Achievements of the ABHS (Advisory Board for Health Standards)

The CEN Advisory Board for Healthcare Standards (ABHS) was created by the CEN Technical Board (CEN/BT) in December 2005 (Resolution BT 67/2005) to replace the CEN Healthcare Forum (CHeF). The first meeting of the ABHS took place on 16th & 17th March 2006 and the second meeting was held on 5th & 6th July 2006. A third meeting has been scheduled to take place on 20th November 2006. It was agreed that the CEN/BT will review the activity and performance of the ABHS at its meeting in December 2006.

The aim of this paper is to summarise the main achievements of the ABHS since its creation.

1. Forum representing the interests of the healthcare standardization sector.

The ABHS is made up of representatives from the following groups:

- National standards bodies;
- Technical committee Chairmen and Secretaries;
- European federations and trade associations;
- European Commission (EC) / European Free Trade Association (EFTA);
- Other European and international standards organizations;
- Staff of the CEN Management Centre.

By benefiting from the participation of key players in the field of healthcare, the ABHS is able to ensure representation of the interests of the healthcare standardization.

2. Forum empowered to establish Task forces dealing with relevant healthcare issues

During its first meeting in March 2006, the ABHS has set up 6 Task Forces in significant areas of the healthcare standardization (see Document ABHS N8), notably:

- *Task force 1 – eHealth* to look into the needs and possibilities of coordination and cooperation in eHealth, to include manufacturers, purchasers, users and regulators;
- *Task force 2 – World Standards Cooperation/HTTF* to provide focused European input to the World Standards Cooperation ISO/IEC/ITU-T Health Technologies group in response to the HTTF (Health Technologies Task Force) Final report TMB 14/2005 MD 1) of February 2006;
- *Task force 3 – Environment* to look into the needs and possibilities of coordinated action in response to the growing environmental agenda for healthcare standards, including design of devices, raw materials, patient safety and risk/benefit analysis.
- *Task force 4 – Risk management* to identify European input to ISO/DIS 14971 *Medical devices – Application of risk management to medical devices*, especially relating to issues pertinent to presuming conformity with the Medical Devices Directives;

- *Task force 5 – Mirror group to ISO/TC210 'Quality management & corresponding general aspects for medical devices'* to provide proposals about the need and type of committee for a more permanent European group to mirror ISO/TC 210 (including risk management)*;*
- *Task Force 6 – Tissue engineering* to advise on standardization needs relating to forthcoming tissue engineering legislation.

These Task forces make the best use of the range of expertise available to the ABHS through its members. They are also very proactive and four of them were already able to provide a report on their activities as well as recommendations to the ABHS during its second meeting held in July 2006. Specifically:

- *Task Force 1 – eHealth* made a number of recommendations to CEN/TC 251 'Health informatics' for follow up
- *Task force 2 – World Standards Cooperation/HTTF* made a recommendation to the ISO TMB for a permanent global standards strategy group in the healthcare sector (see 6 below)
- *Task force 4 – Risk management* prepared a specific European Foreword and annex Z for EN ISO/FDIS 14971 'Application of risk management to medical devices' following wide consultation, obtaining good consensus between many interests and viewpoints for this important horizontal harmonized standard
- *Task force 5 – Mirror group to ISO/TC210* proposed to CEN BT, the setting up of a CEN/CENELEC mirror group (see 3 below)

3. Platform for recommendations to CEN/BT

The ABHS has shown to be a good platform for the preparation of various recommendations to CEN/BT in the field of healthcare. In this way, the ABHS has contributed to ensure that useful information and advice is passed on to the CEN/BT and other relevant committees.

During its 1st meeting, the ABHS recommended that the CEN/TC 204 *In vitro diagnostic medical devices* publishes ISO/TS 11135-2 and ISO/TS 17665-2 as CEN/TSs. This recommendation was accepted by CEN/BT (resolution BT 8/2006).

During its 2nd meeting, the ABHS issued 2 recommendations which have been passed on to the CEN/BT as follows:

- The extension of the scope of CEN/TC 257. This is to allow CEN/TC 257 to fully mirror ISO/TC 210 *Quality management & corresponding general aspects for medical devices*, to take over the work of the CEN/CENELEC Coordination Working Group, as well as work items of ISO/TC 210 in sub-sectors and to include work on risk management;
- The acceptance of mandate M/384 on colour coding systems intended for specimen receptacles used for in vitro diagnostic medical devices.

Both of these recommendations were accepted by CEN/BT (BT C043/2006 and BT C044/2006)

4. Platform to solve problems arising in the field of healthcare standardization

The ABHS has demonstrated to be able to act as a 'trouble–shooter' in order to solve problems occurring with regard to healthcare standardization. In that context, actions have been taken not only to solve specific issues but also to clarify the related procedure.

For instance, the publication in the OJEU of incorrect references of some harmonized standards has been raised during the 2nd meeting of the ABHS. Following this meeting, action was taken by CMC to check the correctness of the references and action was taken the week after the meeting to remove 4 incorrect references from the list provided to the European Commission (EC) for citation in the OJEU. The ABHS decided also that a paper should be drafted jointly by the CMC and the EC to restate the methodology to be followed in order to provide to the EC lists of titles of harmonized standards and who to contact in case of problems.

Another example that can be quoted in that context is the concern which was raised in the 2nd meeting of the ABHS about the preparation of Annex Z for a specific standard being developed in parallel by CEN and ISO under the Vienna Agreement. The ABHS agreed not only on how to solve the specific problem but also on circulating to the National Standardization Bodies (NSBs) a paper reminding TC secretariats & committees members about the procedure to be followed for the preparation of Annex Z in case of standards being developed under the Vienna Agreement. This in turn has resulted in a better understanding of that procedure in ISO/TC 210.

A similar clarification exercise is taking place in relation to the dates of withdrawal of presumption of conformity of previously published harmonized standards.

5. Liaison with the European Commission Services

The ABHS has proven to be a forum being able to liaise easily with the EC Services. The EC has been represented at each meeting that the ABHS held so far. Moreover, the ABHS has made contact with the EC services to clarify pending issues and to support the interests of healthcare standardization. For instance, in the framework of the Medical Devices Experts Group, the Chairman of the ABHS wrote to the European Commission to encourage the participation of regulators in the ABHS meetings. The European Commission has also been contacted concerning the clarification of the classification as medical device or not of biological indicators and chemical indicators for use with sterilizers.

6. Incentive provider for European participation to global standardization initiatives

With the support of Task force 2 – *World Standards Cooperation/HTTF*, the ABHS has made further steps toward strengthening the dialog between the European Standards Organizations (ESO's) such as CEN, CENELEC and ETSI and other corresponding Standards Development Organizations (SDO's) such as ISO, IEC and ITU at international level:

- For instance, the ABHS has recommended the establishment of an advisory global strategic standards group that integrates the 6 main standardization

bodies (ISO/IEC/ITU and CEN/CENELEC/ETSI) to coordinate and integrate work programs in the medical sector. This would aim at connecting with international regulatory structures such as the Global Harmonization Task Force (GHTF). In that context, the ABHS wrote to the World Standards Cooperation Health Care Technology Task Force (WSC) to raise this matter.

Following on from the work of Task Force 2, the ABHS is also considering whether to recommend the provision of an informative annex to global standards that identifies which GHTF Essential Principles are addressed fully or partially in the related standards and by which clauses
In view of providing consolidated comments to the GHTF, its revised document on the role of standards in the assessment of medical devices was circulated to the ABHS members for comment.

By taking the above measures, the ABHS acts as a platform providing incentives at international level to ensure European participation to global standardization initiatives.

Conclusion

Within one year since its establishment, the ABHS has proven to be an efficient tool to assist meeting the principle aims of standardization in healthcare which are to ensure a high degree of patient safety and to support public health objectives, whilst removing barriers to trade.

The ABHS is thus fulfilling its role by providing for coordination and communication on standards matters in view of the specific needs of stakeholders (users) of standards related to healthcare and to further enable the efficient operation of the standardization process. The ABHS has also shown to be able to advise on (European) standards matters to relevant decision bodies as well as to initiate liaisons between ESOs and SDOs at international level.

In the light of the above achievements and considering the need of having a sector forum in the field of healthcare standardization, it would be vital that the CEN/BT would support the maintenance of the ABHS when reviewing its activity and performance in the course of December 2006.