

**EU Commission Public Consultation on Standardization
23 March-21 May 2010**

1. Do you think that service standards (including process standards) and alternative standardization documents should be included in the scope of Directive 98/34/EC or its successor?

The inclusion of service standards within the scope of 98/34/EC would seem to be a logical development of current practice. However the inclusion of alternative standardization documents within the scope may be more problematic as this may facilitate other measures e.g. standstill provisions etc. which may be inappropriate. Care needs to be taken to ensure obstacles to the free movement of goods are not inadvertently created.

2. Are you aware of specific cases where national service standards and alternative standardization documents have caused technical barriers to trade?

Eucomed is not aware of any examples where national service standards have caused a technical barrier to trade.

3. For areas other than Information and Communication Technology (ICT), should it be possible to refer to documents developed by fora and consortia in legislation and public policies? If it should, how should it be implemented?

It is necessary for standardization developed for, or used in support of, legislation or public policy to be constructed with a high degree of rigour, attention to detail and diligence. (The participation of regulators in standardization is especially welcome.) Standards developed outside of the traditional standardization systems may be produced by fora and consortia lacking the necessary depth and breath and dedication to ensure that any standard is fit for purpose. It is perfectly acceptable for fora and consortia to produce standards for use in commercial applications, but standards used to support legislation and public policy needs to meet a (high) minimum level of competence and input from all stakeholders

4. How could ESOs and NSOs be encouraged to accelerate their standards development process? Should for example the Community financing for standardization be subject to conditions in terms of speed of delivery whilst maintaining the openness of the process?

If standards are to maintain any link with the pace of technological change then the speed of standard development is important, however quality and consensus are also important aspects of standard value and these latter two should not be compromised just to develop standards faster. The development time of standards has reduced in recent years though improvements are still desirable, however relying on fiscal incentives may have very undesirable consequences and adversely affect the quality of standards

(5) 6. Should the WTO principles of transparency, openness, impartiality, consensus, efficiency, relevance and consistency be integrated in the legal framework of European standardization (especially in EU Directive 98/34/EC or in its successor)? How should this be implemented?

It is Eucomed's understanding that NSOs/ESOs are already signatories to the WTO Code of Good Practice for Standardizing Bodies and the processes already form the foundation of the procedures of the European standards bodies. It would seem logical to expect that the WTO Code of Good Practice should be included in the revision to Directive 98/34/EC.

(6) 7. How could the participation of consumer organizations, environmental NGOs, trade unions and social partners, and SMEs be best promoted? What should be the role of public authorities (European Commission and Member States) in supporting such a participation in a transparent, open, impartial, consensual, efficient, relevant and consistent European standardization system?

It is important that Standards are developed by experts with as broad a range of applicable expertise as possible yet many potential contributors, especially from SMEs and NGOs etc. are dissuaded by the cost of participation. The better use of IT could go some way to making standardization more accessible. Perhaps the establishment of a fund that can be drawn on by NSOs to support participation by SMEs/NGOs etc., where it is felt to be particularly relevant, would provide a solution.

7. How could the NSOs (National Standards Organizations) deepen their cooperation, and mutualize their activities? Could the following tasks be shared amongst several NSOs?

1. Management of the Secretariats of Technical Committees?

There is already a degree of cooperation between ESOs and NSOs and this needs to be developed further.

2. Notification of new national standardization projects?

As far as Eucomed is aware this is already happening though could probably be improved.

3. Promotion/sales of standards?

Some SMEs are already finding the cost of standards high, especially where standardization is used in support of regulatory compliance. There is an argument for actually reducing the cost of standards used in this role. Other (discretionary) standards will be purchased if there is a perceived benefit from using them, and it should therefore be incumbent on standards writers to ensure their standards have market relevance.

4. Other?

The development of NSO specialization in certain areas may reduce the need for NSOs to be competent at everything.

8. Without prejudice to the national delegation principle, how could the European Standards Organizations (ESOs) manage directly, on a case by case basis, some standardization activities, especially some Technical Committees?

The ESOs have a substantial resource available in the shape of NSOs and therefore ESOs should see their role as coordinating the activities of NSOs in the production of European Standards. ESOs could possibly encourage NSOs to develop or become adept at facilitating Technical Committee expertise in particular areas so as to reduce the amount of duplication across all NSOs. That way standards would be developed by those best suited (centres of excellence) and specializing in a particular area of standardization.

9. What support should the European Commission provide to facilitate the use of European standards as a means to open global markets? What would be the operational means that the Commission should use? (Support experts' participation in international standardization activities, translation of European standards into extra-community languages?)

The contribution of European Standards and standardization at the global level is already significant, possibly in part due to the fact that EU legislation is being imitated in a number of extra-Community countries. Nevertheless, the attractiveness of a standard is down to its market relevance and ease of use, so the best way to make sure standards are adopted globally is to ensure standards meet these requirements. EU experts should be present at international standardization activities to ensure global standards are sympathetic to (or at least do not conflict with) the requirements of the EU market. Eucomed does not see any advantage in translating European standards in non-EU languages.

10. Under which conditions do you think that the European Commission could launch, on a case by case basis, calls for tenders, open to the ESOs and to other organizations, to develop standards supporting EU policies and legislation?

Eucomed does not support this. The development of standards should only be undertaken by organizations that meet a defined level of competence. Different levels/types of document may require different levels of capability and competency; nevertheless it is important that the organization developing a standard has the necessary capability, structure, ethical culture and resources to undertake the work, especially in a regulated area such as medical devices.

11. What is, in your view, the most efficient level of participation in the process of standards development: national, European, international?

The medical device industry is a global industry and consequently has little appetite for accommodating plethora of standards all supposedly addressing the same issue, so greater global integration is desirable and standards should be developed at the highest practical level (e.g. ISO/IEC) acknowledging the fact that some contributors (e.g. SMEs/NGOs etc.) may find it difficult to participate, and may require support. However sight should not be lost of the fact that different nationalities have different cultures and ways of doing things and this needs to be taken into account when standards are developed.

12. In your opinion, where is the major added value in European standardization with respect to national standardization?

European standardization carries the 'authority' of the EU single market and consequently is taken more seriously globally than individual national standards could hope to achieve.

13. What are, in your view, the most serious barriers to the use of standards by enterprises: costs of standards (purchasing price)? Costs of operational implementation? Access to information? Knowledge of existing standards?

The range and structure of standards can be very confusing to those who are not dealing with standards all the time and greater efforts should be made to introduce the philosophy and practical application of standardization into engineering education at an early stage. Standards can be quite daunting when approached for the first time and so there should be more development of, and prominence given to help pages describing what standards are, how they are made and how to use them.

14. What could the standards organizations do, in addition to their current practice, to facilitate the access to standards, especially by SMEs

The cost of standards can be a significant issue for SMEs and they would appreciate purchasing only those standards that are relevant to the areas in which they operate. One of the barriers to this is that the scope of a standard is not visible until the standard has been purchased, and post purchase is the wrong time to find out a standard is not relevant. ESOs/NSOs should therefore consider including the scope of a standard or a professional summary/abstract and access to the Annex ZA/ZZ within the information available prior to purchase. (The Annex ZA/ZZ identifies those Essential Requirements that are covered by the standard.)