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Reprocessing of single-use medical devices - a legislative issue of the EU countries

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ABSTRACT
Due to economical aspects, reprocessing single-use medical devices have been practiced by hospitals and companies raising important issues, mainly concerning to health safety of patients and legislative situation. This paper seeks to assay the situation of reprocessing single-use medical devices in Portugal and the Europe Union, the legislations and the main problems of this practice.

Keywords: reprocessing, medical devices, single-use, standards, legislation

1. INTRODUCTION
Medical Devices (MD) were initially intended to be reusable, this was favoured by their design, size and shape, and the materials that they were made of were resistant to sterilization. For this reason, upon the implement of single-use devices, these were labelled with the designation "single use". In addition, with the technology evolution, medical devices begin to turn more complex and sophisticate, with specific characteristics and properties. These devices with polymeric compounds aren't resistant to physical and chemical aggressive treatments neither to high temperatures and, hence, not resistant to sterilization processes. Also, new devices to mini-invasive procedures were developed with narrower diameters and more intricate and delicate mechanisms. These devices are difficult to clean or sterilize properly, and it is impossible for the manufacturer demonstrate its safety reuse. For these reasons, some devices are labelled with the designation "single use". The use of single-use medical devices (SUMD) has considerably increased in hospitals in particular to reduce the risks of cross contamination between patients. Definition and classification of single-use medical devices emerge in Council Directive 93/42/EC concerning to medical devices, adopted on 14 June 1993 and amended by Directive 2007/47/EC as "a device intended to be used once only for a single patient". However, in the last few years, hospitals have been faced with financial changes resulting in the need to reduce costs. In response, many hospital entities have to explore the reprocessing and reuse of single-use products. Council Directive 93/42/EEC amended by Directive 2007/47/EC not defines reprocessing but impose the need to ensure that the reprocessing of medical devices does not constitute a danger to the safety or health of patients by clarifying the definition of "single use" and the establishment of labeling and instructions for use uniformly. In concerning to reusable devices the Council Directive only refers "if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection and packaging and, if applied, the method of sterilization of the device to be re-sterilized and any restriction on the number of reuses". The reprocessing of medical devices raised issues related to patient safety and ethics. In this way, the aim of this paper is to raise awareness of the problems related to the reprocessing of medical devices and the EU and, specifically, Portugal position regarding this issue.

2. REPROCESSING OF SINGLE-USE MEDICAL DEVICES
Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EC concerning to medical devices establishes the laws that all countries of Europe Union (EU) have to follow in respect to conception, manufacturing, commercialization and entry into service. Each country transposes the Directive to national legislation. Reprocessing of single-use medical devices has been practiced for by different health institutions, and it has received special attention of the Competent Authorities of each European country. The reprocessing practice of single-use medical devices is not regulated by the Community level for the time being and different national legislations regulate this practice throughout Europe. Few countries allow the practice and have developed guidelines, some countries prohibited it and the majority of Member States do not have any specific regulation on this aspect (European Commission, 2010). So, the position concerning to reprocessing single-use medical devices is at legislative level of each country of EU (Table I).

The use of reprocessed SUMD can be an increased risk to the patient when compared to the use of a new single-use device. Therefore, it is important to take into consideration the issue of information to the patient and their prior informed consent before being subjected to the medical procedure, involving this kind of devices. Reprocessing SUMD raises ethical issues in terms of potential inequalities between patients. In concerns to legal responsibility, it is necessary to clarify the responsibilities of each intervenient and inform health professionals in case of using reprocessed medical devices.

Reprocessing should be performed according to the instructions provided by the manufacturer and must follow technical specifications that ensure the conformity of the device at the time of its use towards the essential requirements of the apply Directive (INFARMED, 2008). It rises a difficult situation that single-use medical devices manufacturer instructions don't inform about the reprocessing procedures, once that it's an only once single use product.
2.1. Problems involving reprocessing and reuse of single-use medical devices

Once single-use medical devices are designed to be used only once, any reprocessing may damage or alter it to the extent of making it unsafe to reuse. Reuse them involve some problems related to infections, inability to clean and decontaminate, residues from chemical decontamination products, material alteration and mechanical failure, and reactions to endotoxins.

A satisfactory clean process for medical devices must be able to access all parts of the device. If it is not possible, the cleanliness is compromised and the risk of cross-infection may increase due to the inability of the reprocessing system to remove completely the viable micro-organisms. For example, endotoxin, cell-associated Gram-negative bacteria, once in the device cannot be removed by cleaning or inactivated by sterilization, even when these two processes are effective in killing bacteria. Another problem related with cleanliness and sterilization is the chemical products used. Some type of materials can absorb or adsorb certain chemical agents and, in this way, devices performance can be compromised and increasing the patient risk of being in contact with malefic chemical agents. These chemical agents can cause corrosion and change the material, causing degradation. This leads to mechanical failure, direct contact of the patient with corrosion and degradation products (MHRA, 2011; INFARMED 2010).

On the other hand, reprocess and reuse of SUMD can reduce the costs of the health entity, by reducing the price of products since a reprocessed medical device is 50% cheaper than a new one; costs related to primary and secondary packaging, and informative brochures leading to decrease of hospital residues volume and better management of environmental resources; and mainly avoid non controlled and non-quality reprocessing (Neves, 2008).

2.2. Reprocessing single-use medical devices in Portugal

In Portugal, reprocessing single-use medical devices is covered by national law Despacho n° 7021/2013, of 24 May 2013, and must be completed the following requirements:

- Ensure traceability of MD since the first available on the market, while SUMD, to their use as reprocessed SUMD;
- Ensure the requirements on labeling, in order to avoid potential mistaken with no reprocessed devices;
- Can only be reprocessed the SUMD available and used in accordance with Decreto-Lei n° 145/2007, of 17 June 2007;
- The reprocessed devices can only be used in service or Health National Service establishment (Serviço Nacional de Saúde, SNS) responsible for reprocessing;
- The reprocessed device cannot be marketed in any form neither bear the 'CE' marking and associated information;
- Information that it is a reprocessed single use medical device and the number of reprocessing cycles already performed are mandatory;
- The endorsement must appear on the reprocessed device itself, when this is not possible, on its primary packaging and any other level packaging.

3. FINAL REMARKS

Reprocessing and reuse of single-use medical devices raises questions about the safety, quality and correct performances of the product which in turn are leading to questions concerning ethical aspects.

Health system is challenged to find equilibrium between patient rights and the society goal to give health cost-benefit for everyone. Nowadays, legislation in the EU countries concerning to SUMD reprocessing is different from member state to member state. In Portugal, reprocessing of SUMD is accepted if the quality and security are maintained.

4. ACKNOWLEDGMENTS

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5. REFERENCES


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