MDD fact sheet: Transition period

Introduction

- It is important for all healthcare stakeholders that the transition from the current regulatory framework (outlined in the Medical Devices Directives) to the new Medical Devices Regulation is a smooth one.
- To avoid potentially negative consequences, measures must be taken to ensure that patients, doctors and manufacturers understand which legal requirements apply at which point in time.

The Commission's proposal

- The Commission proposes (in Art. 94) that:
  - The Regulation become fully applicable three years after its entry into force.
  - Manufacturers of devices in any class may claim compliance with the Regulation immediately after its entry into force.
  - Manufacturers may only claim compliance with the Regulation if:
    - For class I devices, the manufacturer has followed the new class I conformity assessment process
    - For class IIa, IIb, and III devices, they have undergone the new conformity assessment process by a Notified Body that has been re-qualified in accordance with the new Regulation.
  - Notified Bodies may request reassessment six months after the entry into force of the Regulation and must be reassessed before the date of application.
  - Certificates gained under the current legislation will continue to be valid after the date of application for a maximum of two years.

INDUSTRY POSITION

Measures must be taken to ensure that patients, doctors and manufacturers and Notified Bodies understand which legal requirements apply at which point in time.

A smooth transition is fully dependent on timely adoption the necessary delegated and implementing acts. Industry suggests that a check is made after two years from the entry into force to verify if all relevant delegated/implementing acts will be ready in due time and then, if necessary, review the deadline for the date of application (Art. 94.1)

To safeguard the continued availability of safe products where the Notified Body requalification has not been completed in time, industry would welcome (Art. 94.2) a statement to the extent that certificates issued by Notified Bodies which have not gone through the re-qualification are not automatically void at the time of application unless there is clear safety issue.