

## MEMORANDUM ON LEGAL ASPECTS OF REPROCESSING AND REUSE OF SINGLE USE DEVICES AS WELL AS OUTSOURCING OF REPROCESSING IN BELGIUM

### **1. The reprocessing of single use devices is not prohibited in Belgium**

A medicinal product may only be placed on the market and/or put into service if it complies with requirements laid down in the annexe to the Royal Decree of 18 March 1999 on medical devices when used in accordance with its intended purpose.

The re-processing of single use devices by hospitals or independent subcontractors is not forbidden by the Royal Decree. The Pharmaceutical Inspection is of the opinion that not all aspects of reuse of single use and multiple use medical devices is regulated by the Belgian Royal Decree of 18 March 1999. Only a few articles of the Royal Decree do refer to the issue of reuse. Point 13.6 h of annexe I of the Royal Decree stipulates that if a medical device is declared as reusable by the manufacturer, information on the appropriate processes to allow reuse, including cleaning, disinfection, and packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses is needed. Point 13.6., g) of the same annexe states that the instructions for use must contain the necessary instructions in the event of damage to the sterile packaging and the methods of re-sterilization.

It is obvious that the reprocessing and reuse should be done in good circumstances that meet high quality levels in order to avoid safety risks (see *infra*).

According to a report of 2003 of the European Parliament, the Medical Devices Directive does not regulate the reuse of medical devices. The Directive regulates only the market placement of a new product and the use of a product. Moreover the Parliament invites member states to conduct research on the reuse of single use devices.

The fact that no full regulation in Belgium is provided for reprocessing and reuse of single use medical devices does not mean that the reuse is not allowed.

### **2. Liability of manufacturer vis-à-vis liability of hospital**

An original manufacturer usually retains responsibility only for the safety and performance of their device, within its stated intended purpose and labelling parameters. The manufacturer is primarily liable for the first use of so-called single use devices. The risk of reuse lies primarily with the reuser.

Nevertheless, some Belgian scholars and some recent case law suggest already that the manufacturer has to anticipate reasonable misuse. If a manufacturer knows that their product is used for years contrary to the notices, this would not be qualified as unforeseeable use.

Some are arguing that the re-processor of a single use device against the instructions of the original manufacturer is likely to be regarded as a manufacturer. However, it seems clear that if reprocessing is conducted within a hospital or by a subcontractor of a hospital where ownership of the device remains with the hospital, reprocessing occurs without the device being placed on the market and the reprocessor is not regarded as a manufacturer. This conclusion will not give rise to an imbalance of safety controls between industry and hospitals or re-processors, since hospital and re-processor may have to adhere to specific norms for careful conduct. These norms may imply e.g. :

- appropriate validated and documented processes,
- tracability of products
- implementing of a quality management system
- a certificate according to the standards, such as EN ISO 13485:2003,
- use of qualified personnel
- use of the premises that are appropriate (concerning storage, size, security, equipment, facilities for the reprocessing, in particular regarding the necessary apparatus, and working appliance

According to art. 17novies of the law on hospitals, the hospital and not the pharmacist is in principle liable (on a civil level) if the pharmacist has not complied with the right to quality of care of a patient. It may be mentioned that one should verify whether hospital insurance companies does not regard a hospital internal reprocessing of single use medical device as a higher risk, that has to be dealt with.

### **3. Outsourcing of reprocessing is not prohibited**

Neither the Hospital law nor the Royal Decrees executing the Hospital law prohibit the subcontractor of a hospital to reprocess a device. The Royal Decree of 4th March 1991 on the norms to be fulfilled by hospital pharmacies does not contain a specific prohibition of reprocessing of medical devices by a subcontractor of the hospital. The Royal Decree regulates only the authorization of the pharmacy in view of public financing. Therefore, it is not because the Royal Decree does not provide for specific rules regarding the reprocessing of medical devices outside the hospital that such a practise would be illegal. Article 12 of the Royal Decree of 4th March 1991 regulates e.g. only the tasks of the hospital pharmacist with regard to the central sterilisation.

The physician responsible for hospital hygiene and the committee for hospital hygiene are taking care of the control of techniques for sterilisation. Sterilisation outside of the hospital is not regulated and therefore is not forbidden.

It is important that even if reprocessing is done outside the hospital, the pharmacists guarantee the storage of sterile devices.

#### **4. Tasks of the pharmacist and liability vis-à-vis liability of hospital**

The pharmacist is usually an employee. In the case of civil liability the employer, i.e. the hospital, and not the employee, will usually have to cover damages in the case of a liability. Moreover, according to art. 17novies of the law on hospitals, the hospital is, in principle, responsible for non-compliance by a hospital pharmacist of the right to quality of care of a patient (see above). An employee, like a pharmacist or a nurse may be held penally liable in case of proof of gross negligence, a criminal offence or misdemeanour – Again, the act of reprocessing as such is not forbidden, and therefore can not automatically be considered as a criminal offence.

#### **5. Inspection**

The Pharmaceutical inspection is competent to check among other things the sterile devices that come into contact with the patient. With regard to the compliance with the Royal Decree of 4th March 1991, the Flemish Ministry is competent to audit the hospital pharmacy. The minister may prohibit after an inspection reprocessing. It is important that facilities that reprocesses single use device should have a documented validated process and have a quality management system according EN ISO 13485/2003 installed, which is certified.

#### **6. Liability and products**

With regard to the use of devices in treating patients and liability under contract law, jurisprudence is willing to accept strict liability. By consequence, the hospital will be held liable if it did not use safe products. Therefore, careful reprocessing of single use devices should meet very high quality levels.

Moreover, under the product liability law a manufacturer or, where the manufacturer cannot be identified, the supplier of a product will be liable for a defective product which does not have the level of safety to be expected of it by persons in general. That is to say by reprocessing of single use medical device the pharmacist in the hospital (and/or the hospital) takes responsibility or also the third party, if the reprocessing is carried out by a third party.

#### **7. Informed consent**

Patients have the right to possess all the information needed to obtain a clear view of their health status. Moreover, the patient has the right to give informed consent for each intervention of the health professional. The information that has to be given to the

patient with a view to obtaining their consent is related to the aim, nature, urgency, duration, risks of an intervention, possible alternatives etc. Other information that is being considered as relevant by patient or health professional, including the legal rules that have to be complied with related to the intervention, have to be communicated. It is not certain that the information on the reprocessing of single use devices can be considered as information related to the intervention of the physician. Moreover, the consent of a patient can be implied if, after the patient has been sufficiently informed, one may deduce the consent from the behaviour of the patient. A more specific informed consent is required, if the patient is put to a higher risk. Express consent for reprocessing will not be necessary under Belgian law provided that the re-processing is carried out in a very safe way.

### **8. Towards new legislation**

It should be encouraged that reprocessing of medical devices intended for single use meets a very high level of quality in order to protect the health and safety of patients and health care workers. A hospital that uses a subcontractor should verify these quality assurances as well as the insurance position of the sub-contractors, vis-à-vis strict liability. Specific legal standards on how to proceed with reprocessing might be needed to obtain a high level of quality of care.

Brussels, 24 June 2005  
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