EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Cosmetics and Medical Devices

WORKSHOP ON REPROCESSING OF MEDICAL DEVICES

5 December 2008

10.00 – 17.00

BREY – Meeting room 11A
DG Enterprise and industry
Avenue d'Auderghem 45
B-1049, Brussels, Belgium

1. BACKGROUND

The Directive 2007/47/EC, adopted on 5 September 2007, inserted the following provisions concerning the reprocessing of medical devices:

"Article 12a

Reprocessing of medical devices

The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.

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

In order to prepare the above mentioned report, the Commission services launched a first public consultation in 2007 on the reprocessing of medical devices, including the reprocessing of single use 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 consultation also to 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.

The consultation was welcomed by the stakeholders, as being an important step in addressing the issue. Following this consultation a synthesis document was published on the European Commission website[1].

2. WORKSHOP OBJECTIVES

On the basis of the findings of the above mentioned consultation, the Commission services intended, through this workshop, to collect further data, in particular on

- **Scientific, technical and public health challenges of the reprocessing practice;**
- **Legal aspects of the reprocessing practice;**
- **Economic aspects of the reprocessing practice;**
- **Environmental aspects of the reprocessing practice**

in order to get a broader picture of the reprocessing practice, including reprocessing of single use medical devices, and to assess what policy options might be appropriate for the reprocessing of medical devices in Europe.

3. WORKSHOP OUTCOMES

This document provides a general overview of the feedback received by the Commission in the context of the 5 December 2008 workshop on the issue of the reprocessing of medical devices.

It is important to note that the statements and opinions expressed in this document are purely those of the speakers and do not therefore necessarily reflect those of the Commission.

The presentations made by the speakers are available here.

3.1. Scientific, technical and public health challenges of the reprocessing practice

The **MHRA**[2] presented their viewpoint on reprocessing of medical devices (single use).

[1] http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/synthesis.pdf

Part of this presentation was dedicated to the MHRA views on the reasons why a decision to market a single use device may be made, *e.g.*

- It may not be feasible to make the device in reusable materials and achieve the desired function;
- It may not be possible to design a device to both achieve the desired function and allow patient safe reprocessing;
- Manufacturers may wish to control or limit their liability for device failure by making a product a single use device, rather than depending on providers to do everything required for reprocessing;
- Residual biological material, including protein, can remain adherent to the surface of surgical steels following current recommended decontamination procedures[3].

The MHRA pointed out identified problems involving the re-use of single use devices.

The main problems were:

- Potential for cross infection;
- Material alteration;
- Inability to clean and decontaminate;
- Mechanical failure;
- Residues from chemical decontamination agents;
- Particular concern was the potential for cross contamination with Prions.

A specific focus was made on the German hygienic requirements for the reprocessing of medical devices through a presentation of the **Robert Koch-Institut**[4] (RKI).

This presentation was complemented by a presentation from the **BfArM**[5] on the report on reprocessing of medical devices in Germany. According to the speaker, the central findings of the survey to date, based on the majority opinion, are as follows:

- The legal framework governing the reprocessing of medical devices in Germany is generally sufficient;

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2 "Reprocessing of medical devices (single use). UK viewpoint" - Allan Hidderley, Senior Medical Device Specialist - Device Technology & Safety, Biologics & Implants - MHRA (Devices) - London, UK

3 SEAC Position Statement – methods to evaluate decontamination technologies for surgical instruments – August 2006

4 "Hygienic requirements for the reprocessing of medical devices" - Prof. Dr. M. Mielke, Robert Koch-Institut, Berlin, Germany

5 "Report on Reprocessing of Medical Devices in Germany" - Dr. Gisela Ininger, Germany - Federal Institute for Drugs and Medical Devices (BfArM)

- A far-reaching correction of the regulation governing the reprocessing of so-called single use devices leading to a complete ban would be neither helpful, nor advisable for other reasons;

- In order to clarify the objectives, however, some adjustments should be made to the upcoming legislative bills;

- Technical guidelines on the reprocessing procedure of critical medical devices should be made concrete;

- There are considerable discrepancies when it comes to awareness of the RKI/BfArM recommendation;

- The supervision of the reprocessing procedures in the healthcare institutions and by external reprocessors is starting to become of central importance;

- Some of the supervisory authorities suffer from staffing shortages;

- The participants must be made more aware of the importance of compliant reprocessing procedures to increase patient protection.

A presentation was made by the **Danish National Center for Antimicrobials and Infection ControlStatens Serum Institut**[6]. The speaker presented a Danish pilot project performed in 2003 with the aim to reduce or stop sub standard reuse of single use medical devices in Danish hospital and to evaluate some aspects of professional reprocessing. The speaker also presented a questionnaire of 2006 on the reuse of single use medical devices.

SMP GmbH[7] made a presentation on how to assess whether the design of a single use medical device allows appropriate cleaning and sterilization.

This presentation concluded that:

- Good cleaning results are an indispensable prerequisite for good disinfection and sterilization;
- The validated cycle has to regard the specific requirements of the device, the washer - disinfector and the chemistry additives used during the cycles;
- There may be a chance for the reuse of single use devices, but due to the high costs for validation and quality assurance, reprocessing of single use devices can not be performed in the healthcare institutions;
- Validated cleaning methods must be mandatory for all health care facilities.

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[6] "Danish experience and considerations on the reprocessing of single use medical devices" - Elsebeth Tvenstrup Jensen, MD

[7] "How to assess whether the design of a single use medical device allows appropriate cleaning and sterilization" – K. Roth – SMP GmbH

According to the viewpoint of the **Chair of the Eucomed Reuse Task Force**[8], the reuse of single use medical devices is a deviation from the normal use and contradictory to the design intent. According to the speaker, such reuse does not provide state of the art devices which can be defined as the performance, quality and hygiene of the new single use device and would therefore require new post market surveillance / vigilance systems. The speaker added that reuse against the design intent does violate the essential requirements safety principles, which call for inherent safe design and construction for the intended (single) use. According to the speaker, current refurbishment practices, especially if conducted by external suppliers, go far beyond the practice of cleaning and sterilization. Complex devices are broken apart, parts are replaced and the devices are glued back together, thus leading to devices with new designs, different performance, generally missing any clinical evidence. The speaker added that manufacturing and design criteria established by the manufacturer critical for the clinical performance of the device may be changed and lead to a new device not covered by the manufacturer's production, design and clinical validation. He concluded by saying that, as of today, clinical evidence proving that a refurbished single use device is as safe as a new device is not available.

Dr. med. **H. Haindl**[9] through his presentation highlighted concerns about scientific, technical and public health aspects of the reprocessing practice for single use medical devices, pointing out that reprocessing of single use medical devices would be unacceptable without a vote of an ethical committee, without informed consent of the patient and without systematic analysis of the results.

The **AFS**[10] presented their positions regarding reuse and resterilization of single use medical devices.

The following issues were pointed out by the AFS:

- How to detect and measure the risk level associated with reprocessing;

- How to check the functionality of the reprocessed medical devices, above all for complex ones, as it was not intended to be reused.

- Determination of a maximum number of reprocessing cycles seems to be impossible;

- Acceptable methods and limits concerning the cleanliness of the medical devices before sterilization;

- Ethical problem when reusing a single use medical device is the needed patient's consent, which has to be based on a comprehensive knowledge of the many risks he should incur.

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8 "Re-use of single use Medical Devices" - Peter Schröer, Chair Eucomed Reuse Task Force - Ethicon Endo-Surgery (Europe) GmbH

9 "Is there a proof for the safety of reprocessed single use devices?" - Dr. med. Hans Haindl

10 "AFS, French Association for Hospital Sterile Supply" - J-M Kaiser

Concluding this presentation, the AFS declared not to be favourable to the reprocessing of medical devices when their reuse is not initially planed when designing them.

On the other hand, according to **EAMDR** viewpoint[11], countries with reprocessing regulations irrespective of devices declaration as single-use or multiple-use have an experience of:

- Higher patient safety;
- Increased cost effectiveness;
- Environmental advantages.

Vanguard[12] pointed out that public health risks may be given by complex construction, missing validation and insufficient reprocessing technology and not by marking as a single use device.

3.2. Legal aspects of the reprocessing practices

Dr Callens[13] presented his viewpoint on legal issues regarding the reprocessing of medical devices such as issues related to competition law, liability, patient rights (informed consent), processing of personal data, pricing and reimbursement.

3.3. Economic aspects of the reprocessing practice

A presentation was made by **D. Larmuseau**[14] on the results of an economic study regarding the impact of reprocessing of single-use medical devices in Belgium.

The main conclusion of this study was that there was no significant difference between the mean purchase price of single-use medical devices and the cost of reprocessed medical devices according state-of-the-art and validated practices for reprocessing

On the opposite, Vanguard [15] pointed out that, especially for highly complex medical devices, an economic benefit is given. Also according to this industry, thanks to reprocessing, innovative medical technology can applied to a broader range of patients

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[11] Nikou Ghassemieh - Managing Director EAMDR

[12] Dr. rer. nat. Dipl.-Ing. Kerstin Klosz – Vanguard - Head of Quality Management & Regulatory Affairs

[13] "Legal and ethical aspects of reprocessing single-use medical devices" - S. Callens

[14] "Economic study on the impact of reprocessing of single-use medical devices in Belgium - David Larmuseau - Erasmus MC University Medical Center - Institute for Medical Technology Assessment - Rotterdam, The Netherlands

[15] Dr. rer. nat. Dipl.-Ing. Kerstin Klosz – Vanguard - Head of Quality Management & Regulatory Affairs

(according to EAMDR in Germany: ~70% of electrophysiological interventions in university clinics are performed with reprocessed medical devices).

According to the EAMDR[16], reprocessing increases the economic efficiency of health care institutions significantly. Reprocessing can save up to 50% of the costs in comparison to new medical devices.
Eucomed pointed out that those cost savings do not include costs related to complications arising due to usage of refurbished single use devices and are based on quality criteria developed by an economic operator e.g. the refurbisher.

EAMDR added that a widespread use of controlled reprocessing motivates manufacturers to:

- Provide more reprocessable medical devices;
- Cooperate with reprocessors;
- Improve the quality of medical devices.

3.4. Environmental aspects of the reprocessing practice

Vanguard[17] pointed out that final cleaning and sterilization are the last steps of every manufacturing process. In their view, especially for highly complex medical devices, reprocessing may have an environmental benefit, if the amount of transport has not too big environmental impact.

Vanguard clarified that the majority of products are manufactured in clean rooms ensuring the cleanliness of products after assembly. A cleaning process is typically not performed due to the difficulty and often impossibility to remove cleaning solutions from complex devices.

It was also pointed out that the environmental impact of reprocessing should also be looked at transport, use of detergents and other cleaning agents, use of energy, etc.

According to EAMDR[18] reprocessing of so called "single-use" medical devices contributes substantially to the protection of the environment: since waste is reduced, resources for producing new medical devices are saved and the amount of environmentally harmful materials (*e.g.* PVC) is reduced. EAMDR pointed out that ecological balance sheet could be a useful instrument to enable ecological assessments but, according to them, manufacturers do not provide data about the use of resources for the production of single-use medical devices.

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16 Nikou Ghassemieh - Managing Director EAMDR

17 Dr. rer. nat. Dipl.-Ing. Kerstin Klosz – Vanguard - Head of Quality Management & Regulatory Affairs

18 Nikou Ghassemieh - Managing Director EAMDR

Eucomed did not share the view of EAMDR that manufacturers refuse to deliver data on environmental aspects. They agree that manufacturers find it difficult to provide data to individual refurbishers or single company trade associations

Both EAMDR and the medical devices manufacturers association confirmed their interest in cooperating with the European Commission should it decide to launch an independent study on the environmental impact of manufacturing and reprocessing medical devices.

Taking into account all aspects of the reprocessing practice and in the light of the information already available the Commission services are currently assessing the need for such a study and its feasibility.