MDD fact sheet: Reprocessing

Introduction

- Single-use medical devices are designed to be used on one single occasion for one single patient.
- Single-use devices are designed for optimal performance during one use and have not been validated by the original manufacturer for a second use, including the necessary cleaning, removal of pathogens and sterilization.
- Certain Member States allow for the reprocessing of single-use devices within their health systems while yet others ban reprocessing on public safety grounds.

The current system

- The current system does not address the reprocessing of single-use devices and as a result, Member States have taken different approaches ranging from a ban in France to the German implementation of general reprocessing guidelines.
- This fragmented approach by Member States has led to different quality standards and a grey zone potentially exposing patients and users to severe risks, including infections, longer hospital stays or additional interventions.

The Commission's proposal

- The Commission considers reprocessing of single-use devices as manufacturing and therefore proposes that reprocessors be assigned the same rights and responsibilities as manufacturers.
- Following the recommendations made by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in April 2010, the Commission proposal restricts the reprocessing of single use devices for "critical use" until the Commission, through implementing acts, establishes a safe list of single use devices for critical use which can be safely reprocessed.
- Lastly, the Commission proposal grants the discretion to Member States to prohibit the reprocessing of single use devices or the making available of such products on their territory.

INDUSTRY POSITION

Reprocessors must be subject to the same controls as manufacturers.

Industry supports the Commission's proposal that the reprocessors of single-use devices be subject to the same full and strict controls as original manufacturers.

Industry also supports the concept of establishing a safe list of single-use devices for critical use which can be safely reprocessed. However, Industry urges the Commission to provide additional clarity on the process, which we believe should be fully transparent, with clearly defined timelines and criteria.