MDD fact sheet: Early scientific advice

Introduction

- Given the rapid pace of medical device innovation (a new product typically supersedes a previous version with 18-24 months) and the sector's predominantly SME nature, access to independent early scientific advice would allow manufacturers to address potential hurdles to approval early in the development process, resulting in more efficient innovation and faster patient access to the latest technology.

The current system

- Though not explicitly provided for in the current legal text, innovators often seek advice from Notified Bodies and Competent Authorities at an early phase of development in order to limit the possibilities of delay in approval due to differences in opinions on the level of evidence needed to demonstrate conformity to the Essential Requirements.

The Commission's proposal

- The proposed text does not contain a provision to allow a European level independent scientific advice to manufacturers on medical technology.
- Under the current text, European Reference Laboratories are entitled to deliver scientific opinions only to the Commission, Notified Bodies and Member States
- The Commission's proposal explicitly prohibits Notified Bodies from communicating with a manufacturer before an actual application has been filed (clause 1.2.3 of Annex VI).

INDUSTRY POSITION

Manufacturers must have access to early scientific advice including advice on the appropriateness of their risk management plan and clinical evidence.

Access to a European level network of independent scientific experts in medical technologies would be of enormous benefit, in particular for SMEs who are the innovation backbone of medical technology and advances in medicine (80% of medical device manufacturers are SMEs).

Industry calls for the extension of beneficiaries of the tasks of the European Reference Laboratories (ERL) referred to at Article 81 , which are now exclusively to the benefit of Commission, Member States and Notified Bodies, to include manufacturers.

Industry believes manufacturers must have access to early scientific advice including advice on the appropriateness of their risk management plan and clinical evidence.