

# Improving international and European healthcare standardization to meet global safety, regulatory and market needs

## A discussion paper from EUCOMED

### **Executive Summary**

*This paper has been produced in order to prompt thinking about a new way forward in the strategic planning of healthcare standardization. In the view of industry, there is a very real need to achieve*

- *a much greater degree of coordination between the international and European standardization bodies*
- *improved strategic input to the standardization bodies to address the needs of an increasingly global medical technology industry, with particular emphasis on the need to reach international solutions that are also suitable for supporting European regulatory requirements*
- *improve strategic input to regulatory agencies cooperating on a global basis, with particular emphasis on the need to reach international solutions that are also suitable for supporting European regulatory requirements*
- *effective input to the standardization bodies in order to ensure safe and timely standardization suitable for a global market.*

*There is currently no joint ISO/CEN group or any other group that effectively addresses these goals (see annex A for a brief discussion of the present situation within ISO/IEC and CEN/CENELEC).*

### **Proposal**

EUCOMED suggests that the time has now come for the establishment of a global strategic healthcare standards group in order to

- identify key strategic objectives and priorities for international and European healthcare standardization in order to encourage common goals and work programmes where this is of benefit to stakeholders
- bring about better coordination between the international and European standards bodies, regulators and professionals, to reduce duplication or divergence and improve the resulting standards in terms of global needs

- facilitate the introduction of these objectives and priorities into standardization programmes at international and European levels
- ensure that revisions of key international and European standards and new standardization programmes continue to meet the needs of global stakeholders
- promulgate the international standardization route, as described in the GHTF guidance document SG 1/NO12 'Role of Standards in the Assessment of Medical Devices', as the favoured solution, incorporating European needs into such work programmes

### **What would be the main benefits to the key stakeholders?**

- to national regulatory authorities and the European Commission
  - clear coordination between regulatory needs (both global and European), public health imperatives and international and European standards
  - improved prioritization of standardization
  - promulgation of the value of standardization to stakeholders
  - better use and targeting of limited resources
  - an opportunity to promulgate the GHTF guidance document SG1/NO12 'Role of Standards in the Assessment of Medical Devices' and draw upon the experience of European regulators
  - opportunities for global consensus on standards needs
  - opportunities for parallel evolution of regulatory harmonization and standards
  - more timely and better defined standards
- to standardization bodies
  - better coordinated strategic input from global users of standards (customers) on key regulatory, market and user needs
  - recommendations on strategic priorities
  - promulgation of the value of standardization to stakeholders
  - improved coordination between different standardization organizations
  - improved targeting of resources
  - valuable feedback on the use of standards
  - improved implementation, recognition of status, and usage of published standards (e.g., as occurs through 'harmonization' in the European regulatory context)
- to industry
  - better availability of globally acceptable standards to meet global regulatory and market needs, and to meet the needs of increasingly convergent international regulatory approaches (e.g. resulting from GHTF initiatives)
  - promulgation of the value of standardization to stakeholders, who provide the major portion of funds for the standardization process
  - improved prioritization of standardization
  - better use and targeting of limited resources

- better opportunity for feedback as the key user of standards
- more timely and better defined standards
- to other stakeholders (e.g. medical professionals, Pharmacopoeia authorities)
  - greater transparency
  - promulgation of the value of standardization to stakeholders
  - opportunities for coordination with programmes outside standardization (e.g. Pharmacopoeia projects)
  - opportunities for feedback on key issues, e.g. patient and professional user safety
  - more timely and better defined standards

### **Possible scope of a new global strategic healthcare standards group**

- to analyze stakeholder needs for international and European standardization in relation to global regulatory and market needs and the emergence of new medical technologies
- to ensure that standardization work is undertaken by the right body of people and that the scope and purpose of the standards in question support global legislation, facilitate global harmonization and ensure a “level playing field” in relation to the competitiveness of industry on the global market
- to formulate proposals for coordinated programmes of international and European standards (including revisions of standards, etc.), based upon the results of analysis and on sound risk management principles, that represent a consensus of interested stakeholders and that are geared towards global solutions
- to focus efforts on achieving an appropriate end product in a timely fashion
- to eliminate duplication of effort
- to encourage key stakeholders to make adequate resources available
- to monitor, on an ongoing basis, the effectiveness of international standards in supporting the needs of medical technology users, patients, regulators and industry, and to recommend improvements where necessary
- to forward proposals on these various issues as recommendations to the international, e.g. ISO Technical Management Board, and European standards organizations as appropriate and to facilitate the realization of these themes in the programmes of those bodies
- as a result of all of the above, to promulgate the value of standardization to stakeholders.

It is envisaged that the new group would not undertake any standardization itself. The existing standards organizations, with their consensus-based processes, are the appropriate vehicle for standards-making. Rather, it is proposed that the new group should assist the standardization bodies in better matching their resources, expertise and priorities to global regulatory and market expectations and needs.

### **Who should be involved?**

The following stakeholders should be invited to nominate the appropriate representatives to the proposed new group:

- Healthcare regulators:
  - from ISO Member Bodies, including any emerging regional groupings
  - from Europe, including regulators from Member States and European Commission
- Representatives of international and European standardization bodies. In the first instance, this should be established for ISO and CEN, with other bodies (IEC/CENELEC/ETSI) joining in if they so wish.
- Representatives of the global medical technology industry:
  - through representatives from industry itself, or
  - from industry associations
- Other international groups as appropriate, e.g.:
  - medical professional groups
  - Notified Bodies/Conformity Assessment Bodies
  - representatives of international, regional or major international Pharmacopoeia

It is suggested that the proposed new group could be Chaired by a regulator. Consideration could be given to the provision of secretariat services by ISO, CEN or one of the national standards organizations in the interests of facilitating communication and cooperation, perhaps on a rotating basis (?)

### **Outputs**

The regulatory bodies and standards organizations have their own, independent decision-making processes and structures. It is therefore envisaged that the primary output of the proposed new group would be to make recommendations to these decision-making structures based upon a reasoned analysis of the needs of the key stakeholders. For standards organizations, it is hoped that such a group would assist in ascertaining the market relevance of standards.

As an alternative, the group could be more than recommendatory, set up in such a way that its decisions must be taken into account, i.e., the output would be closer to Resolutions than Recommendations.

In either case, the group must have sufficient influence to affect the development of regulatory and standardization policies and procedures pertinent to healthcare, or to suggest adaptations of such to the specific needs of healthcare. E.g., the group could make recommendations for mandating of work items within the European regulatory framework.

**Some possible items for inclusion in the initial work programme of a new global strategic healthcare standards group could be:**

- New medical technologies (e.g. tissue engineering, nanobiotechnology, etc.)
  - Where and when standards are needed
  - What the best ways are to use standards in the new technology areas
  - What types of standards are appropriate and how they should be developed
  - How pre- or co-normative R & D can be encouraged
- Resourcing of standardization
  - How standardization can be better resourced
  - How participation by key stakeholders can be improved
- Emerging problems
  - Should new connectors be globally developed to replace Luer connectors used in some potentially hazardous applications?
  - How should the risk benefit be determined?
  - Identification of adverse incidents that occur on a global basis with a view to examining the role of standards in addressing them
- E-commerce
  - Are there any particular issues in the field of e-commerce that need to be addressed in healthcare standardization?
- Use of IT tools
  - IT offers tremendous possibilities to speed up standardization and to facilitate participation in the standards-making and approval processes. How can this IT technology best be used by key stakeholders?
  - Will it be possible and feasible to establish “virtual committees”?
  - Can ISO and CEN initiatives in the use of IT tools be better coordinated and harmonized?

- Implementation and use of standards
  - How can a consistent implementation and interpretation/use of standards be best ensured on a global basis? (e.g., by regulatory authorities, within Notified Bodies, CABs, etc.). An example might be an “agreed” regulatory use of biological safety standards (ISO 10993 series).
  - Why are international standards frequently not implemented nationally and what can be done to improve this situation?
  
- Standards applications to support healthcare-related regulatory work outside the strict “device” field, e.g.
  - Testing for biological safety of chemicals used in medical devices (current EU programme)
  - Chemical characterization of materials to reduce levels of animal testing
  
- Coordination
  - How can effective coordination of programmes between ISO, IEC, CEN and CENELEC be facilitated?
  - How can new areas of work be better selected, controlled and co-ordinated between standards bodies?

## **Conclusions**

EUCOMED considers, in the light of

- experience to date with the “new approach” regulatory system
- experience with the use of international and European standards within this and the global regulatory framework
- the increasing harmonization of regulatory systems mediated by standards and MRAs
- the increasingly global nature of the medical technology industry and trading of its products,

that the time is now right to address the issues detailed in this discussion paper and to establish a strategic group to facilitate effective strategic input into international and European healthcare standardization that truly reflects stakeholder needs.

This paper is provided as input into stimulating further discussions and proposals on this important issue.

## Annex A

### Background

There are currently four principal international or European standardization bodies active in the field of healthcare standardization, namely ISO, IEC, CEN and CENELEC. In addition, ETSI (European Telecommunications Standards Institute) may be involved in certain areas of healthcare standards work.

While there are mechanisms for cooperation between ISO and CEN (Vienna Agreement) and IEC and CENELEC (Dresden Agreement), these cover the development and joint approval of standards rather than strategic decisions related to the design of work programmes and selection of projects.

The Joint Technical Advisory Group 1 (JTAG 1) "Healthcare" used to provide a forum for discussion of matters of mutual interest in the healthcare sector between ISO and IEC but, unfortunately, IEC has now withdrawn from this group. There is currently no joint strategic group within the healthcare sector between CEN and CENELEC although the need for such liaison has recently been raised within the CEN Healthcare Forum (CHeF)(see annex B) and the CEN Technical Board has endorsed this need.

The process of adoption of new standardization work in both ISO and CEN also leaves much to be desired. Both standards bodies have "business plans" for their technical committees but, although established in a genuine attempt to improve planning and execution of programmes, these have rarely resulted in a convincing appraisal of stakeholder needs and the subsequent strategic coordination of standardization programmes.

In too many cases, technical committees have continued with extensive and time-consuming programmes of "vertical" design-restrictive standards. This has sometimes resulted in a scarcity of resource to complete key horizontal projects in a timely manner. In other cases, poor definition of aims and objectives at the outset of projects has caused numerous delays and difficulties in achieving consensus. In still others, standardization work has been undertaken (for example, as a result of a Commission mandate) in areas where standardization may have been premature or only capable of partly addressing a problem that requires other solutions.

In all of the major international standardization organizations, much of the day-to-day technical decision-making has been delegated to technical committees. It is doubtful, however, whether the majority of these technical committees have either the correct constitution or experience to perform a strategic analysis of stakeholder needs and to tailor their programmes accordingly.

On the positive side, there have already been examples of cooperation between the Global Harmonization Task Force and ISO/TC 210 (e.g. GHTF Study Group 1 and ISO/TC 210/WG 2 on "essential principles"; GHTF Study Group 3 and ISO/TC 210/WG 1 on quality systems). These have mutually benefited both global harmonization of standards and regulation.

CEN BTS 3, the now disbanded CEN Healthcare Sector Board, was largely successful in providing a strategic authority that included regulators, industry, other users and standards representatives. Unfortunately, this was lost when CEN went through a process of 're-engineering'. So far as we are aware, ISO looks favourably in their future strategy towards development of individual sector boards, where useful. The past success of BTS 3, if carried into the international arena, should be a joint ISO/CEN venture.

In addition to the international and European standards bodies, there may also be a need to liaise with the major pharmacopoeial organizations, e.g. European and US Pharmacopoeia. Within Europe, there is already a strong need for such coordination because of the interrelationship of projects, and the same is likely to be true globally as the demarcation between medical devices, medicinal products, tissue engineered products, biologics and other medical technologies becomes increasingly blurred.

## **Annex B**

### **Recommendations from the CEN Healthcare Forum (CHeF) to CEN BT, 21 September 2000**

#### **CHeF Recommendation 12 – Concerning international co-operation**

CHeF recommends:

- that CEN/BT takes full account of the global nature of the medical technology industry which calls for ever closer co-operation between Europe, USA, Japan Australia, Canada and other regions
- that CEN/BT notes the efforts of the Global Harmonization Task Force which works to harmonize regulatory requirements for medical technology products across all of these regions and which looks to the development of suitable internationally recognized standards to support such regulatory requirements
- that CEN/BT notes ISO initiatives to develop standards suitable for use in third world countries taking into account their limited resources

#### **CHeF Recommendation 14 – Concerning co-ordination between Standards bodies**

CHeF recommends:

- CHeF draws the attention of CEN/BT to the need to seek means of achieving closer strategic co-ordination with ISO in the field of medical technology, e.g. through a joint ISO/CEN healthcare board, to ensure that strategic issues are addressed on a global basis
- CHeF also notes with regret the withdrawal of IEC from JTAG 1 on healthcare technology and stresses to CEN/BT the need to find renewed modes of co-operation between ISO/CEN/IEC/CENELEC and ETSI
- CHeF offers its support to CEN/BT on discussions concerning any of these issues