INTER-ACADEMIC OPINION –

REPROCESSING OF SINGLE-USE MEDICAL DEVICES FOR REUSE

Tri-academy working group - November 7, 2023

The three French National Academies of Medicine, Pharmacy and Surgery have taken the initiative of a common, objective, and neutral reflection on the reprocessing of single-use medical devices (SUMDs) for re-use.

Reprocessing of medical devices (MDs) is a process that enables a used device to be reused safely.

European Regulation 2017/745 of April 5, 2017 on MDs (MDR) sets out a highly restrictive regulatory, technical and safety framework. However, it leaves Member States the opportunity to authorize or not the reprocessing of some SUMDs by complying with the regulation 2020/1207 of August 19, 2020. Six (6) Member States currently authorize reprocessing, but fifteen (15), including France, have banned it for a very long time.

Supporters of reprocessing have expressed themselves widely, with arguments of an ecological, economic or supply nature in particular, but so far there has been no change of mind on the part of the French public authorities.

The long-standing arguments in favor of this practice have yet to be validated. That's why our three Academies have held a series of hearings* to shed light on the debate. It appears that none of the interested parties interviewed is opposed in principle to the reprocessing of SUMDs, provided that the benefits are demonstrated and the regulatory, technical and safety framework is scrupulously respected.

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Thus, the three Academies are very much in favor of the European survey aimed at assessing the experience acquired by the countries which currently authorize or not the reprocessing of SUMDs, by not contenting themselves with the simple assertion that "it is done elsewhere".

Similarly, the three Academies welcome the announcement by the French public authorities in May 2023 that, as soon as 2024, as part of the "Ecological planning of the healthcare

system" roadmap, they would conduct an experiment on the "feasibility of reprocessing SUMDs, in order to identify the legal framework and practices that would guarantee the safety of care".

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In France, the launch of this experiment is included in the Social Security Financing Bill (PLFSS) for 2024; the precise conditions remain to be defined. With this in mind, the three Academies are drawing attention to the following points in view of the parliamentary debate and beyond.

Eligibility of SUMs for reprocessing / characteristics

Not all SUMDs can potentially be reprocessed, notably for reasons of safety, technical feasibility (possibilities of pre-treatment, cleaning, sterilization, or performance maintenance) and financial profitability, either for the healthcare system or the manufacturer.

Indeed, reprocessing itself has a cost, both financial (technical installation, labor, operation) and environmental (transport, energy) - see below.

Ultimately, therefore, it is the manufacturer (industrial or healthcare establishment) that selects the SUMDs that it can or wants to reprocess. It should not be forgotten that nothing is possible without reprocessing services.

For all these reasons, the field of SUMDs likely to be reprocessed will have to be determined at the end of the experiment.

Technical capacity for reprocessing

Reprocessing requires production units with appropriate resources: premises, specific equipment (cleaning, sterilization, packaging, controls with ad hoc analytical resources) and a trained and competent staff. An expensive investment may be therefore a necessary prerequisite.

In the current situation, only industrial-type units seem able of processing the most complex SUMDs.

While the use of hospital capacities should not be renounced as a matter of principle, they do not appear sufficient on a large scale at this stage. But perhaps would they be sufficient in a specific context (health crisis, shortage, simple MD or ancillary MD). The experience of laryngoscope blades during the health crisis may serve as an example.

Reprocessing circuit

If we first exclude production within a healthcare establishment, there are two possible channels:
- Open: the manufacturer acquires used SUMDs from healthcare establishments, reprocesses them, and then offers them on the European market under its own name after CE marking;

- Closed: a given establishment has its own used SUMDs reprocessed by an industrial service provider, who returns them to the establishment after reprocessing, then regulatory constraints are less stringent. The operator is not obliged to follow a CE marking procedure for the reprocessed medical devices since they are not put back on the general market, but it must comply with technical and safety constraints, published in the form of European technical specifications, like those imposed for CE marking (cf. the implementing regulation mentioned above).

During the trial, the practical feasibility and benefits of this second circuit should be assessed, and not limited to the simple purchase of the reprocessed SUMDs.

Determining the responsibilities of each player

This is a key element: **the responsibility of each actor must be very clearly defined**, whether in terms of the quality and safety of the process, the traceability or general information for users and patients in particular.

Ecological impact

The ecological argument is very important and must obviously be taken into account, but it must be properly assessed.

For example, the reprocessing process itself has ecological consequences: transport (particularly in the case of open circuits), energy, production of packaging and waste, etc.

Indicators must therefore be defined, for both charge and discharge (life cycle analysis, carbon footprint, eco-toxicity, etc.).

Impact on supply disruptions and sovereignty

It has not been established whether some SUMDs currently reprocessed and used abroad (e.g., electrophysiology catheters) are the ones that pose the most supply problems in France.

Furthermore, the issue could be reconsidered in the event of a health, geopolitical or climatic crisis, even a temporary one. We therefore need to take a forward-looking view.

Medico-economic impact

While the announced price level for reprocessed SUMDs seems attractive, the overall cost to the French healthcare system will need to be assessed.
Similarly, an industrial production unit in France is only feasible if a genuine market is created.

Other issues to be explored in parallel

The debate on reprocessing should lead to other issues, such as the more frequent use of reusable medical devices (designed for this purpose) and changes in practices.

In conclusion, the three Academies recommend a rigorous, objective and exhaustive national assessment of the possibilities offered by European regulations.

Safety and ethical impact

Reprocessing of SUMDs is in itself a risky process. All precautions must be taken to ensure the safety of patients and healthcare professionals, and above all, the quality of the entire process itself and its traceability (appropriate material vigilance, etc.). All this while ensuring the same performance and clinical benefits of the reprocessed SUMD.

Acceptability of reprocessing
Acceptability by patients (particularly for pediatric and geriatric use), national representatives and public authorities will only be achieved if the system offers all guarantees of safety, with the utmost transparency. Trust is a key factor.

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In conclusion, the three Academies recommend a rigorous, objective, and exhaustive national assessment of the possibilities offered by European regulations.

The three Academies are at the disposal of all interested parties

Contact :
Jacques CATON (AnM et AnC) – *caton.jacques@orange.fr*
Pierre-Yves CHAMBRIN (AnP) – *pierre-yves.chambrin@aphp.fr*

**Public authorities: ANSM, DGS; learned societies: Collectif EcoResponsabilité en Santé (Ceres), Euro-Pharmat, Sté française d'hygiène hospitalière (SF2H), Sté française de Cardiologie; patients: France Assos Santé; manufacturers: SNITEM, Apperton/Vanguard; interest group: Club des acheteurs en produits de santé/Hospices civils de Lyon (CLAPS/HCL).*