
MDD fact sheet: Delegated and implementing acts

Introduction

- As a result of changes under the Treaty of Lisbon, the Commission may adopt delegated and implementing acts to address many important aspects of the Medical Device Regulation *after* the conclusion of the ordinary legislative procedure.

The current system

- The possibility for the Commission to implement secondary legislation is already present in some parts of the current Directives and has been used to a limited extent in the last 20 years.

The Commission's proposal

- The Commission has widely extended its right to implement secondary legislation, proposing nearly 50 provisions for delegating and implementing acts including:
 - The definition of the regulatory status of a product (Art. 3)
 - The amendment of the general safety and performance requirements (Art. 4)
 - The drafting of Common Technical Specifications for selected families of devices (Art. 7)
 - The amendment of the classification criteria (Art. 41)
 - The amendment of the conformity assessment procedures (Art. 41, 42, 44)
 - Restrictions to market access for certain devices (Art. 74)

INDUSTRY POSITION

Many delegated and implementing acts afford the Commission too broad a mandate and lack mechanisms for essential stakeholder input.

Industry believes that many of these acts afford the Commission too broad a mandate or lack sufficient detail to ensure a stable and predictable legal framework for economic operators. In addition, there is a complete lack of a mandatory consultation with stakeholders (patients, doctors, industry) in the elaboration and adoption of these acts.

Industry believes that stakeholders must be explicitly included in the elaboration and adoption of delegated and implementing acts via a formal advisory group. Furthermore, to ensure that delegated and implemented acts reflect a stable and predictable legal framework, industry has undertaken a case-by-case analysis of the acts and have suggestions on their objectives, content, scope and duration that we believe bring the necessary legal certainty and predictability.