Medical Device Industry Position on the EU Commission Formal Objection (53/2010)

On November 15, 2010 the EU Commission issued a Formal Objection to the harmonization of eleven standards to the Medical Device Directives.

The Medical Device Industry regrets this action by the EU Commission and fails to understand why the EU Commission wishes to use this mechanism, in view of the consequences of it for the practical use of the standards challenged. Not harmonizing standards that have successfully followed the existing process or, worse, possibly 'de-harmonize' standards already harmonized under one of the Medical Device Directives, has both a technical and a political dimension with possible negative impact on patient safety. Such consequences appear not warranted by the evidence provided in 53/2010.

Industry is also concerned that the Formal Objection has a potential for tarnishing, both at European and at global levels, the reputation of the "New Approach" at a sensitive time, even if the intention of the Formal Objection is to give better tools for the correct implementation of this effective system of regulation. Industry wishes to repeat its strong support for the New Approach which has been instrumental in putting Europe ahead of the rest of the world regarding innovation and patient safety.

Regarding the policy and process for the drafting of European standards and the need to, where possible, refer to international standards based on the World Trade Organization (WTO) obligations, Industry respects the treaties and agreements concluded between the EU Commission and the European Standards Organizations (ESOs), between the ESOs and the international Standards Development Organizations, and between the EU Commission and WTO.

Industry believes it is essential that the following roles be kept in mind:

1. The EU Commission has the legal responsibility to ensure that the laws of the European Union are met and to deliver appropriate mandates to the ESOs,
2. The ESOs, in particular the members in the various working groups representing the interested stakeholders, have expertise in drafting standards and ensuring that those standards are understandable to the target audience, appropriate to give presumption of conformity to specific Essential Requirements or conformity assessment procedures, and workable practically, while recognizing that industry requires standards that are globally relevant.

In conclusion Medical Device Industry urges the EU Commission to enter into a constructive dialogue as soon as possible with relevant stakeholders to determine the exact grounds of the Commission concerns (both legal and technical). Such analysis will help, if appropriate, to develop a workable, efficient and effective process for the application of standards that help provide 'presumption of conformity' with the EU Directives. The Advisory Board on Healthcare Standards (ABHS) is already reviewing the construction of Annexes Z and will be providing recommendations later in 2011.

Industry welcomes that the participants to this dialogue be charged with arriving at a solution acceptable to all parties before the EU Commission takes any further action.