Economic and Environmental Impact from Reprocessing Single-Use Products in Spanish Hospitals

(Introduction & Conclusion, Translated from Impacto Económico y Medioambiental Del Reprocesamiento De Productos De Un Solo Uso En Hospitales Españoles)

V Course Project Management

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Coordinator: Alvaro Sáenz de Viteri Bello

AUTHORS:

Juan Carlos Alonso Punter Susana Alvarez Gómez Manuel Carmona Adrados Paloma Casado Durández Celia García Menéndez Aurora González Manso Emilio Rodríguez Pérez Martín Ruiz Grinspan

Introduction

Increasing health expenditures are partly due to population growth, but also, without doubt, to the introduction of new technologies. Among them, new medical devices (MDs). This is the case for single use devices (SUDs), which are not allowed to be reprocessed in Spain, and in certain other countries, which heavily impacts spending growth. Suffice to say, the economic impact that is addressed in SUD EUCOMED Report 20071, indicates that SUDs account for 31% of health spending considering the overall spending on medical devices.

Thus, in an environment of economic crisis like the present, it is necessary to adapt to the new and certain rules issued in another setting, always under the criteria of sustainability, efficiency, ethics and respect for the environment.

One should remember the definition of "single-use product" (SUD) as a product intended to be used once for a single patient. Also for reprocessing of a medical device, it means a series of procedures that allow for further use of the device for a new patient. These procedures include routine maintenance, disassembly, cleaning, disinfection, marking, test functionality, packaging, labeling, sterilization, and warranty traceability.

For regulatory purposes, we distinguish between the reprocessing of reusable medical devices, that is, those medical devices under strict quality control and validated and mandatory compliance processes indicating that the devices can be reprocessed a certain number of times,

and the SUD, the latter object of this work, in which the manufacturer defined as a single use product and that which is not reprocessable. (Table 1).

Table 1

| Not Reprocessable | Reprocessable | |
|------------------------------|--------------------------------|---------------------------------|
| Single-Use Devices | Reusables (with limitations) | Reusable Products |
| Reprocessing isn't possible | Reprocessing is possible for a | Reprocessing is not anticipated |
| Reprocessing isn't permitted | determined number times using | to involve difficulties. |
| | specific technologies with | Validation processes are |
| | strict quality control and | followed. |
| | validation processes required. | |
| Categorized as "Single-use" | | Categorized as "Reusable" |

Author: Vicente Dominguez

Undoubtedly, reusable medical devices must include in their instructions the recommended procedures for correct reprocessing, so as to ensure the absence of infections, pyrogenic reactions, allergic reactions, toxic reactions or alterations of the technical and functional properties of the product.

Moreover, certain SUDs, such as needles, catheters or angioplasty neurostimulators, are not theoretically intended or designed to withstand reprocessing. The manufacturer needs to provide instruction and validation processes to allow safe reprocessing of the product, unlike with the reusable product, but only information on the characteristics or technical factors that could present a risk if the product is reused.

Conclusions

- In view of our results, we can conclude that the reprocessing of certain SUD products is an effective way to generate savings and lower environmental impact. If legislation allows reprocessing, it would be desirable to have system alerts in case of complications.
- It is pertinent to propose to the Ministry the necessary updating of legislation in similar terms to the countries of the European Union that have legislated reprocessing.
- We are inclined to support that the manufacturer itself reprocesses directly or through outsourcing reprocessing companies to ensure the viability of SUDs before being put on the market.
- We understand that reprocessing should guarantee at all times traceability of the product.