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Last News regarding the Reprocessing of Single Use Devices in EU

Today few countries in EU allow the reprocessing of single use medical devices and have developed guidelines (*e.g.* Germany), while some countries prohibit it (*e.g.* France).
The new "Article 12a of the Directive 93/42/EEC such as amended by Directive 2007/47/EC requested that the Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.
This report has been published end of August and represents an assessment of the issue regarding public health, ethical, legal, economic and environmental aspects. It includes the scientific opinion of the Committee on Emerging and Newly Identified Health Risks (SCENIHR) concerning the safety of reprocessed medical devices marketed for single use

Let's have a look at the main findings:

Risks and hazards identified by the SCENIHR
A remaining contamination, the persistence of chemical substances used during the reprocessing process and the alterations in the performance of the single use medical devices due to the reprocessing represent the three major hazards with a specific problem for the elimination of prion contamination, since only relatively aggressive cleaning methods, not compatible with the commonly used materials, can ensure prion inactivation.
The risk is highest when the reprocessed single use medical device is used in a critical procedure, *i.e.* when used for an invasive medical procedure. In contrast, the risk is much lower for non-critical medical procedures in which reprocessed single use medical devices are
used.

Ethical and liability considerations on the reprocessing of single use medical devices in the current situation
Ethical concerns are raised in terms of potential inequalities between patients and consent of patients needs to be considered. We may understand that patient with poor insurance coverage would accept more likely second hand devices.
Regarding the liability, it would be necessary to clarify the responsibilities of each Stakeholder such as the responsibility of the original manufacturer in case of failure and medical complication due to and only to the reprocessing practice.
The requirements regarding the labelling of reprocessed single use medical devices shall be clarified, in particular for the purpose of traceability of these devices.

Economic considerations
The economic considerations are the main driver in the reprocessing of single use medical devices. To date, most of the published economical data do not allow drawing any conclusion on the cost effectiveness of the reprocessing practice for single use medical devices because indirect costs are not included or because the reprocessing is not performed with a sufficient level of quality and safety. However, a recent study performed in Belgium demonstrates that, in the case where this equivalent level of safety and quality is achieved for reprocessed single use angiography catheters, the cost of these reprocessed devices is higher than the cost of new single use angiography catheters.

Environmental considerations
Environmental considerations are usually advocated as another argument in favor of reprocessing single use medical devices.
The increasing use of single use medical devices has a negative impact on the environment, due in particular to the resources needed for the raw material production, the manufacturing, the transport and the management of the waste generated after their use.
However, the reprocessing practice presents also some negative environmental impacts that must be taken into consideration such as for example the use of chemical substances.

Next step . . .
The EC is currently assessing the appropriate measures to be put forward in the context of the Recast of the Medical Devices Directives.
Our opinion is that reprocessing of single use devices will be permitted only for device which are not used in surgically invasive medical procedures and with a validated reprocessing procedure for each device. Since the hospitals will not be able to validate their processes, only third party reprocessing companies will be able to comply.

You can download the full EC commission report at:
http://ec.europa.eu/consumers/sectors/medical-devices/files/pdfdocs/reprocessing_report_en.pdf

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