Council of the European Union

Brussels, 5 December 2024
(OR. en)

16624/24

PHARM 167
SAN 699
MI 1014
COMPET 1196

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 November 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2024) 560 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the operation of Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council on single-use devices and their reprocessing

Delegations will find attached document COM(2024) 560 final.

Encl.: COM(2024) 560 final

EUROPEAN
COMMISSION

Brussels, 29.11.2024
COM(2024) 560 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the operation of Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council on single-use devices and their reprocessing

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1 EXECUTIVE SUMMARY

Regulation (EU) 2017/745 on medical devices (MDR), which is applicable since 26 May 2021, aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users. For the first time at EU level, the MDR sets out specific rules on single-use devices (SUDs) and their reprocessing.

This report presents data and information on the implementation of Article 17 of the MDR on single-use devices and their reprocessing. Data and information refer to the period from December 2022 to December 2023 and have been collected, by a dedicated study, from relevant groups of stakeholders in 30 countries (27 EU Member States, Iceland, Liechtenstein and Norway).

Reprocessing and further use of SUDs may only take place where permitted by national law and only in accordance with the provisions set out in Article 17 of the MDR. Currently, only 10 countries allow reprocessing of SUDs while the remaining 20 do not allow it. Most of the countries permitting reprocessing established further restrictions or prohibitions at national level. The non-harmonised and fragmented regulatory framework is a challenge for the affected stakeholders.

Only 6 out of 38 surveyed notified bodies certify reprocessed SUDs or the reprocessing of SUDs. No certificates have been issued so far. A very low number of manufacturers reprocessing SUDs have been identified (less than 10) and only two are active and operate in the EU. The main reason for the limited interest shown by manufacturers seems to be linked to the difficulty in finding a notified body that can certify reprocessed devices. 10 out of 19 surveyed health institutions are not interested in reprocessing SUDs due to the lack of competences and resources.

The main perceived opportunities of reprocessing of SUDs by all stakeholder groups are environmental benefits, possible cost savings and a possible solution for shortages of devices.

The main challenges and obstacles for the implementation of Article 17 of the MDR are the fragmented regulatory landscape for reprocessing of SUDs, the lack of resources and a scarce interest in reprocessing of SUDs from the notified bodies. Possible health risks, liability issues and lack of evidence on the reprocessing are also considered obstacles by competent authorities on medical devices and health institutions.

The market of reprocessing SUDs is very limited and not attractive for notified bodies that are currently mainly focused on the transition of certificates from the former directives on medical devices to the MDR.

The Commission will further assess the operation of the provisions on reprocessing also in the light of new data. If appropriate, the Commission will consider possible options to address any shortcomings.

2 INTRODUCTION

Regulation (EU) 2017/745[1] on medical devices (MDR), which is applicable since 26 May 2021, aims to ensure the smooth functioning of the internal market as regards medical devices, and high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, while fostering innovation and improving the competitiveness of the medical device sector.

Under the MDR, medical devices are divided into four risk classes. Depending on the risk class of the product, a different conformity assessment procedure is required before the product can be placed on the EU market. In case of medium or high-risk classes, notified bodies (NBs) are involved in the conformity assessment process.

For the first time at EU level, the MDR in its Article 17 sets out specific rules on single-use devices (SUDs) and their reprocessing. The MDR defines 'Single-use devices' as devices '*intended to be used on one individual during a single procedure*[2] *and* 'Reprocessing' as '*a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device*'[3] .

Reprocessing and further use of SUDs may only take place where permitted by national law and only in accordance with the requirements laid down in Article 17 of the MDR.

In accordance with Article 17(10) of the MDR, the present report assesses the practical functioning of the provisions on SUDs and their reprocessing and will be submitted to the European Parliament and to the Council[4].

3 STUDY ON THE IMPLEMENTATION OF ARTICLE 17 OF THE MDR

In December 2022, the Commission contracted a "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market"[5], hereinafter referred to as the study.

The study provides data and information on how the provisions established in Article 17 of the MDR have been implemented by the 27 EU Member States, Iceland, Liechtenstein and Norway (hereinafter referred to as the study countries) and on how such provisions operate. Data and information gathered under the study refer to the period from December 2022 to December 2023.

The contractor identified four relevant stakeholder groups: all competent authorities on medical devices (CAs), all notified bodies designed under the MDR (NBs), a sample of reprocessors considered manufacturers of the reprocessed SUD (MFs) and a sample of health institutions reprocessing SUDs (HIs). Data and information were collected through dedicated surveys from each stakeholder group. Surveys were followed up by interviews conducted on a sampling base. All CAs and all NBs replied to the survey, while data and information from MFs and HIs were collected from the sampled stakeholders.

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[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - http://data.europa.eu/eli/reg/2017/745/2023-03-20.

[2] Article 2(8) MDR.

[3] Article 2(39) MDR.

[4] In August 2010, the Commission submitted to the European Parliament and the Council the "Report on the issue of the reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC", which provided the factual basis for the regulation of reprocessing of SUDs in Article 17 MDR - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52010DC0443.

[5] European Commission, European Health and Digital Executive Agency, Windisch, F., Zimmermann, N., Knoll, V. et al., *Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market – Final report*, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2925/210943.

The study is the main source of data and information used for the preparation of the present report, complemented by information provided by Member States to the Commission[6] before May 2024. Information from the study is repeated in this report where useful to clearly describe a topic or a recommendation or a proposal for amendment of the MDR and is clearly referenced.

A dedicated dashboard[7] offers the possibility to get more comprehensive and interactive access to the study results.

4 LEGAL FRAMEWORK ON REPROCESSING OF SUDS

4.1 Article 17 of the MDR

Reprocessing and further use of SUDs may only take place only where permitted by national law and only in accordance with requirements set out in Article 17 to the MDR.

Any natural or legal person who reprocesses a SUD to make it suitable for further use within the Union is considered to be the manufacturer of the reprocessed device and assumes the obligations incumbent on manufacturers laid down in the MDR. Such obligations include those relating to the traceability of the reprocessed device.

As regards SUDs that are reprocessed and used within a health institution, Member States may decide not to apply all the rules relating to manufacturers' obligations laid down in the MDR, provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and it complies with certain requirements of Article 5(5)[8] of the MDR ;
(b) the reprocessing is performed in accordance with the common specifications (CS)[9] detailing the requirements concerning risk management, validation of procedures for the entire process including cleaning steps, product release and performance testing, quality management system, reporting of incidents involving devices that have been reprocessed, and traceability of reprocessed devices.

Member States must encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States may choose to apply the CS also as regards SUDs that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements of the CS.

Compliance with the CS must be certified by a NB, both for health institutions and external reprocessors.

Member States that permit reprocessing of SUDs may maintain or introduce national provisions that are stricter than those laid down in the MDR and which restrict or prohibit, within their territory, certain operational aspects of the reprocessing.

The full text of Article 17 of the MDR states the following:

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[6] Among others, notifications of Member States on how Article 17 MDR has been implemented at national level.
[7] https://app.powerbi.com/view?r=eyJrIjoiODQxYjQ4ZDItZTUwYi00ZjkxLTk4YzctYWQ0MzZmMWRkNzhjIiwidCI6ImIyNGM4YjA2LTUyMmMtNDZmZS05MDgwLTcwOTI2ZjhkZGRiMSIsImMiOjh9.
[8] Article 5(5) MDR sets out conditions to be met, such as, the device cannot be transferred to another legal entity, the device use occurs under appropriate quality management system, the health institutions draw up appropriate technical documentation and review experience gained from the use of the device.
[9] Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices (OJ L 273, 20.8.2020, p. 3) - http://data.europa.eu/eli/reg_impl/2020/1207/oj.

"1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:

- *risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,*
- *the validation of procedures for the entire process, including cleaning steps,*
- *the product release and performance testing,*
- *the quality management system,*
- *the reporting of incidents involving devices that have been reprocessed, and*
- *the traceability of reprocessed devices.*

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2021. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2021 reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2021 in accordance with Directive 93/42/EEC, may be reprocessed.

7. Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation."

4.2 National laws on reprocessing of SUDs

Member States may permit the reprocessing of SUDs in their territories. There is no deadline for the Member States to take such a decision. Without that permission under national legislation, the reprocessing of SUDs is not allowed. Based on the notifications and the information received, the current state-of-play is as follows:

- 10 countries (Belgium, Croatia, Germany, Iceland, Ireland, the Netherlands, Poland, Portugal, Spain, Sweden) have adopted national rules allowing reprocessing of SUDs;
- 20 countries (Austria, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Romania, Slovakia, Slovenia) have not (yet) adopted national rules allowing reprocessing of SUDs.

Pursuant to Article 17(3) MDR, a Member State that permits the reprocessing in its territory can also allow, under certain conditions, health institution to reprocess SUDs in accordance with the CS by way of derogating from the need to assume the obligations incumbent on manufacturers in accordance with Article 17(2). In addition, such derogations can be extended to external reprocessors that reprocess SUDs at the request of a health institution. An overview of the state of play in the concerned study countries is included in the following Table 1.

COUNTRY	**MF obligations** Country decided to apply Article 17(2) MDR	**Common specifications** Country decided to apply Article 17(3) MDR	**Outsourcing** Country decided to apply Article 17(4) MDR	**Patient information** Country encourages/requires health institutions to provide information to patients	**Restrictions and prohibitions** Country imposed restrictions and prohibitions according to Article 17(9) MDR
Belgium	yes	yes	yes	yes	yes
Croatia	no	yes	yes	yes	yes
Germany	yes	yes	yes	no	yes
Iceland	yes	yes	yes	no	no
Ireland	yes	no	no	no	no
The Netherlands	yes	no	no	no	yes
Poland	yes	no	no	no	yes
Portugal	yes	yes	yes	yes	yes
Spain	yes	yes	yes	yes	yes
Sweden	no	yes	yes	no	yes

Table 1: options, restrictions, and prohibitions according to Article 17 MDR.

Restriction and prohibitions imposed by seven of the countries listed in Table 1 include, for example:

- bans for the reprocessing of certain devices (e.g., SUDs with non-removable batteries and/or where data cannot be cleared; SUDs emitting ionising radiation; implantable devices);
- limitations to EU Member States for the outsourcing of reprocessing;
- prohibition to reprocess SUDs that have come in contact with certain tissues (e.g., brain; backbone; retina; optic nerve; spinal nerve node; Gasser's ganglion; pituitary gland; hard dura mater) or have been used for procedures on patients affected by Creutzfeldt-Jakob disease or a variant of it; and,
- prohibition to transfer SUDs to any other country for reprocessing.

In accordance with Article 17(3) and (9) MDR, the Commission makes the information about national rules concerning the reprocessing of SUDs publicly available on its website[10].

The possibility for Member States to permit or not to permit reprocessing of SUDs, to allow derogations for 'in house' reprocessing and/or to set further restrictions on the reprocessing of SUDs has led to a fragmented implementation of the provisions on reprocessing of SUDs. In fact, two-thirds of the study countries do not allow reprocessing of SUDs. Each country that decided to permit reprocessing of SUDs made use of the possibility to provide for derogations and/or prohibitions or restrictions at national level in a unique way.

Additional information on national legislation on reprocessing, derogations, prohibitions/restrictions and notifications is available in Section 3.2 of the study.

5 OPERATION OF PROVISIONS ON REPROCESSING OF SUDS

The non-harmonised and fragmented regulatory framework is a challenge for stakeholders interested in reprocessing SUDs.

5.1 Notified Bodies (NBs)

NBs designated under the MDR and listed in the Single Market Compliance Space[11] have a fundamental role in the reprocessing of SUDs. NBs must be involved in the conformity assessment procedures of devices that are reprocessed SUDs by MFs in accordance with Article 17(2) of the MDR (hereinafter referred to as reprocessed SUDs) and must certify the compliance with the CS for HIs that reprocess and reuse SUDs in accordance with Article 17(3) (hereinafter referred to as reprocessing of SUDs). NBs must certify the compliance with the CS also for external reprocessors that, at a request of HIs, reprocess SUDs in accordance with Article 17(4).

Only 6 out of 38 surveyed NBs certify reprocessed SUDs and 5 of out of those 6 certify reprocessing of SUDs. The remaining 32 NBs do not offer those services. At the time of the completion of the study (December 2023):

- no certificates were issued either for reprocessed SUDs or for the reprocessing of SUDs;
- applications were lodged with only two NBs: two clients (manufacturers) submitted applications for conformity assessment procedures (CE marking) and one client (health institution/external reprocessor) submitted an application for certification of compliance with the CS.

The main issues identified by NBs that do not certify reprocessed SUDs or reprocessing of SUDs are related to the designation codes, to the fact that reprocessing is not allowed in the country where the NB is based and to the fact that there is a very limited number of clients interested in reprocessing. Other challenges and obstacles are summarised below in point 5.4.

[10] Reprocessing of medical devices - European Commission (europa.eu)

[11] https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=bodyTypeId:3,legislationId:34.

Some unclarity was reported regarding the identification of the relevant designation process[12] and designation codes[13] for NBs which are involved in the conformity assessment of reprocessing SUDs. NBs that certify reprocessed SUDs indicated that the designation code MDT 2013 (devices which have undergone reprocessing) plus additional product-specific MDR codes are relevant. Most NBs that certify the reprocessing of SUDs indicated that the designation codes are the same as those necessary for the certification of reprocessed SUDs. Some of those NBs indicated that the designation codes are not clear, and that no specific MDT code is available for reprocessed devices. One NB declared that the necessary designation codes should be defined by national measures and that at the time of the study such measures have not been adopted yet.

Additional information on NBs is available in Section 3.3.1 of the study.

5.2 Manufacturers (MFs) / external reprocessors

A very low number of MFs of reprocessed SUDs were identified (less than 10) and only two are active and operate in the EU. Both are small and medium-sized enterprises. While only one of the companies acts as a manufacturer of reprocessed SUDs (CE-marked devices) and offers reprocessing as a service complying with the CS, the other offers reprocessing as a service (CS) only.

About half of the reprocessed SUDs are cardiovascular devices, but arthroscopic, orthopaedic, laparoscopic and SUDs for general surgery are also reprocessed. All risk classes, from class I to class III, are represented.

The main reason for the limited interest shown by MFs in reprocessing SUDs seems to be linked to the difficulty in finding a NB, especially for the certification of the reprocessing of SUDs in accordance with the CS.

Information on MFs is available in Section 3.3.2 of the study.

5.3 Health Institutions (HIs)

19 replies from HIs were considered in the framework of the study. All HIs are based in countries that allow reprocessing. Unlike for the other stakeholders that were contacted directly, the survey for HIs was disseminated via various channels (e.g., members of the European Hospital and Healthcare Federation, members of World Federation for Hospital Sterilisation Sciences) due to the difficulty in identifying all the reference persons for each institution.

9 out of 19 HIs indicated that they reprocess or plan to reprocess and/or reuse SUDs. Three of them are also considering the outsourcing of the reprocessing to an external reprocessor. At the time of the survey, none of them held a certificate and none of them had lodged an application with a NB for the certification.

Eight HIs are aware of national rules on reprocessing SUDs and three of them are aware about national restrictions and prohibitions. One HI that is currently reprocessing SUDs indicated to not be aware of any restrictions.

Four HIs indicated that they reprocess/plan to reprocess SUDs and/or to purchase and use reprocessed SUDs. Three of those HIs indicated that the decision was made for economic reasons and to reduce shortages issues in special circumstances, such as the COVID-19 pandemic.

[12] MDCG 2019-6 "Questions and answers: Requirements relating to notified bodies", in Section V.1, clarifies that activities described under Article 17 to the MDR are not covered by Chapter IV and Annex VII - https://health.ec.europa.eu/document/download/9c9c532f-013a-477c-9378-0a9e714e5549_en?filename=md_mdcg_qa_requirements_notified_bodies_en.pdf.

[13] Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council - http://data.europa.eu/eli/reg_impl/2017/2185/oj.

10 out of 19 HIs are not interested in reprocessing. The main reasons for this decision are the lack of competences and resources on SUDs, possible concerns about patient safety and the lack of interest on the reprocessing of SUDs.

Information on HIs is available in Section 3.3.2 of the study.

5.4 Challenges and obstacles

Despite the availability of five NBs offering their services to reprocessors, finding a NB for the certification of reprocessing of SUDs in accordance with the CS remains a challenge. NBs highlighted that their available resources are still working on the transfer of certificates issued under the former directives on medical devices and that this determines a lack of capacity for the certification of reprocessing. In general, reprocessing SUDs requires specific expertise and resources to comply with the applicable requirements and decisions on investing such resources in reprocessing are negatively affected by the uncertainties surrounding applicable requirements (e.g., criteria for and availability of NBs, suitability of SUDs to be reprocessed), despite some MFs see possible advantages.

Another challenge is linked to the perception within CAs, NBs and HIs of reprocessing of SUDs as a source of possible health risks for the patients. In addition, specific characteristics of SUDs, such as the geometry or the materials, bring in concerns on the suitability of the device for the reprocessing.

Changes to the SUD made by its manufacturer (e.g., geometry, components, materials) may not be easily detectable by reprocessors and could undermine the validation of the reprocessing processes.

Alongside these empirical considerations, CAs, NBs and HIs emphasised the need for more evidence and comparative data to validate the suitability of reprocessing SUDs. Ethical considerations were also raised as regards the manufacturers practice to label devices as single-use instead of as reusable.

CAs and HIs finally noted that ad hoc surveillance activities, monitoring and communication of incidents should be put in place for the reprocessing of SUDs and that there are concerns on liability issues related to reprocessed SUDs.

Table 2 below summarises the most common challenges and obstacles identified by each stakeholder group with the number of stakeholders who identified each challenge.

PERCEIVED CHALLENGES	**INDICATED BY THE FOLLOWING STAKEHOLDER GROUP** (number of stakeholders that perceived the challenge)			
Finding a NB for the certification	-	-	MF (1)	HI (4)
Lack of capacity of the certification	-	NB (9)	-	-
Possible health risks	CA (30)	NB (25)	-	HI (6)
Complexity of reprocessing SUDs	-	NB (28)	MF (2)	-
Differences in the suitability of devices for reprocessing	CA (17)	NB (15)	-	HI (2)
Issues of liability	CA (19)	NB (24)	-	HI (5)
Lack of evidence	CA (16)	NB (18)	-	HI (3)
Practice of manufacturers	CA (8)	NB (8)	-	HI (2)

Table 2: General challenges for reprocessing SUDs as indicated by the stakeholders.

Information on challenges is available in Section 3.4.1 of the study.

5.5 Opportunities

The main perceived opportunities of reprocessing of SUDs by all stakeholder groups are environmental benefits, possible cost savings and a possible solution for shortages of devices. MFs and HIs consider reprocessing of SUDs beneficial also for increasing competition and some HIs highlighted a possible enhancement, in some specific instances, for the quality of care (e.g.,

reprocessed electrophysiology catheters could have reduced stiffness, enabling cardiologists to perform treatments more effectively in patients with challenging anatomies).

Table 3 below presents the most common opportunities identified by each stakeholder group with the number of stakeholders who identified each opportunity.

PERCEIVED OPPORTUNITIES	INDICATED BY THE FOLLOWING STAKEHOLDER GROUP (number of stakeholders that perceived the opportunity)			
Environmental benefit	CA (21)	NB (21)	MF (2)	HI (8)
Cost savings	CA (25)	NB (25)	MF (1)	HI (6)
Solution for shortages	CA (21)	NB (14)	MF (1)	HI (6)
Increase of competition	-	-	MF (1)	HI (5)
Improved quality of care	-	-	-	HI (1)

Table 3: opportunities for reprocessing SUDs indicated by the stakeholders.

Information on opportunities is available in Section 3.4.2 of the study.

6 OUTCOME OF EVIDENCE GATHERING

6.1 Stakeholders' views

Stakeholders recommended to take some actions to improve the implementation of Article 17 of the MDR. Among others, amending the MDR to strengthen regulatory requirements (e.g., require suitable qualifications for operators conducting the reprocessing; adding preconditions for the reprocessing in Article 52[14] of the MDR to ensure that reprocessors have the technical ability to reprocess SUDs) was mentioned. In addition, drafting guidelines, including a step-by-step manual for the implementation of the MDR and the CS has been considered as a useful tool to ease the implementation. Furthermore, HIs recommended strengthening the support from regulatory authorities at national or EU level, which might help to address the lack of NBs willingness to certify reprocessing of SUDs according to the CS. Stakeholders recommended that ad hoc task forces or working groups at EU level could be also established.

In Stakeholders' opinion, a clear tracking system and an improved surveillance system could be useful as well as an increased availability of scientific studies on the safety of SUDs. In addition, improving staff education and strengthening risk management for reprocessed SUDs were also considered as relevant.

Some stakeholders would welcome EU-wide lists that identify SUDs suitable to be reprocessed (positive lists) or SUDs not suitable to be reprocessed (negative lists). While overall CAs and NBs were in favour of both positive or negative EU-wide lists of SUDs, MFs opposed the idea, suggesting that a single list could not be fully justified from a scientific perspective and would be difficult to establish, in the light of the variety of SUDs which might be reprocessed.

One industry association reported that, as the MDR's implementation currently stands, for economic reasons there is a strong incentive for MFs to label products as 'single-use' rather than reusable. This actively hinders the aim of achieving a circular economy in the medical devices sector. According to this association, there are variations in the extent to which products are reusable in practice, and this should be determined on a product-by-product basis by NBs as an independent third party.

Table 4Table 3 below presents the main recommended actions identified by each stakeholder group with the number of stakeholders who recommended each action.

[14] Article 52 of the MDR on conformity assessment procedures sets out requirements for the assessment of the conformity of the device to the MDR in view of its placing on the market.

RECOMMENDED ACTIONS	INDICATED BY THE FOLLOWING STAKEHOLDER GROUP (number of stakeholders that recommended the action)			
Regulatory requirements	CA (18)	NB (22)	MF (2)	HI (5)
Identification of suitable products for reprocessing	CA (20)	NB (25)	-	HI (5)
Clear tracking system	CA (20)	NB (19)	-	HI (2)
Improving staff education	CA (16)	NB (11)	MF (1)	HI (3)
Risk management	CA (17)	NB (15)	-	HI (4)
Extended producer responsibility	CA (10)	NB (12)	-	HI (4)
Clarification on designation codes	-	NB (14)	MF (1)	HI (2)
Amendments in the MDR	CA (5)	NB (6)	MF (1)	HI (2)

Table 4: potential actions and recommendations indicated by the stakeholders.

Information on recommended actions from the stakeholders is available in Section 3.5 of the study.

6.2 Study outcome

Taking into consideration the study results, the study contractor provided recommendations for removing the existing obstacles in the implementation of Article 17 of the MDR. Those recommendations take stock of information provided by all the surveyed stakeholders and have been clustered in the following five categories:

- General recommendations: promote generation of evidence; support clarity and transparency of national provisions; improve communication and collaboration among Member States; establish task forces/working groups involving stakeholders;
- EU legal framework and guidance documents: clarify terms and concept to ensure common understanding; develop guidance documents about the reprocessing of SUDs and establish a dedicated monitoring mechanism for the implementation of Article 17 of the MDR;
- Certification: inform MFs about NBs designated for certifying the reprocessing of SUDs; clarify concepts and accountability of NBs for certification of compliance with the CS; clarify the requirements for the designation of NBs, including qualifications needs and related codes;
- Product-related recommendations: develop EU-wide lists on the suitability of different types of SUDs for reprocessing; use of EUDAMED; support improved risk management and market surveillance; and,
- Measures at national level: take measures to support the implementation of reprocessing SUDs; implement targeted measures for HIs.

More detailed information on recommended actions proposed by the contractor is available in Section 5 of the study.

7 STOCKTAKING

The study identified challenges and obstacles for the implementation of Article 17 of the MDR and provided recommendations for addressing them on the basis of key stakeholder positions. Considering that the current situation is fragmented and not harmonised across the EU, providing clarifications and guidance on how to implement the existing provisions on reprocessing of SUDs might not be sufficient. Alternative solutions may have to be explored.

In particular, the MDR includes a specific definition of 'reusable surgical instruments'[15] and requires that the instructions for use of those reusable devices include information on the appropriate processes

[15] See Section 2.3 of Annex VIII to the MDR: *'Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar*

for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation. In addition, instructions for use must provide information to identify when the device should no longer be reused (e.g., signs of material degradation, maximum number of allowable reuses)[16].

Provisions on the reuse of a device other than SUDs are established in the MDR and harmonised. Contrary to Article 17(1) of the MDR that introduced some flexibility and allows Member States to prohibit reprocessing, there are no possibilities for Member States to prohibit or restrict the reuse of a device. Responsibilities of manufacturers, NBs and HIs are defined in the MDR for reusable devices. The manufacturers must provide information to allow the reuse, NBs are involved in the conformity assessment procedure depending on the class of the device and HIs have to follow the manufacturer's instructions to reuse the device.

Even if the MDR definition of the term 'reprocessing'[17] refers to devices in general, in the MDR that term is used only for SUDs. Nevertheless, the processes for allowing reuse of certain devices explicitly referred to in the MDR are very similar to those for reprocessing and both share the same objective, namely allowing the reuse of a device.

Exploring the possibility to bring the concept of reprocessing of SUDs closer to that of reuse of a device appears promising and would remove most of the obstacles identified for the implementation of reprocessing addressing also the ethical considerations as regards manufacturers practice of labelling devices as single-use instead of as reusable.

Considering that the MDR does not provide requirements for the manufacturers when deciding whether a device is 'single-use' or 'reusable', it would be beneficial to also explore the possibility of establishing criteria to be followed when deciding whether a device is single-use or reusable, provided that a specific assessment has been carried out in this respect. The aim of such approach would be to ensure that a reusable device would not be labelled as 'single-use'.

Natural or legal persons who reprocess SUDs in accordance with Article 17(2) of the MDR and comply with MDR obligations incumbent on manufacturers would be able to continue doing so and would be considered as manufacturers of fully refurbished devices[18].

Reprocessing might be an opportunity for reducing environmental impact and pursue cost savings; However, additional evidence needs to be generated and collected to explore the relevant aspects at stake. Further, scientific evidence is still necessary to support the feasibility of possible options for the way forward.

8 CONCLUSIONS

The implementation of Article 17 of the MDR is fragmented across the EU. Only 10 countries allow reprocessing of SUDs and only six NBs offer certification services for reprocessed SUDs and/or reprocessing of SUDs in accordance with the CS. Most of the countries allowing reprocessing of SUDs have established national measures which limit reprocessing and/or subject it to conditions.

Relevant requirements on reprocessing, especially those established in the CS, are complex to be implemented. This leads to a potential knowledge gap and a need of developing new expertise.

The market of reprocessed SUDs (MFs) and of reprocessing SUDs in accordance with the CS (HIs) is very limited and not attractive for NBs that are currently mainly focused on the transition of certificates from the former directives on medical devices to the MDR. In addition, the existence of the relevant competences and expertise within the NBs to certify reprocessing is not confirmed, especially for reprocessing SUDs in accordance with the CS.

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procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

[16] Point (n) of Section 23.4 of Annex I to the MDR.

[17] See definition of 'reprocessing' in paragraph (39) of Article 2 of the MDR.

[18] See definitions of 'manufacturer' and 'fully refurbishing' in paragraphs (30) and (31) of Article 2 of the MDR.

The Commission will further assess the operation of the provisions on reprocessing also in the light of new data[19],including as part of the targeted evaluation of the MDR[20]. If appropriate, based on the outcome of this assessment, the Commission will consider possible options to address any shortcomings.

[19] New data may concern changes in national legislation on reprocessing, number of applications and certificates for reprocessed SUDs and reprocessing of SUDs in accordance with the CS, NBs offering their services on reprocessing.

[20] See "EU rules on medical devices and in vitro diagnostics – targeted evaluation" on the Have your say portal of the Commission - EU rules on medical devices and in vitro diagnostics – targeted evaluation (europa.eu)