
MDD fact sheet: Funding

Introduction

- Manufacturers fund the regulatory system in different ways across Europe. Based on national budgetary policy each Member State takes its own approach in levying fees on manufacturers to fund their regulatory bodies.

The current system

- Today industry pays government differently in each Member State, for example:
 - a class III product approval (class III design dossier review) typically costs between €30,000 (for generic products and line extensions) to €100,000;
 - National registration databases such as the Italian database charge €100 per product;
 - In France a 2% sales tax applies; and
 - VAT is levied on the industry's €95 billion annual sales in Europe
- These fees are generally appropriate and reflect the industry's predominately SME nature (80% SMEs). However, a trend has emerged recently toward more duplicate funding regimes, such as national registration databases. These create unnecessary bureaucratic burden and contribute to an ever more fragmented and unsustainable funding model.

The Commission's proposal

- The Commission proposal clarifies in articles 40 and 86 that Member States may charge a fee for the services they provide.
- The Commission also introduces a Unique Device Identification System (Article 24) and a single central European registration database (Article 27)

INDUSTRY POSITION

Fees paid by manufacturers to support the system must be appropriate and reflect the industry's predominantly SME nature.

Industry welcomes the Commission's clarification, as well as the introduction of a Unique Device Identification System and a single central European registration database. It is important that a central registration databases would eliminate existing national databases thus avoiding duplicative costs and administrative burden.

Industry calls on the European Parliament and Council to ensure that any amendments to fees are subject to a comprehensive impact assessment and take into consideration the significant costs to Manufacturers (which are predominantly SME in nature) of adapting to the new system. Industry also strongly suggests that prior to adoption, a final assessment be made of the full impact on manufacturers to ensure that the final costs including any fees, are appropriate and reflect a sustainable funding model that demonstrates benefits to both the regulator and the regulated.