MDD fact sheet: Governance

Introduction

- The governance and implementation of the system stands on two pillars: the Member States, through their national Competent Authorities for Medical Devices and the European Commission, through the Directorate for Health and Consumers, DG SANCO.

The current system

- While the current system delivers on safety and encourages life-enhancing innovation, one of the main criticisms of the system is its poor implementation due to a lack of coordinated management of the system by Member States together with the Commission, especially in the areas of designation and monitoring of notified bodies, vigilance and market surveillance.
- The Commission supports harmonized implementation and broad stakeholder dialogue.in particular through:
    - the Regulatory Committee (referred to in Article 7 of the current regulation)
    - an informal Medical Devices Experts Group (MDEG) with representatives of national authorities and stakeholders (industry, patients, doctors)

The Commission's proposal

- The Commission's proposal has provided the tools for better coordination and management of the system by Member States and the Commission including:
    - A new Member State Medical Device Co-ordination Group (MDCG) to replace the MDEG
    - A mandate for the Commission to provide technical, scientific and logistic support to the MDCG including EU level monitoring and control of Notified Bodies;
    - Scientific resources to Member States and the Commission from the Commission's Joint Research Centre (a concept that has proven successful in the food sector).

INDUSTRY POSITION

The current, working system must prevail with strengthened roles for Member States and the Commission.

Industry welcomes the strengthening of the Member States' role and the enhanced role of the Commission to improve the co-ordination and management of the system.

Industry opposes any proposal that seeks to discard this working, device-specific system. Such an approach, and its inherent confusion, bureaucracy and expense would halt EU advancement in medicine and add no safety.