MDD fact sheet: Economic operators

Introduction

- Economic operators are the various actors involved throughout the medical device supply chain, i.e. manufacturers, authorized representatives, importers and distributors.

The current system

- The current system defines legal responsibilities and obligations for only manufacturers and authorized representatives.
- Obligations linked to supply chain are not defined.

The Commission's proposal

- The Commission has introduced requirements applicable to importers (Art. 11), distributors (Art. 12) and has redefined the role of authorized representatives (Art. 9).
- The Commission has also introduced the concept of the responsible person for regulatory compliance (Art. 13).

INDUSTRY POSITION

Roles and responsibilities of economic operators must be clearly defined in order to avoid potentially catastrophic effects on certain operators and SMEs.

Industry welcomes in broad terms the Commission's outline of the respective roles and obligations of these operators, as well as diagnostic services and internet sales, but believes the proposal lacks adequate detail.

Industry stresses the need for the overlapping obligations and responsibilities of different economic operators to be clarified in the areas of device registration, vigilance reporting and market surveillance. Failure to define clear roles and responsibilities could have catastrophic effects on certain operators and SMEs within the supply chain effectively closing their businesses overnight and risking unavailability or increased costs to hospitals and patients.