MDD fact sheet: Scope

Introduction

- The scope of any legislative measure must be as clear as possible to avoid potential confusion and fragmentation in its implementation. It is also essential that product categories included in the scope, are defined clearly and based on sound scientific and technical criteria.

The current system

- The scope of the current system has proven appropriate and is in line with that applied by global regulators (e.g. US, Japan).
- The current system has certain gaps, such as novel product categories including devices made of or containing human-derived tissues and non-medical products such as cosmetic implants.

The Commission's proposal

- The Commission has included in the scope:
  - A certain number of identified devices for aesthetic purposes (Annex XV);
  - Devices containing or made of human-derived tissues and cells which have been rendered non-viable (Art 1.2.e).
- Devices containing living micro-organisms (Art. 1.2.f) have been excluded.

INDUSTRY POSITION

The scope of the Medical Devices Regulation must be clear to avoid confusion and fragmentation in its implementation.

Industry believes the list of items covered in Annex XV is neither exhaustive nor accurate and would welcome the opportunity to work with other stakeholders to further elaborate this important list.

The proposed text erroneously excludes on technical grounds the very products it is trying to include (Articles 1.2e and 1.2f). Industry welcomes the opportunity to work with stakeholder to ensure that the legal scope avoids gaps and clearly covers all medical technologies.