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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Report on the issue of the reprocessing of medical devices in the European Union, in
accordance with Article 12a of Directive 93/42/EEC**

(Text with EEA relevance)

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1. INTRODUCTION

1.1. Scope and structure of the report

This report addresses the issue of the reprocessing of medical devices in the European Union, in accordance with Article 12a of Council Directive 93/42/EEC of 14 June 1993¹ concerning medical devices.

The first section of this document includes some background information while the second and third parts of the report distinguish between the reprocessing of reusable medical devices and the reprocessing of single use medical devices. This report assesses in further detail the public health, ethical, liability, economic and environmental aspects of the reprocessing of single use medical devices.

The reprocessing of a medical device, for the purpose of this report, includes steps needed such as routine maintenance, disassembly, cleaning, disinfection and/or sterilisation to allow safe reuse.

1.2. Background of the report

1.2.1. 1980s, the shift to the use of single use medical devices

Historically, 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.

However, the emergence of blood transmitted diseases, like hepatitis 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. The discovery of the Human Immunodeficiency Virus and its transmission by, among others, contaminated blood has put more pressure on the development of single use 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 plastics not resistant to aggressive physical / chemical treatments, to high temperatures and therefore to steam sterilisation processes, but allowing mass production and giving them specific qualities and properties. New instruments were also developed for mini-invasive procedures, with smaller lumens and with more intricate, delicate working

¹ OJ L 169, 12.7.1993, p. 1

mechanisms. These devices were not as easy, or even impossible, to clean or sterilise properly and it was therefore impossible for the manufacturer to demonstrate that they were safely reusable. Because of this, some devices were labelled as "single use".

1.2.2. *Medical devices European regulatory framework*

Rules relating to the safety and performance of medical devices were harmonised in the European Union in the nineties, beginning with Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices² and later followed by Council Directive 93/42/EEC concerning medical devices and by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices³.

These three legal texts form the core legal framework for medical devices. Their aim is both to ensure a high level of protection of human health and safety and the functioning of the internal market.

Directive 93/42/EEC concerning medical devices distinguishes between reusable devices and those intended for single use.

In particular:

- The medical devices intended for single use must bear on their label an indication that the device is for single use⁴.
- For the reusable medical devices, the manufacturer must provide information on the appropriate process to allow reuse, including cleaning, disinfection, and packaging and, where appropriate, the method of sterilisation to be used, and any restriction on the number of reuses⁵.

Directive 93/42/EEC was lastly amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007⁶ which, in order to address some concerns about patient safety, provides further clarification on the definition of the term "single use" and introduces new requirements for single use medical devices.

In particular, Directive 2007/47/EC provides that:

- "single use device" means a device intended to be used once only for a single patient⁷;
- The manufacturer's indication of single use must be consistent across the Community⁸;

² OJ L 189, 20.7.1990, p. 17

³ OJ L 331, 7.12.1998, p. 1

⁴ Annex I section 13(3)(f) of Directive 93/42/EEC

⁵ Annex I section 13(6)(h) of Directive 93/42/EEC

⁶ OJ L 247, 21.9.2007, p. 21

⁷ Article 1(2)(n) of Directive 93/42/EEC

⁸ Annex I section 13(3)(f) of Directive 93/42/EEC

- If a 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 reused must be provided in the instruction for use⁹.

In addition to the above, in order to ensure that the reprocessing, and in particular the reprocessing of single use medical devices, does not endanger patients' safety and health, Article 12a of Directive 93/42/EEC requests the Commission to engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients, and to submit this report on the issue of the reprocessing of medical devices in the European Union to the European Parliament and to the Council.

1.3. Methodology

1.3.1. Medical Devices Expert Group consultation

In order to start its analysis of the issue, the Commission services consulted the members of the Medical Devices Expert Group¹⁰ from 23rd May 2007 to 31st July 2007.

This group includes representatives from national competent authorities, medical device industry and other stakeholders in the area of medical devices.

National competent authorities' representatives were invited to describe the situation in their country with regards to the reprocessing of medical devices, while industry and other stakeholder representatives were asked to give information in their fields of activity.

1.3.2. Public consultation

With the aim to broaden the consultation, a questionnaire was published on the Commission's website from 6th July 2007 to 15th August 2007.

Contributions were received from a wide range of stakeholders, including national competent authorities, medical device companies, public and private associations (*e.g.* medical device manufacturers and reprocessing service providers), hospitals, national health services as well as individuals.

Following these two consultations, a synthesis document was published on the Commission's website on 29th May 2008¹¹.

1.3.3. Workshop

Based on the findings of the above mentioned consultations, and in addition to meetings with various stakeholders and fact finding missions both in single use medical device manufacturer premises and reprocessing facilities, the Commission services organised a workshop¹² on 5th December 2008 with the aim to collect further data and get a clearer picture of the reprocessing practice, in particular on public health, economic and environmental aspects of the reprocessing of single use medical devices.

⁹ Annex I section 13(6)(h) of Directive 93/42/EEC

¹⁰ <http://ec.europa.eu/transparency/regexpert/detail.cfm?ref=1574&l=M>

¹¹ http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/synthesis_en.pdf

¹² http://ec.europa.eu/enterprise/newsroom/cf/itemshortdetail.cfm?item_id=3280

Representatives from the national competent authorities, the medical device industry and the reprocessing services providers, as well as various experts of the medical devices sector, attended the workshop.

The outcome of this workshop was published on the Commission's website on 18th May 2009¹³.

1.3.4. The SCENIHR opinion

With the aim to ensure the highest level of health protection and in order to be provided with a sound and independent scientific analysis on the issue, the Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks¹⁴ (SCENIHR) for its scientific opinion on the safety of reprocessed medical devices marketed for single use.

In particular, the Committee was asked to assess whether the use of reprocessed single use medical devices constitutes a hazard for human health, and if applicable, to characterise the risk for human health and to establish under which conditions or uses the reprocessing of single use medical devices poses a risk.

2. THE REPROCESSING OF REUSABLE MEDICAL DEVICES

Some medical devices, such as many of the surgical instruments, are intended by their manufacturers to be reused. Therefore their reuse is taken into account in the development process of the medical devices and has particular implications on the choice of the raw materials and the design of the device.

Directive 93/42/EEC requires that, where a manufacturer intends its device to be reused, this manufacturer must provide information on the appropriate process to allow reuse, including cleaning, disinfection, and packaging and, where appropriate, the method of sterilisation to be used, and any restriction on the number of reuses¹⁵. This implies that the manufacturer, on the basis of the materials used and the design of the product, must validate the reprocessing process to be applied in order to ensure that the medical device will not be altered by such reprocessing process, will perform as intended and will be safe for a number of reuses.

3. THE REPROCESSING OF SINGLE USE MEDICAL DEVICES

During the years following the implementation of Directive 93/42/EEC, the shift of some categories of medical devices from reusable devices to single use devices was progressive. Therefore, reusable and single use medical devices intended for the same use have been coexisting on the market. This was misleading for hospitals, and sometimes, in order to face increasing financial pressures, some medical devices have continued to be reprocessed, either in hospitals or via third party reprocessing providers, despite the fact that they were intended for single use.

Single use medical devices, such as needles or angioplasty catheters, are not developed and designed to withstand a reprocessing procedure and the manufacturer does not need to provide any instruction or validated process to allow a safe reprocessing of the device but only

¹³ http://ec.europa.eu/consumers/sectors/medical-devices/files/pdfdocs/summary_5_12_2008_workshop_en.pdf

¹⁴ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/04_scenihr_en.htm

¹⁵ Annex I section 13(6)(h) of Directive 93/42/EEC

information on the characteristics or technical factors known to the manufacturer that could pose a risk if the device were to be reused. The reprocessing is therefore carried out on the basis of procedures developed by the user or by the reprocessing service provider, but without complete information on the design and composition of the product. According to a report from the Netherlands¹⁶, the validation of a reprocessing process for single use medical devices, especially the cleaning, is a task that usually cannot be performed in a hospital since the required equipment, knowledge, experience and resources are unlikely to be available.

Contrary to reusable medical devices, for which requirements are set out in Directive 93/42/EEC to ensure their safe reuse, the reuse of single use medical devices may not be without risk from a public health point of view. In addition ethical, liability, economic and environmental aspects of reprocessing single use medical devices should also be looked at and are therefore further developed in this report.

3.1. Situation at the European Union's level

The reprocessing practice of single use medical devices is not currently regulated in the European Union and different national legislations regulate this practice throughout Europe. Few countries allow the reprocessing of single use medical devices and have developed guidelines (*e.g.* Germany), while some countries prohibit it (*e.g.* France) and some Member States do not have any specific regulations on this aspect.

3.2. Situation at International level

At international level different situations may occur, in particular the following:

In the **United States**¹⁷, before medical devices can be reprocessed and reused, a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers, including submitting documents for pre-market notification or approval, registering reprocessing firms and listing all products, submitting adverse event reports, tracking devices whose failure could have serious outcomes, correcting or removing from the market unsafe devices and meeting manufacturing and labelling requirements.

In **Canada**, Health Canada does not regulate the reuse of single use medical devices, as under the current Act and Regulations Health Canada does not have provisions for that authority. Certain provinces have banned reuse of single critical use devices and other provinces have stated that hospitals should use a licensed reprocessor.

In **Australia**¹⁸, a reprocessor who reprocesses a medical device originally intended for single use only becomes the manufacturer of the reprocessed device, and as such is required to apply the relevant conformity assessment procedure for the product.

In **Japan**¹⁹, the requirements for single use devices are that the label must contain “single use” and the instruction for use must contain “reuse is prohibited”.

¹⁶ National Institute for public Health and environment – "Reprocessing of medical devices, Possibilities and limiting factors"

¹⁷ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm>

¹⁸ <http://www.tga.gov.au>

¹⁹ Article 222(5), Ministerial Ordinance on Pharmaceutical Affairs Law
Notification by Director-General, Pharmaceutical and Food Safety Affairs Bureau, Yakusyokuhatsu #0310003, March 10, 2005

3.3. Public health considerations on the reprocessing of single use medical devices

To identify and characterize the potential hazards and risks associated with the use of reprocessed single use medical devices, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) was asked for its scientific opinion on the safety of reprocessed medical devices marketed for single use.

This opinion²⁰ was adopted on 15th April 2010. SCENIHR's answers to the terms of reference are detailed in the annex to this report.

3.3.1. Risks and hazards identified by the SCENIHR

For both categories of devices, single-use and reusable medical devices, cleaning, disinfection and/or sterilisation are needed before the device can be reused. For reusable medical devices, the procedures, conditions and number of reuses are already considered at the design stage of the device. The choice of the material and geometry (shape) of the device are also considered at this stage.

Information on the reprocessing procedures to be followed must be provided by the manufacturer of reusable medical devices, and this is not the case for single use medical devices.

The SCENIHR in its opinion identified the main following hazards and risks linked to the reprocessing of single use medical devices.

After use, all medical devices that have been in contact with patients may contain contaminants including pathogenic micro organisms, the elimination of which during the cleaning, disinfection and sterilisation steps may be difficult. If the efficacy of these steps is not properly validated the resulting persistence of the contamination poses a hazard of infection for the next patient on whom the medical device is used. Some simulation studies and a few clinical studies have shown that reprocessing of single use medical devices may result in improper cleaning, disinfection and/or sterilisation leaving a bioburden on the reprocessed single use medical device, which introduces a risk of infection when using the reprocessed single use medical device.

A specific problem pointed out by the SCENIHR is the elimination of prion contamination since only aggressive cleaning methods, not compatible with the commonly used materials, can ensure complete prion inactivation. This issue was further developed in a previous SCENIHR opinion on the safety of human derived products with regard to Variant Creutzfeldt-Jacob Disease²¹.

Chemical residues as a result of reprocessing may pose a toxic risk when a device is reused. In addition, changes of the physical and chemical characteristics of the devices may occur which may eventually have an impact on the performance of the reprocessed single use medical device.

It has been shown that a reprocessed single use medical device can be modified in its structure or functionality and may potentially cause some damage to the patient or health-care workers, *e.g.* mechanical failure of the device.

²⁰ http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf

²¹ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004.pdf

The risks are related primarily to the use of the device.

Three categories of devices could be identified based on the Spaulding classification, reviewed by Alvarado²². This classification is based on the risk linked to the use of the device, depending on the degree of invasiveness, independently from the fact that these devices are intended for single or multiple uses.

- (1) **Non-critical use** (in general, for intact skin contact only or no contact with the patient) *e.g.* basins, thermometers, blood pressure cuffs;
- (2) **Semi-critical use** (contact with intact mucous membranes without penetration of tissues) *e.g.* flexible endoscopes, laryngoscopes, endotracheal tubes;
- (3) **Critical use** (surgically invasive medical procedures) *e.g.* catheters, implants, needles, surgical instruments.

In case of reprocessing, the highest risk occurs when a reprocessed single use medical device is used for invasive medical procedures, while the lowest risk is associated with external (skin contact only) use.

The number of documented incidents is very small, although it can be speculated that the reporting of incidents is incomplete. However, regarding adverse events, there may be a “grey” area for which the recognition and reporting of incidents is difficult, such as a prolonged surgical procedure due to stiffness of a reprocessed single use catheter, and a prolongation of hospital stays. Furthermore, long-term effects may not be identified and attributed to the use of reprocessed medical devices.

3.3.2. *Conclusion on public health considerations on the reprocessing of single use medical devices*

Three major hazards were identified by the SCENIHR *i.e.* 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.

A specific problem is the elimination of prion contamination, since only relatively aggressive cleaning methods, not compatible with the commonly used materials, can ensure prion inactivation.

In order to identify and reduce potential hazards associated with reprocessing of a specific single use medical device, the whole reprocessing cycle starting with the collection of these single use medical devices after (first) use until the final sterilisation and delivery step, including its functional performance, needs to be evaluated and validated.

Not all single use medical devices are suited for reprocessing in view of their characteristics or the complexity of certain single use medical devices.

²² Alvarado CJ. Revisiting the Spaulding classification scheme. In: Rutala WA, editor. Chemical germicides in healthcare. Washington DC: APIC; 1994. p. 203-8

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.

It must be noted that the World Health Organization identified similar hazards, risks and limitations of reusing single use medical devices in a report titled "Medical device regulations – Global overview and guiding principles"²³.

3.4. Ethical and liability considerations on the reprocessing of single use medical devices in the current situation

In addition to public health considerations, the reprocessing of single use medical device may raise ethical and liability concerns.

3.4.1. Ethical considerations

As highlighted in the SCENIHR opinion, the use of a reprocessed single use medical device may pose an additional risk to the patient in comparison with using a new single use device. Therefore, the issue of patient information and prior informed consent before she/he undergoes the medical procedure needs to be considered.

Furthermore, the reprocessing of single use medical devices may create different levels of healthcare provisions and, as a consequence, may create inequalities between patients.

The above mentioned ethical considerations should be however balanced with the potential cost savings generated by the reprocessing practice which, in a context of costs containment for healthcare services, could be seen as a way to facilitate and increase access to innovative technology for the patients.

However, cost savings are very much dependent on the type and level of quality of the reprocessing practice and, to date, there is no clear evidence and data to quantify the cost savings that could create the reprocessing of single use medical devices and to establish to what extent the patient would benefit from these potential cost savings.

The economic aspects of reprocessing single use medical devices are further developed in section 3.5.

3.4.2. Liability considerations

3.4.2.1. Liability of healthcare professionals

Healthcare professionals may be liable in case of mishandling of a medical device with regard to patients' health. Since their liability may be engaged, healthcare professionals should be informed in case they are using reprocessed single use devices, in view of the fact that it may have consequences on the handling of the device, for instance in terms of stiffness of a reprocessed catheter, and may constitute an additional risk of medical complications.

²³ http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

3.4.2.2. Liability of the original manufacturer

The original manufacturer is responsible for the safety and performances of his product when it is used in accordance with its intended purpose.

For reusable devices, the manufacturer shall remain responsible for product related aspects when the device is reused if the hospital or the third party reprocessing service provider has followed the information the manufacturer has provided on the appropriate process to reprocess the device.

Directive 93/42/EC requires for single use medical devices that the instruction for use contains information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused²⁴. However, the responsibility of the original manufacturer shall be clarified in case of reprocessed single use medical device failure and medical complication due to and only to the reprocessing practice.

Currently, such reprocessed single use medical devices are usually labelled under the name of the original manufacturer. The requirements regarding the labelling of reprocessed single use medical devices products might therefore need to be clarified in order to reflect the liability in case of product failure and ensure the traceability of reprocessed single use medical devices.

3.4.2.3. Liability of the reprocessing service provider

Where a user or a third party reprocessing service provider develops and validates a procedure for reprocessing single use medical devices, this user or this third party reprocessing service provider shall be responsible for the implications of the reprocessing along the guidelines developed and validated.

Where the reprocessing of single use medical devices is done via a third party reprocessing service provider, the sharing of liability between the user and the reprocessing service provider currently appears unclear.

3.4.2.4. Conclusion on ethical and liability considerations on the reprocessing of single use medical devices in the current situation

In the current situation, the reprocessing of single use medical devices raises ethical concerns in terms of potential inequalities between patients. In addition, the issue of prior information and consent of patients needs to be considered.

Regarding the liability, it would be necessary to clarify the responsibilities of each stakeholder and to inform healthcare professionals in case they are using reprocessed single use medical devices, as their responsibility may be engaged in case of adverse events. The requirements regarding the labelling of reprocessed single use medical devices shall be clarified, in particular for the purpose of traceability of these devices.

3.5. Economic considerations on the reprocessing of single use medical devices

The economic considerations are the main driver in the reprocessing of single use medical devices.

²⁴ Annex I, section 13(6)(h) of Directive 93/42/EEC

In the current context of increasing resources constraints and the needs for cost-containment in healthcare, the reprocessing of single use medical devices has been used by some hospitals to reduce their expenses. Indeed, new single use medical devices might be expensive and their reuse offers the possibility of dividing their purchasing costs over multiple patients.

However, the reduction of the purchasing cost of a device, even if very visible and not disputable, is only one of the elements needed to assess any potential cost reduction when using reprocessed single use medical devices. Various other costs and considerations need to be taken into account (*e.g.* number of reuses, costs for developing and validating a reprocessing process, costs for performing the reprocessing process, costs for logistics and transport, insurance costs, liability costs in case of failure of the reprocessed single use medical device).

In the light of the above, to date, there are few and poor quality scientific evidence and economic evaluation to demonstrate that the reprocessing of single use medical devices is globally a cost-saving practice.

According to a systematic literature review on the economic analysis of reprocessing single use medical devices²⁵ published in 2008, although this practice is used routinely, there is little available evidence of sufficient quality in the published literature. The published evidence on the cost-effectiveness of reprocessing single use medical devices is inconclusive and the authors concluded that their review indicates that the cost-effectiveness of reusing single use medical devices is not established.

3.5.1. Methodology for costs calculation

The methods used for the calculation of the costs are often vague and not well described.

The costs generally do not include several elements like the costs linked to potential adverse events and clinical consequences for patients. In addition, the costs are generally calculated but not really based on a direct observation. Therefore, several elements of the costs could be missing, like the cost of the facilities, the real cost of the consumption of water, energy, etc. The costs can vary a lot between healthcare facilities depending on the existence of a central sterilisation unit in the hospital, the number of medical devices reprocessed per year (scale effect) and the existence of a quality management system for the sterilisation process.

In addition, these studies do not include a validation to ensure that, after the reprocessing, the reprocessed single use medical device presents an acceptable level of safety, in particular, on functionality and on biocontamination aspects. This validation process should include the determination of the number of safe reuses for a type of single use medical device, the verification of the functionality of the reprocessed single use medical device and a quality management system for the reprocessing process ensuring that the complete process was performed with a sufficient level of quality and safety. The cost of this validation process is never included in the published studies.

²⁵ Jacobs.P and al. Economic analysis of reprocessing single use medical devices: a systematic literature review. *Infect Control Hosp Epidemiol* 2008;29:297-301

3.5.2. *Economic studies perspective*

The studies published on the reprocessing of single use medical devices are always conducted from the hospitals' perspective and do not take into account other costs of the reprocessing practice, like the cost for the insurance systems or the patients in case of clinical consequences or liability.

3.5.3. *Level of quality and safety of the reprocessing*

A recent study performed in Belgium²⁶ demonstrates that, in the case where an 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. Such equivalent level of safety and quality would be ensured by following the standards harmonised under Directive 93/42/EEC. In addition, this study demonstrates that without scale benefits (taking into effect the decrease of the costs brought by a scale effect), and taking into account the cost of an estimate rate of adverse event, the reprocessing costs are generally higher than buying single use medical devices.

3.5.4. *Prices of single use medical devices*

A major parameter in these economic studies is also the prices of single use medical devices. These prices are highly variable between hospitals, countries and medical devices and could evolve a lot during the marketing life of a medical device. Therefore, even if the high price of a new single use medical device could lead to the assumption that the reprocessing is cost-effective, a variation in the price of this device due to an increase in the market competition could reverse completely this assumption.

3.5.5. *Conclusion on economic considerations on the reprocessing of single use medical devices*

To date, the published economical data do not allow drawing any conclusion on the cost-effectiveness of the reprocessing practice for single use medical devices when performed with a sufficient level of quality and safety. This cost-effectiveness needs to be demonstrated by long-term studies including a large number of patients and clear calculation of the direct and indirect costs.

3.6. **Environmental considerations on the reprocessing of single use medical devices**

Environmental considerations are usually advocated as another argument in favour of reprocessing single use medical devices.

On the one hand, 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 of the devices from the manufacturer or the retailer to the user and the management of the waste generated after their use.

²⁶ The impact of reprocessing single use devices in Belgium - An economic study - Larmuseau David, Siok Swan Tan - Erasmus MC University Medical Center, Institute for Medical Technology Assessment, Rotterdam, Netherlands – April 2008

It is not disputable that the reprocessing of single use medical devices has the environmental benefit of reducing products' end of life waste management to some extent. However, this environmental impact has some limitations since, according to some data provided by a reprocessing company, only 38% of the highly complex medical devices can be reprocessed²⁷.

On the other hand, the reprocessing practice presents also some negative environmental impacts that must be taken into consideration.

The reprocessing of single use medical devices requires adequate equipment, specific knowledge, skills and resources, which are likely to be present only in specialised reprocessing companies and therefore would require the collection and the transport of the devices from and to the user, which have an impact on the environment. In addition, the cleaning, disinfection and sterilisation process implies important resources and energy consumption (*e.g.* water and electricity), the use of chemical substances and the re-packaging of the reprocessed devices. All those steps have a direct and negative impact on the environment. The environmental impact is also very dependent on the level of quality of reprocessing required and on the scale effect.

3.6.1. *Conclusion on environmental considerations on the reprocessing of single use medical devices*

To date, no comprehensive study balances quantitatively all the environmental implications of reprocessing single use medical devices versus discarding those devices.

Available data very much focus only on the waste reduction that the reprocessing of single use medical devices creates to some extent. Various elements, such as the environmental impact of transport, resources and energy consumption, as well as the use of chemical disinfectants, must be taken into consideration.

4. CONCLUSION

In the absence of quantitative data, it is not possible to quantify the risk associated with the use of reprocessed single use medical device. The number of documented incidents is very small, although it can be speculated that the reporting of incidents is incomplete. Regarding adverse events there may be a “grey” area for which the recognition and reporting of incidents is difficult. In addition, long-term effects may not be identified and attributed to the use of reprocessed medical devices.

Three major hazards were however identified by the SCENIHR *i.e.* 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.

In addition, not all single use medical devices are suited for reprocessing in view of the characteristics (*e.g.* material used, geometry), their complexity and their intended use (non critical, semi-critical, critical). In order to identify and reduce potential hazards associated with the reprocessing of a specific single use medical device, the whole reprocessing cycle

²⁷ Dr. Matthias Tschoerner, Reprocessing of highly complex medical devices, accessed on 22/04/2010 at http://www.eamdr.com/mm/Matthias_Tschoerner.pdf

starting with the collection of these single use medical devices after (first) use until the final sterilisation and delivery step, including its functional performance, needs to be evaluated and validated.

It must be noted that the SCENIHR expressed specific concern about the potential contamination with transmissible agents such as prions, for which elimination and inactivation is not possible, or the procedure is not compatible with the materials generally used for a single use medical device.

It is not disputable that reprocessing single use medical devices leads to a waste reduction to some extent and offers the possibility of dividing the purchasing costs of these devices over multiple patients. However, to date, no comprehensive study clearly demonstrates that reprocessing single use medical devices is globally a cost effectiveness and environmental friendly practice when done under high quality standards.

In the light of the above, taking into account the potential hazards and risks identified by the SCENIHR in terms of the remaining contamination, persistence of chemical residues and alteration of the functionality, the Commission will assess which are the appropriate measures to be put forward in the context of the Recast of the Medical Devices Directives with regards to the reprocessing of single use medical devices in order to ensure a high level of protection for patients. This assessment will also take into account potential economic, social and environmental consequences that any envisaged measure may have.

ANNEX

SCENIHR answers to the terms of reference

Does the use of reprocessed single use medical devices constitute a hazard for human health (patients, users and, where applicable, other persons) causing, for example, infection/cross contamination and/or injury?

Inadequate cleaning, disinfection, and/or sterilisation during the reprocessing of single use medical devices introduces the hazard of persistence of a bioburden resulting in a risk of infection during subsequent use of the reprocessed single use medical device for patients and users, as a single use medical device is not designed to be reprocessed. This hazard which also occurs with devices designed for reprocessing and reuse, is characterised by the presence of contaminants of biological origin on the used single use medical device including proteins and micro-organisms such as bacteria and viruses. In addition, residues of chemicals used for cleaning, disinfection or sterilisation pose a hazard of toxic reactions. Furthermore, alterations in the performance of the device due to reprocessing may pose a hazard such as device failure during subsequent medical procedures. Of special concern is the potential contamination with transmissible agents such as prions, for which elimination and inactivation is not possible, or the procedure is not compatible with the materials generally used for a single use medical device.

If yes, please characterise the risk for human health.

In the absence of quantitative data related to the eventual residual biological and chemical contamination after reprocessing, it is not possible to quantify the risk associated with the use of reprocessed single use medical devices.

Some experimental laboratory simulation studies have demonstrated the risk of both microbiological and chemical residues occurring after reprocessing. The number of documented incidents is very small, although it may be speculated that the reporting of incidents is incomplete. In the existing inventory in the United States²⁸, no evidence of an increased risk was noted for patients from reprocessed devices. This apparent lack of an increased risk may be associated in part with the limitations that the United States impose on the reuse of reprocessed medical devices.

If yes, under which conditions or uses does the reprocessing of single use medical devices pose a risk? Please consider in particular, the following:

- **Intended use of the device;**
- **Reprocessing method used: cleaning, sterilisation and/or disinfection (depending generally on the material of the device) and lack of instruction on the reprocessing method to be used; and**
- **Other characteristics such as functionality, handling, raw material or design of the device.**

²⁸ <http://www.gao.gov/new.items/d08147.pdf>

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.

The design and choice of material of the single use medical devices is very important for the outcome of cleaning, disinfection, and/or sterilisation and the risk of persistence of a bioburden.

The choice of the method of cleaning, disinfection, and/or sterilisation must depend on the chemical composition and nature of the single use medical device. Inappropriate methods may lead to the introduction of chemical contaminants with adverse biological effects.

Possible changes in the physico-chemical characteristics (*e.g.* stiffness, brittleness, and surface characteristics) of the material of a reprocessed single use medical device may pose a risk in terms of performance of the device. Material deterioration resulting in device failure may occur with repeated reprocessing cycles.

Additional critical issues in using reprocessed single use medical devices may be the identification and traceability of the reprocessed medical device, and for more sophisticated and complex medical devices, the continued availability of documentation needed for proper use of the medical device.

SCENIHR recommendation

Not all single use medical devices are suited for reprocessing in view of their characteristics or the complexity of certain single use medical devices. The possibility for reprocessing is dependent on the material used and the geometry of the medical device. In order to identify and reduce potential hazards associated with reprocessing of a specific single use medical device, the whole reprocessing cycle starting with the collection of these single use medical devices after (first) use until the final sterilisation and delivery step, including its functional performance, needs to be evaluated and validated.

