

EAMDR comments on the outcome of the public consultation on the reprocessing of medical devices

The European Commission recently published the outcome of the public consultation on the reprocessing of medical devices which was held in 2007. Nikou Ghassemieh, Managing Director of the EAMDR, welcomes the results of the consultation and calls for a EU-wide regulation for reprocessing of medical devices under high quality standards. "The consultation shows that there is a need to have a common European legislative framework for reprocessing. Positive experiences in Germany show that reprocessing of so-called single-use medical devices is feasible and reasonable under high quality standards", Ghassemieh emphasized.

The summary report unveils that no European regulatory framework in the European Community exists and that only half of the Member States have actually a regulation in force. The German law was extensively referred to by respondents. In Germany the regulatory framework does not differentiate between single-use and multiple use labelling but requires high quality standards and validated procedures for reprocessing based on risk assessment instead.

The majority of the responses throughout Europe still follow the labelling placed on medical devices by the manufacturer. Consequently, the majority states that only medical devices labelled as multiple-use are being reprocessed. Nevertheless, while some participants consider around 16% of 'single use' medical devices to be 'reprocessable' without impairing either the safety or security of patients, the consultation shows that the reprocessing practice raises a lot of public health concerns as regards health risks associated with re-use of 'single-use' medical devices in general.

Another aspect frequently mentioned by respondents is the cost saving potential of reprocessing medical devices. The reprocessing industry points to cost savings of up to 50% for certain reprocessed medical devices (for example for electrophysiology / ablation catheter for treating cardiovascular constrictions).

Patients' safety is top priority for the EAMDR. Therefore the EAMDR calls on political decision-makers to legalize the reprocessing of medical devices under high and strict quality standards, taking into account

Germany as best practice. The EAMDR believes that a EU-wide regulatory framework for the reprocessing of medical devices is essential to protect patients and guarantee a high level quality of healthcare. Otherwise there is constant danger that reprocessing of medical devices, in particular of the so-called single-use devices, will further on be carried out unqualified under low quality standards and without validated procedures.

The EAMDR highly appreciates the European Commission's intention to fulfil its obligations to elaborate the status quo of reprocessing in the European Union. The European Commission is obliged to submit a report on this status by September 5, 2010. According to the European Commission, the public consultation was a first step in the process of gathering information on the topic. Altogether around 60 stakeholders took part in the consultation and answered the Commission questionnaire, among them the EAMDR.

About EAMDR

The European Association for Medical Device Reprocessing (EAMDR) represents and promotes the interests of associations and research institutes, companies, opinion leaders on hygiene and microbiology, as well as members of the medical device industry involved in the reprocessing of medical devices throughout Europe.

The EAMDR seeks to increase the quality of health care systems, to further professionalise the reprocessing of medical devices, to achieve the creation of a European-wide legal framework for reprocessing as well as to promote scientific research and education in the field of health.