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SYNTHESIS DOCUMENT

-

OUTCOME OF THE FIRST PUBLIC CONSULTATION

ON THE REPROCESSING OF MEDICAL DEVICES

In line with the Commission's commitment to transparent and interactive policymaking, this document provides an overview and general impression of the feedback received by the Commission in the context of the first public consultation on the issue of the reprocessing of medical devices.

The statements and opinions expressed in the document do not therefore necessarily reflect those of the Commission.

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1. INTRODUCTION

1.1. Structure of the report

This synthesis document presents an overview of the results of the Commission's first public consultation on the [reprocessing of medical devices](#).

The first section of this document includes some background information. The second section provides an overview of the contributions received during the consultation process and contains the analysis of the responses received. Preliminary conclusions can be found in the final section followed by a glossary of the terminology used.

1.2. Background of the report

1.2.1. *History of the reprocessing of medical devices*

1.2.1.1. Introduction of the concept

The reprocessing of medical devices has been an expanding industrial practice since the introduction of the concept in the late 1970s. While reprocessing of some medical devices has been done for many years within hospitals, the market of professional third-party reprocessing service providers has only started during the last decade due to recent economic and political developments as well as scientific and technological advancements.

For the purpose of this report, 'reprocessing' is generally understood to mean situations where a product was previously used on a patient and is being made suitable to be used again, but may also cover some situations such as:

- o Where product's shelf life has expired and it was never used on a patient;
- o Where a product was not used on a patient, although the package was opened (e.g. procedure cancelled), or
- o Where a product was on the sterile field during a surgical procedure but was not used on the patient.

1.2.1.2. 1980s, the shift to the use of ['single-use'](#) medical devices

Before the shift to the use of 'single-use' medical devices occurred in the 1980s, the re-use of some medical devices was facilitated by their shape, their size and the fact that they were usually made of glass, metal or rubber, and therefore the reprocessing of these devices was a relatively straight forward process.

However, with advancements in technology, including the use of novel plastics, instruments with smaller lumens and more intricate, delicate working mechanisms, devices were not as easy to clean or sterilize properly as before. Because of this, some products were labelled as 'single-use'.

‘Single-use’ medical devices also evolved from a time when hospitals asked for disposable products to cut down on reprocessing costs and risks of cross contamination from one patient to the next. Interest in these products further increased with the concerns regarding HIV transmission, the prevalence of hepatitis, etc.

1.2.1.3. Reprocessing of ‘single-use’ medical devices

However, over the years and sometimes in order to face increasing pressures to implement cost control, the number of ‘single-use’ medical devices that are reprocessed has grown.

Both the medical device industry and the medical device reprocessing industry are innovative and dynamic. As the medical devices industry advances, so too does the reprocessing industry and may continue to do so rapidly, which means that the number of medical devices labelled as ‘single-use’ that are made re-usable by the reprocessing industry may continue to increase over time.

As the reprocessing industry expands, and the number of ‘single-use’ medical devices being reprocessed is increasing, several concerns begin to be raised, including patient safety, patient informed consent, equivalent manufacturing standards for both the original manufacturer and the reprocessing company, and the potential ethical issues of ‘single-use’ device re-use. Concerns were also raised regarding public perception of re-use. In spite of the fact that reprocessing is a cost-saving and waste-reduction practice, it can be perceived as having little direct benefit to patients.

1.2.2. *Medical devices European regulatory framework*

Based on the New Approach, rules relating to the safety and performance of medical devices were harmonised in the European Union in the nineties, beginning in 1990 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 devices**¹ and later followed in 1993 by Council Directive [93/42/EEC](#) of 14 June 1993 concerning **medical devices**² and in 1998 by Directive [98/79/EC](#) of the European Parliament and of the Council of 27 October 1998 on **in vitro diagnostic medical devices**³.

These three legal texts form the core legal framework. They have been supplemented over time by **six modifying or implementing** Directives, including the last technical revision brought about by Directive [2007/47/EC](#) of the European Parliament and of the Council⁴.

¹ Official Journal L 189, 20/07/1990 P. 0017 - 0036

² Official Journal L 169, 12/07/1993 P. 0001 - 0043

³ Official Journal L 331, 07/12/1998 P. 0001 - 0037

⁴ Official Journal L 247, 21/09/2007 P. 0021 - 0055

1.2.3. Directive 2007/47/EC

The Directive 2007/47/EC, adopted on 5 September 2007, amended the Directive 93/42/EEC and 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."

1.3. Consultation process

1.3.1. Methodology

In order to prepare the above mentioned report, the Commission services launched a first public consultation on the reprocessing of medical devices. This consultation took the form of two questionnaires.

An [initial questionnaire](#) on the reprocessing of medical devices was developed and provided to the Medical Devices Expert Group members. This group includes, among others, experts from Member States' Competent Authorities, the Commission services and the medical devices industry representatives. National Authorities representatives were invited to describe the situation in their country while industry representatives were asked to give information in their fields of activity. This first step of the consultation took place from 23/05/2007 to 31/07/2007.

In order to broaden the contribution and to have as full a consultation as possible (from medical devices industries but also from reprocessing service providers, national health systems, hospitals, healthcare professionals, individuals), a [second questionnaire](#) was published on the Commission's Europa website from 6/07/2007 to 15/08/2007.

Within these two questionnaires, participants were asked to answer questions regarding reprocessing while making a distinction between 'single-use' versus 'multiple-use' medical devices, 'in-house' versus 'external' reprocessing and product types, where necessary.

The consultation was welcomed by the stakeholders, as being an important step in addressing the issue.

1.3.2. Aspects covered by the consultation

The two questionnaires were similar and included the following fields:

- o Definitions of reprocessing versus refurbishment;

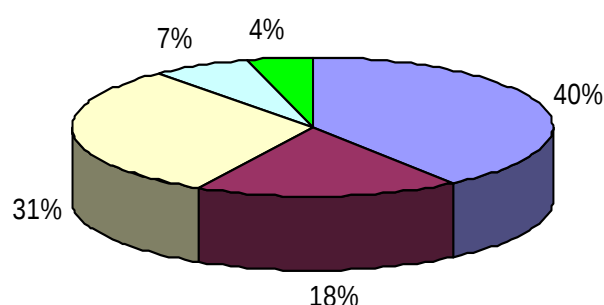
- o Existence of national laws on reprocessing;
- o Data / Surveys / Studies already available ;
- o Public health considerations;
- o Risk-Benefits analysis;
- o Liability considerations;
- o Economic aspects etc.

1.3.3. Composition, sample representativeness and limitations of the consultation

The feedback was collected from different types of organisations, Member States Competent Authorities, individual companies, public and private associations (including medical devices manufacturers and reprocessing service providers), hospitals and national health services as well as individuals.

The **Figure 1** illustrates the origin of the responses that were provided.

Figure 1: Origin of the responses provided



■ Member States Competent Authorities

■ Individual companies

■ Public and private associations (including medical devices manufacturers association and reprocessing service providers)

■ Hospitals and national health services

■ Individuals

This report considers each answer to be one contribution despite the different kinds of respondent profiles. This means that the responses of public institutions, organisations and companies carry the same weight as responses given by individual consultants or

members of the public. In some instances, multiple submissions were made by the same entity. For the purpose of analysis, these were considered as one single contribution. On the basis of this calculation, around 60 contributions were received.

It is important to note that the results of this consultation should not be seen as the opinions of the European population as a whole, but as a representation of the views of those who were interested in the question of the reprocessing of medical devices, were aware of the consultation and were able to fill in the questionnaires. Particularly, the respondents had to have internet access and had to understand English (as the questionnaires were only available in English).

2. OUTCOME OF THE PUBLIC CONSULTATION

2.1. Definitions

2.1.1. A wide range of definitions of reprocessing practice

The first aim of the questionnaires was to evaluate whether a clear definition of reprocessing of medical devices exists at national level and if there is a clear understanding of the reprocessing practice within the European Community. Most of the participants answered that a national legal definition does not exist or, at least, they were not aware of such definition. The answers received revealed a wide and varying range of different definitions and understandings of reprocessing as a practice.

On the basis of the answers received, it can be stated that reprocessing as a practice is generally perceived to mean the [cleaning](#), [disinfection](#) and [sterilization](#) of a medical device, including related procedures, as well as the functional testing and repackaging, carried out on a medical device after it has been put into service, for the purpose of re-use.

2.1.2. ‘In-house’ versus ‘external’ reprocessing practice

Reprocessing can be done either in the hospital or by an outside contractor. The contributions received estimate that around 90% of the reprocessing of reusable medical devices is done in-house while around 10% is external. For single use medical devices no representative data were received.

In that context, difference was also made as regards the concept of ownership of a device during or after the reprocessing. In some situations, the reprocessing practice is done in a hospital or (partly) by a third party, but the ownership of the device during and after the reprocessing remains the same. In some other situations, the reprocessing practice is done by a third party. This third party may become the owner of the device and may sell it after it has been reprocessed.

2.1.3. Distinction between reprocessing and refurbishment practices

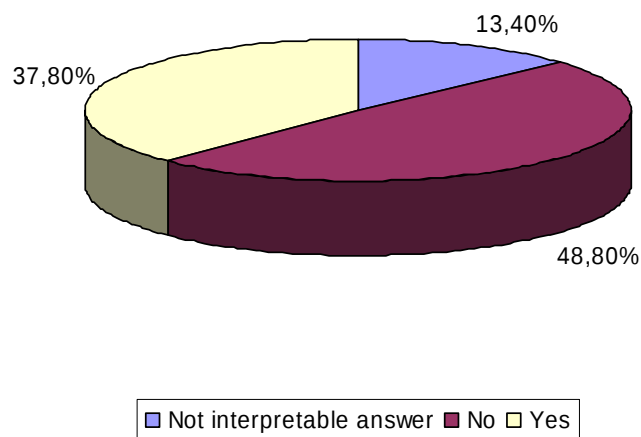
While 21.42% of the respondents did not clearly distinguish between these two activities, the distinction between reprocessing and refurbishing was made by some participants, refurbishing being generally understood as the extensive re-manufacturing of a medical device, which goes beyond reprocessing. In refurbishing, the medical device was

described by the respondents as restored to its original specifications, including the regeneration or the exchange of parts of the device.

2.1.4. Distinction between ‘single-use’ and ‘multiple-use’ medical devices

Another aspect of the consultation was to distinguish the practice of reprocessing on ‘single-use’ and ‘multiple-use’ medical devices. On this aspect opinions were divided and not always interpretable, as illustrated in **Figure 2**. But according to the majority of the responses, the practice of reprocessing should only cover the reprocessing of ‘multiple-use’ medical devices. Some participants were of the opinion that, for ‘single-use’ medical devices, the more appropriate term would be “refurbishment”.

Figure 2: Does reprocessing cover both ‘single-use’ and ‘multiple-use’ devices?



In the case of ‘multiple-use’ medical devices, the reprocessing activity was described as being performed on the basis of the instructions provided by the original manufacturer. This data includes information on the appropriate processes to allow re-use, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of re-uses⁵.

In the case of ‘single-use’ medical devices, as re-use is not part of the original intended use of the device, instructions are not provided by the original manufacturer. In these cases, reprocessing is carried out on the basis of procedures developed by the user or the reprocessing service provider.

2.1.5. The ‘single-use’ label

On the basis of the answers received, it must be noted that the meaning of the ‘single-use’ label was perceived differently among the respondents.

⁵ Directive 93/42/EEC, Annex I, part II ‘Requirements regarding design and construction’, section 13(6)h.

The majority of the views expressed during the consultation process perceived the ‘single-use’ label as a guarantee of safety and reliability of the medical devices concerned.

However, some respondents pointed out the arbitrary use of ‘single-use’ labelling and argued that there are medical devices that are labelled ‘single-use’ which have been proven ‘reprocessable’. According to these respondents, it is estimated that around 16% of all complex medical devices labelled as ‘single-use’ are in fact ‘multiple-use’ devices, technically ‘reprocessable’ for a limited number of times. Therefore, the difficulty in giving a clear guidance on which devices can be re-used is, according to these respondents, primarily due to the fact that the ‘reprocessability’ of a medical device does not seem to always correspond to it being labelled either ‘single-use’ or ‘multiple-use’. According to these respondents, even traditional ‘multiple-use’ devices cannot be indefinitely reprocessed and a growing number of ‘single-use’ labelled devices can be reprocessed for re-use for a limited number of times. These respondents estimate that about 84% of the medical devices that have been labelled as ‘single-use’ are for one application only. However they pointed out that, dependent on technical and scientific progress and proper risk assessments, more devices which are nowadays not safely ‘reprocessable’ may be ‘reprocessable’ in the future.

2.2. A fragmented regulatory framework within the European Community

Due to incoherent information provided during the consultation process, it is not possible to form a clear and precise picture of the current situation within the European Community as regards the regulation of the reprocessing practice.

However, what is clear is that the reprocessing service providers are facing a fragmented situation due to different health care systems and legislation in the European Member States. In some Member States, reprocessing practices on ‘single-use’ medical devices are regulated or accepted under quality standards (e.g. Germany⁶), in some it is not recommended or explicitly prohibited (e.g. France⁷), and in some Member States regulation just does not exist.

The German law was extensively referenced by some respondents. However, on analysis, this law does not differentiate ‘single-use’ or ‘multiple-use’ medical devices, but rather requires quality standards and validated procedures for reprocessing of all medical devices based on a risk assessment. Some other references were given such as the “MHRA Device Bulletin DB2006(04) – Single-use medical devices: implications and consequences of re-use”.

While asking for the existence of national law on reprocessing, distinction had been made in the questionnaires between ‘single-use’ and ‘multiple-use’ medical devices. However, the answers concerning the existence of national law were more or less similar, as it is illustrated in the **Figures 3 and 4**.

⁶ German Act on Medical Devices (MPG) and the Medical Devices Operator Ordinance (MPBetreibV)

⁷ DGS/DH/DHPM n°669 of 14 April 1986 and DGS/SQ3, DGS/PH2, DH/EM1 n°51 of 29 December 1994

Figure 3: Existence of a national law on reprocessing of ‘single-use’ devices

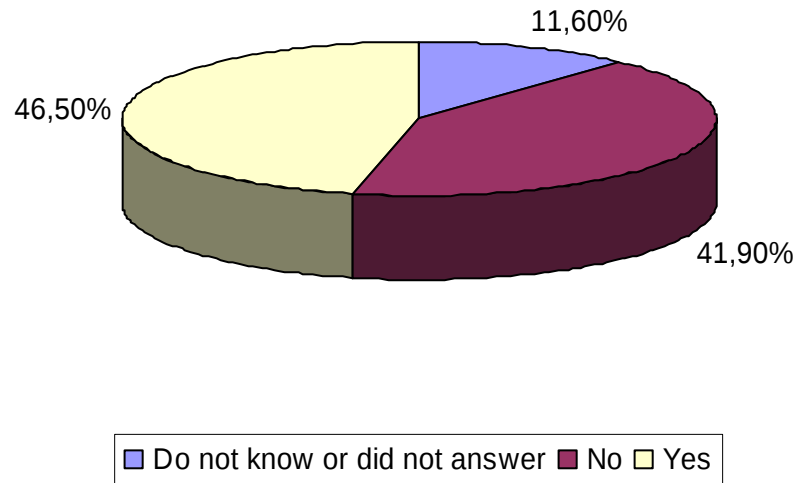
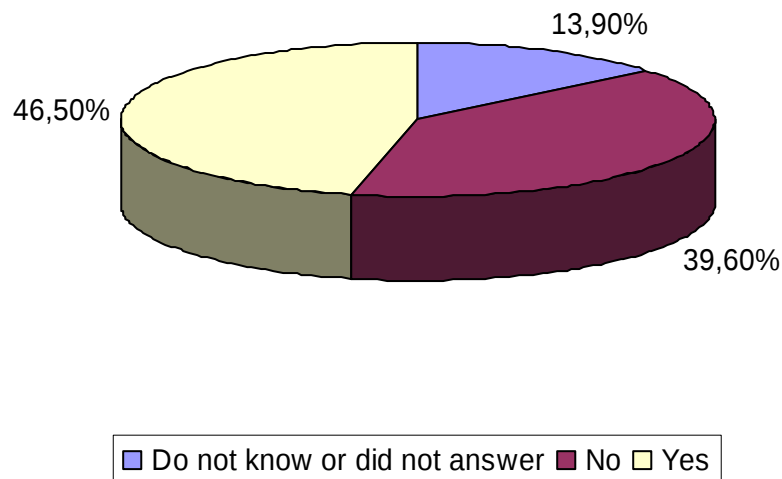
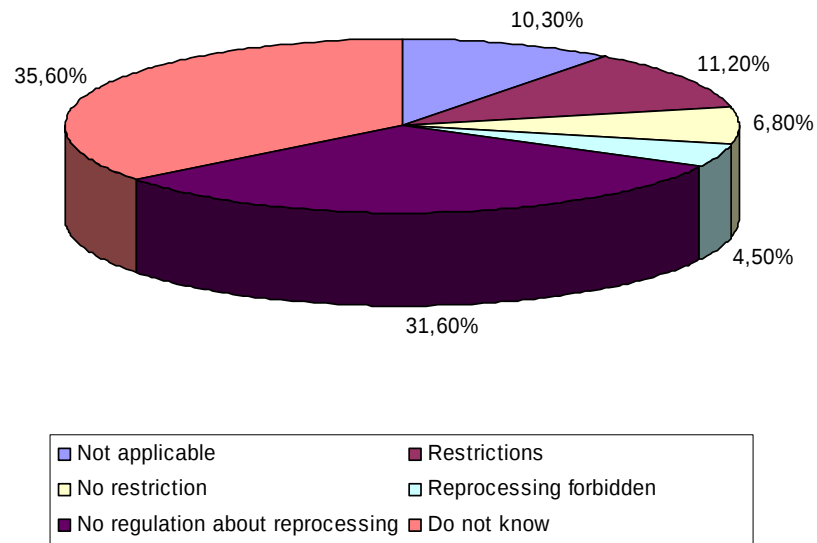


Figure 4: Existence of national law on reprocessing of ‘multiple-use’ devices



Moreover, a specific question relating to the existence of restrictions on the types of ‘single-use’ medical devices that can be reprocessed was included in the questionnaires. Most of the contributions pointed out that, where national laws and/or re-imbursement system(s) accept the reprocessing of ‘single-use’ medical devices, there are restrictions (**Figure 5**). However, in general rule, no interpretable information was given on the nature of these potential restrictions.

Figure 5: Restrictions on the types of ‘single-use’ devices that can be reprocessed

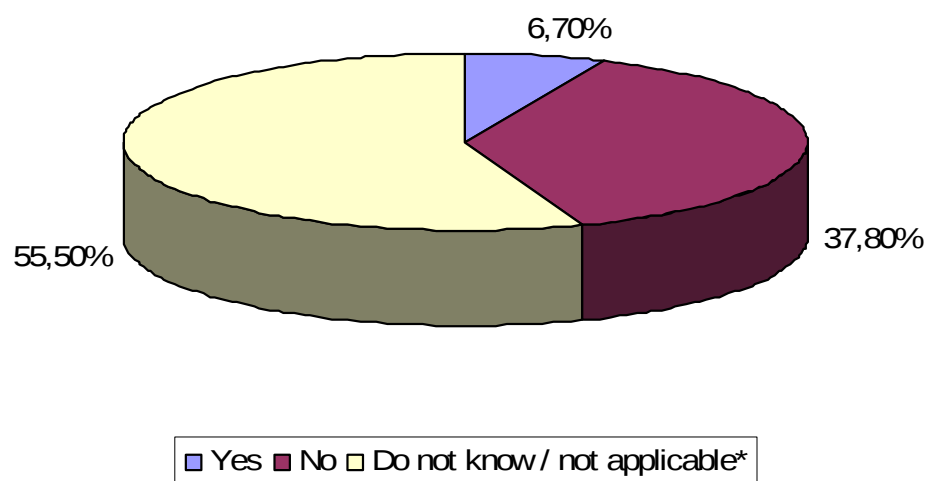


2.3. Public health aspects

2.3.1. Risk-Benefit analysis of the practice of reprocessing

The Commission services asked if the participants were aware of a risk-benefit analysis on the practice of reprocessing, from a public health point of view. The majority of the submissions gave no information on the issue. It must be noted that 46.6% of the contributions were not aware of any risk-benefit analysis on the practice of reprocessing, as illustrated in **Figure 6**.

Figure 6: risk-benefit analysis of the reprocessing practice



*Do not know: 46.6% - Not applicable: 8.9%

2.3.2. Patient safety and public health aspects

Among the respondents concerns were made about the health risks associated with re-use of medical devices, particularly 'single-use' devices, since improper cleaning may potentially result in transfer of pathogens from one patient to another, and since decontaminating, cleaning and sterilizing of 'single-use' devices may affect their functionality.

The majority of respondents believe that no 'single-use' medical device can be reprocessed without risk. Furthermore, some respondents pointed out that adverse events associated with re-use of 'single-use' medical devices might be under estimated due to insufficient and/or inadequate reporting.

The main public health related aspects that were highlighted during the consultation process were:

o Potential for cross-infection and Hospital Acquired Infections (HAI)

According to some respondents, in some circumstances, the risk of cross-infection may increase due to the inability of some reprocessing processes to completely remove viable micro-organisms.

Also, the fact that invasive devices, for instance intubation tubes, catheters, surgical drains and tracheotomy tubes bypass the body's natural lines of defense against pathogens and therefore may provide an easy route for infection was raised by some participants. These participants consider that reprocessed 'single-use' medical devices could potentially lead to an increase of cross infection from patient to patient in such cases.

o Problem of inadequate decontamination and cleaning

The fact that the cleaning process must be able to access all parts of the device to enable complete decontamination was pointed out by some participants. It was also highlighted that the cleaning agents must be completely removed at the end of the process and this process must be validated by the processor. Some 'single-use' devices have difficult to access angles, coils, long or narrow lumens (e.g. balloon angioplasty catheters, flexible endoscopes, instruments for minimally invasive surgery etc.) or surface coatings which make cleaning and validation of that cleaning difficult.

o Residues from chemical decontamination agents

According to some respondents, some materials can absorb certain chemical decontaminants which will gradually leach out over time causing harm. The example of glutaraldehyde was given since, according to these respondents, this substance can be absorbed by certain plastics and leach out during use, resulting in chemical burns or risk of sensitisation of the patient or user.

o Performance, safety and reliability

41% of the contributors think that no ‘single-use’ medical device can be reprocessed without risk because they have been created for only one use. According to these respondents, reprocessing ‘single-use’ devices may affect the capabilities and/or the materials from which the device is made and therefore performance, safety and reliability of a reprocessed device [intended purpose](#) may not to be guaranteed.

Some respondents highlighted that, for ‘single-use’ medical devices, testing and validation are targeted to limit initial failure, as opposed to ‘multiple-use’ devices, which are designed and tested to ensure the reliability for a number of usages. These respondents argued that, if repeatedly reprocessed, some ‘single-use’ medical devices could be affected by unpredictable fatigue-induced failure and fracturing. Difference was made between medical devices designed for re-use (‘multiple-use’ medical devices) for which the manufacturer provides adequate reprocessing instructions at the time the device is placed on the market and medical devices designed for ‘single-use’ (‘single-use’ medical devices) where the manufacturer cannot provide reprocessing instructions, as a validation method has not been developed.

o Material alteration

The issue that exposure to some agents may cause material alteration such as corrosion was raised during the consultation. Also, some respondents highlighted that exposure to high temperatures or pressures (e.g. during the sterilization process) may alter the properties or cause degradation of the device materials (e.g. plastics).

o Reactions to [endotoxins](#)

Some respondents pointed out that the sterilization process may not inactivate all toxins, even when sterilization is effective in killing bacteria.

o [Prion](#) removal

It was highlighted that the abnormal proteins associated with prion diseases are highly resistant to conventional methods of decontamination and sterilization.

In this context, reference was made to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) [opinion](#) as regards the safety of Human-derived Products with regard to [Variant Creutzfeldt-Jakob Disease](#) (vCJD). This opinion addresses also the issue of the evaluation of prion decontamination procedures for surgical instruments and concludes the following:

- *“No procedure for the decontamination of surgical instruments has yet been adequately validated to the extent that its universal introduction can be recommended. However, state of the art cleaning should be used as it is a prerequisite to ensure subsequent inactivation methods.*
- *Disinfectants with fixative properties such as those containing aldehydes must not be used for decontamination of instruments suspected to be contaminated with TSEs as they tend to stabilise rather than inactivate prions.*

- *Drying of instruments before cleaning or decontamination is likely to reduce the effectiveness of the decontamination procedure*
- *The implementation of whatever procedures are introduced should be monitored”⁸*

As regards the risk assessment on transmission by surgical instruments or invasive procedures the SCENIHR opinion concludes the following:

“Because of the actual limitations for conducting a full risk assessment process (lack of knowledge both on the level of contamination of the instruments before reprocessing and on the minimal infectious dose linked to new variants of prion according to the route of transmission) the edited guidances are based on the precautionary principle:

- *specific precautions for symptomatic patients (definite, probable and possible) and asymptomatic patients potentially at risk of CJD*
- *general precautionary measures for surgical procedures and endoscopy.*

A patient ‘at high risk’ is defined as a patient exposed to materials from individuals who are thought to have been infected with vCJD. For all symptomatic patients, use of ‘single-use’ protective clothing and ‘single-use’ disposable surgical instruments and equipment are necessary. All ‘single-use’ items must be destroyed by incineration. In some Member States general precautions have been taken in respect to high risk procedures like tonsillectomy.

For asymptomatic patients but who are known to be at risk the same precautions apply, but where ‘single-use’ instruments are not available, the handling of reusable items depends on the kind of activity and the tissue in contact with the instrument (tissue considered in the WHO classification as possibly contaminated or not).”

o Appropriate testing, validation and documentation

It was pointed out that reprocessing a medical device designed as ‘single-use’ requires the process and the device to undergo extensive testing, validation and documentation to ensure the device is safe to re-use. According to some respondents, it seems that there are few healthcare establishments equipped to carry out these procedures. These respondents pointed out that, without these procedures, the use of a reprocessed ‘single-use’ device is likely to be associated with significant risk for patient safety.

2.4. Ethical aspects

Some participants questioned to what extent reprocessing can be of benefit to the patient.

The ethical concerns of reprocessing cover, among others:

- o Previous usage** of the medical device (e.g. implants);
- o Patient informed consent**, i.e. whether the patient was informed sufficiently of all procedural or treatment risks, including use of reprocessed ‘single-use’

⁸http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004b.pdf

devices, which would be necessary for him to decide whether to undergo the procedure;

- o **Equal access to the same quality level of treatment**, regardless financial resources. The use of reprocessed devices was regarded by some respondents as creating different level of treatment for patients;
- o **Patient safety**, i.e. the level of risk associated with the re-used product;
- o **Cost of care**, i.e. is it ethical to charge patients based on the costs for a new device when a re-used device is employed?
- o **Healthcare professionals consent**: i.e. it may happen that clinicians are unaware that they are using reprocessed products.

2.5. Economic aspects

Medical devices have become increasingly important with regards to their impact on patient health and influence on health care expenditures. According to latest data from a medical devices association, the total industry is currently worth €64 billion, the yearly growth is around 5-6% and the yearly research investment is €4 billion, which represents 5-6%.

2.5.1. Economic attractiveness of reprocessing practice

Reprocessing of 'single-use' devices can be very attractive from an economic point of view, in particular for expensive single use devices (e.g. microsurgical instruments etc.). 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). Savings from reprocessing can be as high as 90% when reprocessing in-house. One could also argue that these savings could potentially increase the research or the access to healthcare services and innovative technology for patients since, due to an increased life cycle for a given and sometimes expansive medical device, more patients may have access to innovative products.

2.5.2. Limitations

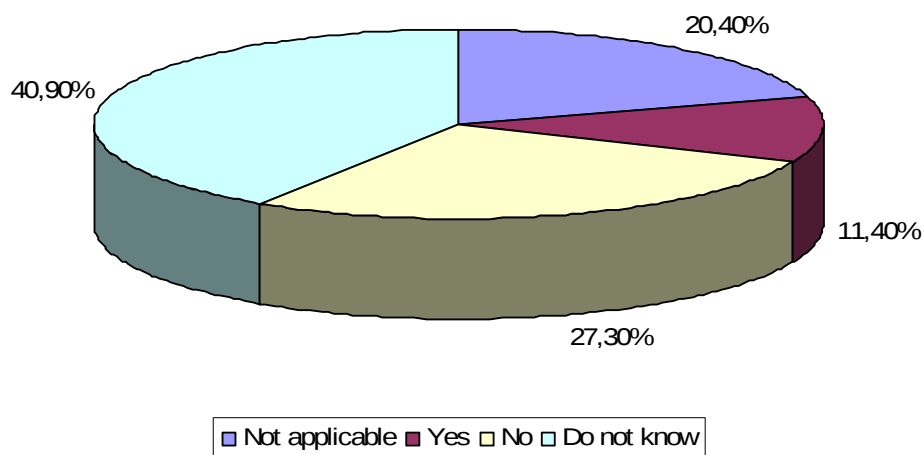
It was highlighted that the economic aspects can be also, in certain cases, a limitation factor to reprocessing. Medical devices have to be reprocessed in line with documented and validated procedures. This may need a high investment in terms of material and personnel. If new devices can be purchased cheaper than reprocessed items, or if only a small amount of instruments are needed, the efforts for validation is not justifiable, e.g. simple catheters, wires, plasters etc. For the same reason, where the energy, chemicals or water needed causes an unjustified cost /value ratio, reprocessing will not be a chosen option. To be meaningful, any cost calculation should also take into account indirect and full costs such as employment of qualified staff or third parties providers, machinery, administrative costs for the follow-up of traceability, batch release, insurances, documentation and validation of procedures etc.

2.5.3. Potential hidden costs

The consultation pointed out that the potential hidden costs should also be taken into consideration when looking at the economic aspects of the reprocessing (e.g. costs of potential Hospital Acquired Infections which resulted in extra days in hospital, an extra cost on healthcare and extra days off work, etc.).

In order to further assess the economic aspect, the Commission services asked the participants if they were aware of any economic incentives for reprocessing of 'single-use' medical devices. The Commission services went further in the question and asked for more details such the kind of incentives, the procedure, the limits and the products concerned by the incentives. The submissions were not really helpful since the majority had no information to provide about any economic incentive, see **Figure 7**.

Figure 7: Economic incentives for reprocessing of 'single-use' medical devices



2.6. Data / Surveys / Studies already available

2.6.1. National standards applicable to reprocessing either of 'single' or 'multiple' uses

The contributors have been asked if they were aware of any national standards, which are applicable to the reprocessing of medical devices. While the answers were divided, some references were given, such as:

- o Vertical standards concerning certain product types (e.g. cardiac catheters);
- o International standards for sterilization such as
 - ISO 11137:2006 Parts 1-3 - Standard for Gamma Radiation Sterilization
 - ISO 17665-1:2006 - Moist Heat Sterilization;

- ISO 17664 - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices;
- ISO 11135: 2007 - Standard for Ethylene Oxide Sterilization;
- ISO 10993-7 - Ethylene oxide sterilization residuals;
- ISO 11138:2006 Parts 1-5 - Sterilization of health care products; Biological Indicators;
- o Guidance on good practices such as
 - <http://www.swissmedic.ch/md/pdf/steri-praxis-f.pdf>;
 - <http://www.swissmedic.ch/md/pdf/steri-vali-f.pdf>;
- o Health Technical Memorandum HTM2010 (sterilization - Validation and verification, HTM2030 (Washer disinfectors), HTM2031 (Clean steam for sterilization);
- o Guideline from the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch-Institute (RKI) and the German Federal Institute for Drugs and Medical Devices (BfArM) on the “Hygienic requirements for (re-)processing of medical devices”;
- o The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections;
- o Decontamination of re-usable medical devices in the primary, secondary and tertiary care sectors (NHS and Independent providers) 2007 clarification and policy summary.

2.6.2. Data, surveys or studies on risks of reprocessing, from the public health point of view

45.3% of the respondents were aware of the existence of data, surveys or studies on risks of reprocessing, from the public health point of view.

Some specific references were given, such as for instance

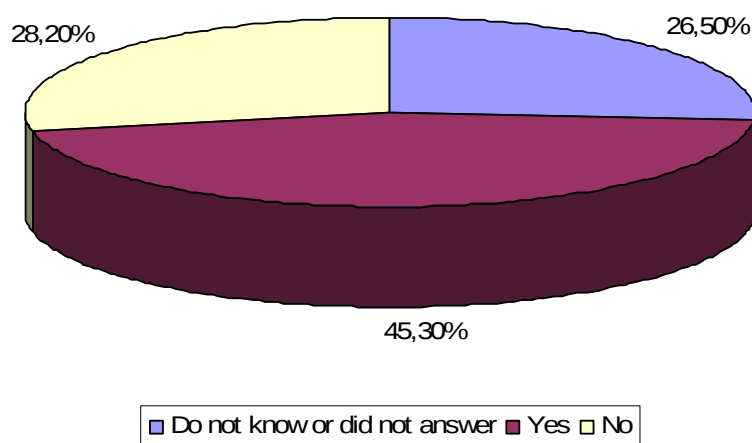
- o the study “Investigations to Demonstrate Amenability to Cleaning of Surgical Instruments” published in the journal Zentralsterilisation;
- o the study “Sterilisability of Reusable Surgical Instruments” published in the journal Zentralsterilisation;
- o the study of the Institute for Environmental Medicine and Hospital Hygiene (IUK) at the University of Freiburg on the hygienic, practical and legal aspects of the reprocessing of single-use medical devices in Europe.

Reference was also given to a study conducted in the Kerckhoff-Klinik Bad Nauheim, Germany, between 2000 and 2003 which assessed 202 catheter interventions in patients,

about half of them new electrophysiological catheters. Some respondents also mentioned a pilot study launched in two major Danish hospitals on behalf of the Staten Serum Institute (National Institute under the Danish Ministry of the Interior and Health) in 2003.

However, it must be noted that 28.2% of the participants think that such data does not exist and that 26.5% do not have a clear answer on the issue. These figures are represented in the chart below (**Figure 8**).

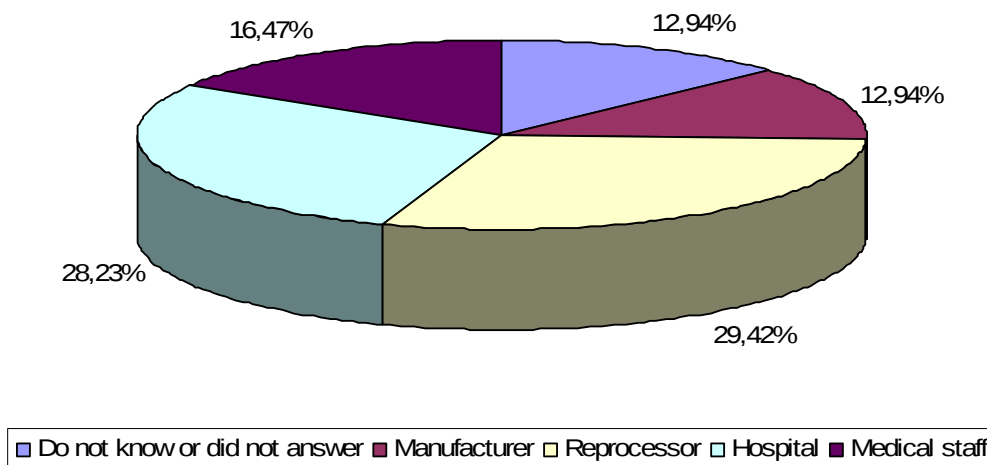
Figure 8: Existence of data, surveys or studies on risks of reprocessing, from the public health point of view



2.7. Liability considerations

The public consultation also raised the aspect of the liability, as foreseen by the legal system of each Member State. As seen in **Figure 9**, highest liability was attributed to the reprocessing service provider and in second place, to the hospital where the reprocessing takes place.

Figure 9: Liability for a reprocessed ‘single-use’ medical device:



More specifically, according to the reprocessing industry, the liability for reprocessing should be allocated between the manufacturers and the reprocessing industry as follows:

- o In those cases where the original manufacturer decides to provide a validated procedure for reprocessing, he is responsible for the implications of reprocessing along the guidelines provided.
- o In those cases where independent professional reprocessing service providers develop validated procedures for reprocessing, the reprocessing service providers can be held responsible for the implications of reprocessing along the guidelines provided which they themselves develop.
- o Medical staff remains liable in case of mishandling or misuse of a medical device with regard to patients' health, independent from the fact whether the medical device was a new or reprocessed product (different causation for liability). However on this point some respondents also pointed out that it may happen that clinicians are unaware that they are using reprocessed products.

According to the medical devices industry, the liability for the manufacturer ends at the time the device is not used in accordance to the intended use specified by him in the accompanying documentation, the label and the promotional material. According to these respondents, in case of reprocessing of ‘multiple-use’ medical devices, the medical devices Directive already clearly specifies the requirements to be fulfilled by the manufacturers, as well as their responsibilities, and the nature of the information, which shall be given to the users in order to allow the subsequent safe use of a product after it has been used. For these products the manufacturer bears full responsibility for the first use and the subsequent uses, provided that its instructions are correctly applied.

3. CONCLUSION

This synthesis document provides an overview and general impression of the feedback received by the Commission services in the context of this first public consultation on the issue of the reprocessing of medical devices. It must be noted that the statements and opinions expressed in the document do not therefore necessarily reflect those of the Commission.

Several key findings emerge:

3.1. Definitions

There is no clear definition and/or common understanding of what constitutes ‘reprocessing’ within the European Union; the difference between reprocessing and refurbishing was not clearly made by the majority of the participants. On the basis of the answers received, it can be stated that reprocessing is understood as the cleaning, disinfection and sterilization of a medical device, including related procedures, as well as the functional testing and repackaging, carried out on a medical device after it has been put into service, for the purpose of re-use. In some cases, differentiation was made with refurbishing, perceived as the extensive re-manufacturing of a medical device, which goes beyond reprocessing. In such cases, the medical device was referred to as ‘made as new’.

3.2. The ‘single use’ label

Through the consultation the meaning and the arbitrary use of the ‘single use’ label was questioned by some respondents who made a distinction between the ‘single-use’ label of a medical device and its ability to be reprocessed or not. However, this does not reflect the majority of the views expressed during the consultation process which see the ‘single-use’ label as a guarantee of safety and reliability of the medical devices concerned and understand the ‘single-use’ label to mean a device intended to be used once only for a single patient.

3.3. Regulatory aspects

Even if the information provided during the consultation process does not allow setting up a clear and precise picture of the current situation in the European Union as regards the regulation of reprocessing, the consultation revealed a fragmented situation within the Community. While the situation is regulated in some countries (i.e. permitted, not recommended or forbidden), the situation remains unclear in some other Member States in the absence of any specific regulation.

3.4. Public health aspects

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. Some specific transmission risks were pointed out, e.g. prion transmission in the context of variant Creutzfeldt-Jakob disease.

3.5. Economic aspects

Reprocessing is presented as a cost-saving and waste-reduction practice that can lead to substantial savings for a hospital or a clinic. However, the consultation shows that, according to some participants, this economic advantage should be carefully balanced with indirect and hidden costs.

3.6. Ethical aspects

On the one hand, the consultation pointed out major ethical concerns with regard to reprocessing. Especially, as regards the extent to which reprocessing practice can be of direct benefit to the patient and the risk to create different levels of healthcare provision. On the other hand, the potential cost savings generated by the reprocessing practice could contribute to facilitate access to healthcare services and innovative technology for the patients.

3.7. Liability aspects

The consultation raised the issue of liability aspects in the context of the reprocessing practice.

Despite some discrepancies in the answers received, the majority of the answers pointed out that the liability for the original manufacturer ends at the time the device is not used in accordance with its intended purpose, i.e. specified in the accompanying documentation, the label and the promotional material. In case of reprocessing of 'multiple-use' medical devices, the medical devices Directive clearly specifies the requirements to be fulfilled by the manufacturers, as well as their responsibilities, and the nature of the information, which shall be given to the users in order to allow the subsequent safe use of a product after it has been used. For these products the manufacturer bears full responsibility for the first use and the subsequent uses, provided that its instructions are correctly applied.

According to the answers received, if a 'single-use' medical device is reprocessed, the liability for the product is incumbent on the reprocessing service provider. If a hospital reprocesses single-use medical devices itself, the hospital is subject to the same obligations as a professional reprocessing service provider. Some respondents pointed out that even if the healthcare professionals are liable in case of mishandling or misuse of a medical device with regard to patients' health, it may happen that clinicians are unaware that they are using reprocessed products.

GLOSSARY

The following terms have been defined for the purpose of this report:

- **Cleaning**⁹: physical removal of organic matter and infectious agents⁰
- **Cross-infection**¹⁰: cross infection refers to the transmission of a pathogenic organism from one person to another.
- **Decontamination**¹¹: combination of the processes which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or other harmful response.
- **Disinfection**¹²: reduction in viable infectious agents.
- **Endotoxin**¹³: endotoxins form part (the lipopolysaccharide (LPS) complex) of the outer membrane of the cell wall of Gram-negative bacteria. The toxin is released when the cell wall of the bacteria is destroyed.
- **Hospital Acquired Infection**¹⁴: Hospital-acquired infections (HAIs), or nosocomial infections, are defined as infections acquired in a hospital by a patient who was admitted for a reason other than that infection. Any infectious agent has the potential to be transmitted nosocomially, whether a bacterium, virus, fungus, parasite, or prion.
- **Informed consent**¹⁵: person's agreement to allow something to happen after the person has been informed of all the risks involved and the alternatives.
- **Intended purpose**¹⁶: use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.
- **Manufacturer**¹⁷: natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
- **Medical device**¹⁸: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and

⁹ <http://www.mhra.gov.uk>

¹⁰ Gale Encyclopedia of Public Health

¹¹ <http://www.mhra.gov.uk>

¹² <http://www.mhra.gov.uk>

¹³ <http://www.pharmaceutical-technology.com>

¹⁴ <http://www.euro.who.int>

¹⁵ <http://www.legal-definitions.com>

¹⁶ Article 1(2)g of Directive 93/42/EEC, as last amended by Directive 2007/47/EC

¹⁷ Article 1(2)f of Directive 93/42/EEC, as last amended by Directive 2007/47/EC

¹⁸ Article 1(2)a of Directive 93/42/EEC, as last amended by Directive 2007/47/EC

necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

- **Prions**¹⁹: disease-causing agent that is neither bacterial nor fungal nor viral and contains no genetic material.

- **Prion diseases**²⁰: disease due to a prion, a proteinaceous infectious particle that lacks nucleic acids. Prions are composed largely, if not entirely, of an altered form (an abnormal isoform) of a normal cellular protein.

- **Reprocessing**²¹: cleaning, disinfection and sterilization of a medical device, including related procedures, as well as the functional testing and repackaging, carried out on a medical device after it has been put into service, for the purpose of re-use.

- **‘single-use’ medical device**²²: ‘single-use’ device means a device intended to be used once only for a single patient.

- **Sterilization**²³: render an object free from all viable infectious agents.

- **Variant Creutzfeldt Jacob disease**²⁴: Variant Creutzfeldt-Jakob disease (vCJD) is a rare and fatal human neurodegenerative condition. As with Creutzfeldt-Jakob disease, vCJD is classified as a Transmissible Spongiform Encephalopathy (TSE) because of characteristic spongy degeneration of the brain and its ability to be transmitted.

¹⁹ <http://www.medterms.com>

²⁰ <http://www.medterms.com>

²¹ Definition for the purpose of this analysis

²² Article 1(2)n of Directive 93/42/EEC, as last amended by Directive 2007/47/EC

²³ <http://www.mhra.gov.uk>

²⁴ <http://www.who.int>

ANNEX I

Questionnaire provided to the Medical Devices Expert Group members



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Cosmetics and Medical Devices

Brussels,
ENTR F3 MK/bl D(2007)

QUESTIONNAIRE FOR THE MEDICAL DEVICES EXPERTS GROUP

Subject: Reprocessing of Medical Devices

In order to prepare a report on the reprocessing of medical devices in the Community, as mentioned in Article 12a of the revised Directive 93/42/EEC, soon adopted, the Commission services would like to ask the experts a first couple of questions.

The representatives of the national authorities are invited to describe the situation in their Member States. The representatives of industry are invited to give information in their fields of activity. Please differentiate, if necessary, between (a) single-use and multi-use medical devices (MD), (b) in-house versus external reprocessing / refurbishment, and (c) product types:

1. Is there national law on reprocessing and refurbishment? (Please attach copy if not available on internet!)
2. How do you define reprocessing and refurbishing?
3. In which cases does your legal and/or re-imbursement system accept reprocessing or refurbishment? Is there a risk-benefit analysis in these cases?
4. Are there national standards applicable to the reprocessing and refurbishing? (Please attach copy if not available on internet!)
5. From the public health point of view, do you have data, surveys or studies on risks of reprocessing and refurbishing?
6. Can you indicate which MD can be reprocessed or refurbished without risk from the public health point of view (if properly done)?
7. Which MD cannot be reprocessed or refurbished without risk from the public health point of view (even if properly done)?
8. What liability is incumbent to the original manufacturer, what to the reprocessor/refurbisher, what to the hospital or the medical staff?

9. Please describe the reprocessing and refurbishment practice:
 - percentage of in-house versus external reprocessing/refurbishment;
 - reprocessing/refurbishment by OEMs (original equipment manufacturers) or independent service providers;
 - MD mainly reprocessed / refurbished;
 - percentage of reprocessed/refurbished MD imported from a third country or introduced from another Member State.
10. Are there de facto financial incentives for reprocessing and refurbishment? For which products? Which kind of incentives? How does the incentive work? Where are the limits? *E.g., lump sums for patients / treatments can create an incentive for reprocessing.*

A reply to these questions would be appreciated for end July.

ANNEX II

Questionnaire published on Europa webiste



QUESTIONNAIRE ON REPROCESSING OF MEDICAL DEVICES

In order to prepare a report on the reprocessing of medical devices in the Community, as mentioned in Article 12a of the revised Directive 93/42/EEC, soon to be adopted, the Commission services would like to invite interested parties to answer the following questions.

When answering this questionnaire, differentiation can be made, if necessary, between:

- a) single-use versus multi-use medical devices
- b) in-house versus external reprocessing
- c) product types

Question 1. How would you define reprocessing?

Question 2. Do you consider reprocessing to cover both single use and multiple use devices?

Question 3. a) Are you aware of any national law on reprocessing of single use devices?

b) Are you aware of any national law on reprocessing of multiple use devices?

Question 4. a) Where national legal and/or re-imburement system(s) accept reprocessing of single use medical devices, are there any restrictions on the types of single use devices that can be reprocessed?

b) Is there a risk-benefit analysis in these cases?

Question 5. Are you aware of national standards applicable to reprocessing either of single use or multiple use?

Question 6. From the public health point of view, are there data, surveys or studies on risks of reprocessing?

- Question 7.** According to you, from a public health point of view, which single use medical devices can be reprocessed without risk (if properly done)?
- Question 8.** According to you, from the public health point of view, which single use medical devices cannot be reprocessed without risk (even if properly done)?
- Question 9.** According to your domestic legal system, for a reprocessed single use medical device, what liability is incumbent on:
- a) the original manufacturer?
 - b) the reprocessor?
 - c) the hospital?
 - d) the medical staff?
- Question 10.** Could you please describe the reprocessing practice (e.g. in-house versus external reprocessing, types of medical devices reprocessed, methods used, etc)
- Question 11.** Are you aware of any economic incentives for reprocessing of single use medical devices? For which products? Which kind of incentives? How does the incentive work? Where are the limits?

Thank you very much for your contribution.



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