards in the context of the MDR and IVDR. EU citizens expect a competent, consistent and predictable level of diagnosis, treatment and aftercare, and standards created by a multi-professional and multi-stakeholder group have a key role to play.

5. Impact for European standardization

Product and process standardization will remain the core of healthcare standardization. Healthcare services* must take into account regulatory requirements. The ESOs therefore need to develop strategic alliances with all relevant European organizations/associations including providers of healthcare, whether they be institutions responsible for providing the healthcare service or the clinical experts involved in actually caring for the patient.

*The use of healthcare services in this document relates to care, diagnosis and treatments.

Updated June 2017