

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Request for a scientific opinion:

The safety of reprocessed single-use medical devices

1. Background

Historically, before the 80's medical devices were usually developed as reusable medical devices. Their reuse was facilitated by their shape, their design, their size and the fact that they were usually made of resistant materials like glass, metal or rubber, and reprocessed by steam sterilisation process. At this time, the notions of hygiene and cross contamination or transmission of infection between patients by the reuse of medical devices were generally unknown. The emergence of blood transmitted diseases like hepatitis as major public health concerns in the early 1980s and the risk of nosocomial transmission by reuse of contaminated syringes have heightened interest in the development of single-use injection medical devices. Later on, the discovery of the HIV and its transmission by, among others, contaminated blood has put more pressure on the development of single-use¹ medical devices.

In addition to these major public health concerns, the advancements in technology led to the development of more sophisticated and complex medical devices. These devices were generally made in novel plastics, not resistant to high temperatures and therefore to steam sterilisation processes. New instruments were developed for mini-invasive procedures, particularly in cardiology, with smaller lumens and with more intricate, delicate working mechanisms. Therefore, these devices were not as easy, or even impossible, to clean or sterilize properly. It was therefore impossible for the manufacturer to demonstrate that these devices were safely reusable and because of this, these products were labelled as 'single-use'.

The use of single-use medical devices has considerably increased in hospitals in particular to reduce the risks of cross contamination between patients.

Directive 93/42/EEC on medical devices², adopted on 14 June 1993, distinguishes between those devices that are intended by the manufacturer to be reused and those which are intended for single-use.

- For medical devices intended by the manufacturer to be reused according to the essential requirements, the manufacturer must provide information on the appropriate process to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization to be used, and any restriction on the number of reuses. The decision to have a reusable or a single-use medical device is a responsibility of the manufacturer.
- Medical devices intended for single-use must bear on their label an indication that the device is for single-use.

During the years following the implementation of the Medical Devices Directive, the shift of some categories of medical devices from reusable devices to single-use was progressive. Therefore, for the same use, reusable and single-use medical devices have been coexisting on

¹ Directive 2007/47/EC defines a 'single-use' medical device as 'a device intended to be used once only for a single patient'

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:EN:PDF>

² Directive 93/42/EEC concerning medical devices (OJ L 169, 12.7.1993)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML>

the market. This was misleading for hospitals, and sometimes, in order to face increasing pressures to implement cost control, some medical devices have continued to be reprocessed (either at hospital or via third party reprocessing providers) despite the fact that they were intended for single-use. In that context several concerns began to be raised, including patient safety.

The reprocessing practice of single-use medical devices is not regulated at the Community level for the time being and different national legislations regulate this practice throughout Europe. Few countries allow the reprocessing of single-use medical devices and have developed guidelines, some countries prohibit it and the majority of Member States do not have any specific regulation on this aspect.

To address the concerns about patient safety and to clarify the notion of single-use, Directive 2007/47/EC, adopted on 5 September 2007, amending Directive 93/42/EEC provided further clarification on the definition of the term 'single use', and introduced new requirements for single-use medical devices. First, the manufacturer's indication of single-use must be consistent across the Community. The Directive also introduced the requirement that if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used must be provided in the instruction for use.

In addition to these new requirements and to ensure that the reprocessing, and in particular the reprocessing of single-use medical devices does not endanger patients' safety or health, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients.

In that context, Directive 2007/47/EC inserted the following provisions as regards the reprocessing of medical devices:

"Article 12a

Reprocessing of medical devices

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.

In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection."

In order to prepare the above mentioned report, the Commission services launched a public consultation³ on the reprocessing of medical devices, focussing on the reprocessing of single-use medical devices.

³ http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/synthesis.pdf

Based on the findings of the above mentioned consultation and further to bilateral meetings with various stakeholders, the Commission services organized a workshop⁴ in December 2008. The aim was to collect further data to get a clearer picture of the reprocessing practice of single-use medical devices, and to assess what policy options might be appropriate for the reprocessing of single-use medical devices in Europe.

2. Terms of reference

The SCENIHR is requested to assess the following:

1. Does the use of reprocessed single-use medical devices constitute a hazard for patients' health (causing e.g. infection/cross contamination and/or injury)?
2. If yes in ToR 1, please characterize the risk for patients' health.
3. If yes in ToR 1, under which conditions or uses does the reprocessing of single-use medical devices pose a risk? Please consider in particular, the following:
 - Specific characteristics associated with the intended use of the device
 - Reprocessing method used: sterilization and/or disinfection (depending generally on the material of the device) and lack of instruction on the reprocessing method to be used
 - Other characteristics such as raw material or design

⁴ http://ec.europa.eu/enterprise/medical_devices/pdfdocs/summary_5_12_2008_workshop.pdf
http://ec.europa.eu/enterprise/medical_devices/reprocessing.htm