INTER-ACADEMIC OPINION (summary)

REPROCESSING OF SINGLE-USE MEDICAL DEVICES FOR REUSE

Tri-academic working group – November 7, 2023

INTRODUCTION: The three French National Academies of Medicine, Pharmacy and Surgery have taken the initiative of a joint reflection on the issue of reprocessing single-use medical devices (SUMDs) for re-use under safe conditions. European regulation 2017/745/EU (RDM or MDR) leaves it up to member states the opportunity whether or not to authorize the reprocessing of some SUMDs (implementing regulation 2020/2017 of 08/19/2020). To date, 6 states authorize it and 15 bane it, including France. The arguments in favor of reprocessing are of an **ecological, economic or supply** nature. The three Academies are very favorable to the European investigation intended to take advantage of the experience acquired and welcome the announcement by the French public authorities in May 2023 to also carry out a 2-year experiment on this subject as part of "ecological planning of the healthcare system" reinforced by the announcement by the Council of Ministers of the 09/27/2023 on the occasion of the PLFSS 2024 (art 29)

EXPLANATORY MEMORANDUM: With this in mind, after ten hearings, the three Academies draw attention to the following points in view of the parliamentary discussion and beyond:

- Eligibility of SUMDs for reprocessing / what scope? Not all of them can be reprocessed, and it is ultimately up to the manufacturer (industrial or healthcare establishments) to selects those likely to be reprocessed.

- **Technical capacity to reprocess**: Suitable means are necessary.

- **Reprocessing circuit**. Two channels are possible: - **open**: the manufacturer acquires used SUMDs, reprocesses them and then offers them on the market after CE marking (according to the RDM/MDR). **- closed**: the healthcare establishment has its own used SUMDs reprocessed by an industrial service provider (CE marking is not necessary) while respecting the same constraints.

- Determination of the responsibility of each: These must be clearly defined in terms of quality, safety, traceability and information for users and patients.

- Ecological impact: This argument is very important, and its positive or negative indicators need to be precisely defined.

- Impact on supply disruptions and sovereignty: The issue is not urgent in France, but will have to be reconsidered in the event of a health, geopolitical or climatic crisis.
- Medical-economic impact: As the price level of reprocessed SUMDs seems attractive, their production is only possible if a market exists.
- Other questions to be addressed in parallel: For example, the more frequent use of reusable medical devices designed for this purpose, the problem of waste recovery (rare metals, etc.) as well as the relevance of the "single use" qualification of some medical devices by the manufacturer.
- Safety and ethical impact, and acceptability of reprocessing: All precautions must be taken, patients must be informed with the greatest transparency.

RECOMMENDATIONS

1) The three Academies recommend a rigorous, objective, and exhaustive national assessment of the possibilities offered by the European regulations.
2) The three Academies are at the disposal of all interested parties for any comments or proposals on an ecological, economic or supply level.