2021-03-18

Legislation on reprocessing of single-use devices

Tomas Byström

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

1

At first:

The fact that the Swedish MPA is giving this talk on the legal provisions **is not** a **prognosis** on whether reprocessing will be allowed in Sweden, or **any indication on the position** of the Swedish MPA on the subject.

2

Relevant legislation

- MDR: Article 17 – Single-use devices and their reprocessing
  EUR-Lex - 02017R0745-20200424 - EN - EUR-Lex (europa.eu)
- Implementing Regulation 2020/1207 – Common specifications for the reprocessing of single-use devices
  EUR-Lex - 32020R1207 - EN - EUR-Lex (europa.eu)

The foundation

- Article17.1 in MDR: *Reprocessing and further use of single-use devices* ***may only take place where permitted by national law*** *and* ***only in accordance with this Article***
- At the the time of speaking, reprocessing and further use of single-use devices **is not permitted** by Swedish legislation
- There are no provisions for reprocessing and further use by any other conditions than article 17 (and what follows from the article)
- No transitional provisions – reprocessing and further use from the 26 May 2021...
  - ...is prohibited until permitted by Swedish legislation
  - ...shall be performed according to the provisions in MDR in case it is permitted

Article 17 in brief

- Anyone that reprocesses a single-use device shall be considered as the manufacturer of the reprocessed device and shall be subject to the requirements on manufacturers laid down in MDR (Article 17.2)
- **Health institutions** that perform reprocessing of single-use devices and subsequently use them within the institution **may be subject to derogations** from the requirements on manufacturers. This is subject to a number of conditions, most notably that the **Common Specifications shall be met**. Decided by the member state. (Article 17.3)
- **External reprocessors that work at the request of a health institution may also be subject to derogations** on the same terms as the health institution itself. Decided by the member state. (Article 17.4)
- The EU-commission shall adopt common specifications that address the application of the the general requirements on safety and performance on the reprocessing of single-use devices by . (Article 17.5)
- **The reprocessor's compliance with the common specifications shall be certified by a notified body. (Article 17.5)**

Highlight: Two types of reprocessors

- Article 17.2: Any natural or legal person that reprocess a single-user device and places it on the union market as any new device
  - Subject to the requirements of any manufacturer according to the MDR
- Article 17.3 and 17.4: Health institutions or external reprocessors that work at the request of a health institution for further use within the health care institutions
  - Subject to the requirements laid down in the common specifications (2020/
- In Sweden, the focus has been on the latter category.
- Reprocessing on 17.2 has not been subject to investigation.

Article 17 in brief, cont'd

- **Only devices that have been lawfully placed on the market may be reprocessed**
  - Prior to 26 May 2021: In conformity with the provisions of the MDD
  - From 26 May 2021: In conformity with the provisions of the MDR (Note! Devices covered by the transitional provisions in article 120 are still placed on the market with support of the MDR)
- *Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.* (Article 17.7)
- The **name and address of the reprocessor shall replace** the name and address of the **original manufacturer** of the single-use device. The name and address of the original manufacturer shall be mentioned in the IFU. (Article 17.8)
- **Member states that permit reprocessing may maintain or introduce stricter provisions** than MDR, including the restriction and prohibition of the making available of reprocessed devices. (Article 17.9)
- The EU-commission shall draw up a report on the operation of article 17 by 27 May 2024 and propose amendments to the article, if appropriate. (Article 17.10)

Common specifications – Introduction

- Only applicable for health institutions or external reprocessors that work at the request of a health institution (article 17.3 and 17.4)
- Five chapters – dealing with the entire process and the measures to follow up reprocessed devices
- More hands-on than the corresponding text in article 10 and annex I in MDR…
- …but not necessarily more lenient
- In short: **You need to think and act as a manufacturer!**

Common specifications – Chapter I

- Chapter I: SUBJECT MATTER AND DEFINITIONS
  1. Subject matter
  2. Definitions

Common specifications – Chapter II ”Before”

- Chapter II: ORGANISATION OF REPROCESSING AND RISK MANAGEMENT
  3. Sub-contractors
  4. Staff, premises and equipment
  5. Preliminary assessment of the suitability of a single-use device for reprocessing
  6. Original intended purpose and monitoring of changes made by the manufacturer of the original single-use device
  7. Determination of reprocessing cycle
  8. Maximum number of reprocessing cycles
  9. Technical documentation

Common specifications – Chapter III ”During”

- Chapter III: PROCEDURES AND STEPS OF THE REPROCESSING CYCLE
  10. Establishment of procedures
  11. Steps of the reprocessing cycle
  12. Pre-treatment at the point of use and transportation
  13. Preparation before cleaning
  14. Cleaning
  15. Thermal disinfection
  16. Chemical disinfection
  17. Drying
  18. Inspection, maintenance, repair and functionality testing
  19. Packaging
  20. Labelling and provision of instructions for use

Common specifications – Chapter IV ”After/Bookeeping”

- Chapter IV: QUALITY MANAGEMENT SYSTEM, ANNUAL AUDIT AND REPORTING OF INCIDENTS
  21. Quality management system
  22. Annual audit
  23. Reporting of incidents

Common specifications – Chapter V ”Bookkeeping”

- Chapter V: TRACEABILITY OF SINGLE-USE DEVICE AND FINAL PROVISIONS
  24. Tracking of reprocessing cycles
  25. Records
  26. Entry into force and application

13