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Reprocessing of Single-Use Medical Devices in the Context of the Ecological Transition of the Healthcare System

Report

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N°2023-085R

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SUMMARY

The reprocessing of single-use medical devices (SUDs), as authorized under Article 66 of the 2024 Social Security Financing Act (LFSS), will be piloted through a two-year experimental program beginning this year. This measure is part of the "Ecological Transition Roadmap for the Healthcare System," published in May 2023. The General Inspectorate of Social Affairs (IGAS) and the General Inspectorate for the Environment and Sustainable Development (IGEDD) were tasked with preparing the implementation of this pilot.

SUD reprocessing—defined as the safe reuse of devices following sterilization and refurbishment—has been banned in France since the 1980s. Although EU Regulation 2017/745 provides a framework for such reprocessing, France reaffirmed its ban in 2022, in contrast to nine other member states that allow the practice. Consequently, no domestic reprocessing industry currently exists. Yet, under the 2024 LFSS, reprocessing must be performed for four healthcare facilities by an external company. Given the required investments—particularly for obtaining CE marking of reprocessed devices—it is unlikely that a domestic industry will emerge within two years. A viable sector can only develop if public authorities clearly support SUD reprocessing.

The German company Vanguard is currently the only viable candidate to conduct this pilot. It operates three reprocessing facilities in Germany, serving both domestic and international clients. German health authorities do not closely monitor SUD reprocessing, and no safety alerts have been raised regarding these practices. As of now, the European Commission has no data on the volume or types of reprocessed devices, pending an evaluation report expected in May 2024.

The scope of the pilot will depend on Vanguard's product catalog. Of the 600 items it reprocesses—98% of which are electrophysiology devices (especially diagnostic and ablation catheters)—only 74 hold CE marking and are currently used by French university hospitals (CHUs). The mission recommends excluding any device that lacks CE marking, even if used in France, as it would not meet external quality assurance standards.

Two reprocessing models are under consideration for the pilot. An **"open-loop"** model where the healthcare facility sells used SUDs for reprocessing and purchases reprocessed devices in return. A **"closed-loop"** model where the facility outsources reprocessing of its own devices. Provided there are no exclusivity clauses in existing procurement contracts—or if such contracts can be amended—the mission recommends the open-loop model. This approach maximizes cost savings (up to 60% of annual catheter acquisition costs) and offers greater flexibility in inventory management.

Multiple criteria can guide the selection of the four pilot facilities. Selected hospitals should perform a sufficiently high volume of electrophysiology procedures to interest the reprocessing firm. It would also be beneficial to include a mix of institutions by size and

governance type. Most importantly, the involvement of all key stakeholders—electrophysiologists, nurses, pharmacists—must be secured within a broader strategy to reduce the environmental impact of medical devices.

Logistically, reprocessing—including the traceability of SUDs—should impose only a modest workload on participating facilities. Vanguard will handle transportation to and from its sites. Used SUDs must be cleaned beforehand. The mission recommends that the French Society for Hospital Hygiene (SF2H) develop a SUDs cleaning protocol that aligns with national standards, the company's requirements, and environmental waste regulations.

The mandatory patient information, required under Article 66 of the LFSS for 2024, is a key consideration. To avoid disrupting the pilot, the mission suggests creating a national patient information document—developed with patient advocacy groups—emphasizing both the absence of health risks and the environmental benefits. Unlike clinical trials, an opt-out system should be adopted, whereby patients must explicitly object to the use of a reprocessed SUD. This objection would be documented by the participating hospital in the trial.

While the mission affirms the environmental value of SUD reprocessing, it recommends objectively evaluating this approach alongside other decarbonization strategies for medical devices. Preliminary studies suggest reprocessing can reduce environmental impact, but the pilot's final assessment must confirm this benefit. To that end, an expert in Life Cycle Assessment (LCA) should be contracted early in the process. This pilot should not overshadow other avenues for decarbonizing SUDs, some of which are highlighted in the ecological roadmap. Following the United-Kindom's "Greener NHS" strategy, hospital procurement could play a greater role—encouraging manufacturers to design greener products and to supply multiple-use medical devices (MUMDs).

Finally, the resources and governance structure supporting France's healthcare ecological transition warrant re-examination. With only 0.5 full-time equivalent staff dedicated to ecological transition at the Ministry of Health, and despite increased involvement from the National Agency for Health and Social Care Performance (Anap), the roadmap remains primarily driven at the ministerial level. Hospitals are engaging independently and without significant incentives. A lack of technical support and guidance hinders the broader adoption of promising practices. Greater involvement from environmental transition agencies would help prioritize actions within the framework of France's cross-ministerial "Green Nation" strategy.