MDD fact sheet: Standards & guidelines

Introduction

- Standards exist for the safety of users, patients and consumers and to provide common technical specifications for regulators and manufacturers of products to demonstrate the correct application of the legal Safety and Performance Requirements.
- Using standards to underpin safety is a core principle of all global regulatory systems and as such should prevail in Europe as a core vehicle to ensure the safety and compliance of medical devices.

The current system

- Mandated by the European Commission and adopted by the Member States, harmonized standards under the current legal framework provide precise technical specifications that both products and processes must meet in order to give a presumption of conformity to the Essential Requirements set out in the Medical Devices Directives.
- To allow for innovation and scientific progress, standards are voluntary, meaning manufacturers can choose other, more up-to-date methods to show compliance with the legislative requirements; standards provide a recognized path to compliance with the legislation.

The Commission's proposal

- While maintaining the role of standards, the Commission proposal expands the possibility to use Common Technical Specifications (CTS)—a legally binding technical specification—commonly used in in vitro diagnostics to all medical devices.
- CTS can be employed where no standard exists or where a standard is considered "insufficient".
- In addition, the formal responsibility to elaborate guidance is given to the new Member State Medical Device Co-ordination Group (MDCG).

INDUSTRY POSITION

Changes to standards must be clear and subject to relevant stakeholder involvement.

Industry fully supports an effective implementation of the revised rules for standards, Common Technical Specifications and guidelines development.

Industry points out however, that the Commission proposal does not provide the criteria to be used as a basis for determining insufficiency of currently harmonized standards.

Industry believes that current proposed measures must be strengthened to ensure that they are transparent and supported by a policy of full stakeholder involvement via a formal advisory committee made up of representatives from relevant stakeholder groups (industry, patients and physician groups).