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Medtech Denmark response to the new version of the Nordic Criteria for more Sustainable Packaging

1. Introduction

Medtech Denmark appreciates the opportunity to provide input to the new version of the Nordic Consultation on the Criteria for More Sustainable Packaging.

We support the Nordic procurement authorities' objective of promoting sustainability in healthcare packaging and share the goal of reducing environmental impacts while maintaining the highest standards of patient safety, product quality and regulatory compliance.

Packaging for regulated medical devices serves a defined and essential function. It ensures product sterility, integrity, and traceability in accordance with the EU Medical Device Regulation (MDR 2017/745) and the In Vitro Diagnostic Regulation (IVDR 2017/746) and important horizontal European legislation such as REACH and RoHs etc.

Thus a 'simple' change in composition of product or packaging requires typically 2-3 years of implementation due the regulatory requirements. Altering the composition of a medical device or its packaging is a complex and time-consuming process. Removing or substituting a substance/material may alter the product's specifications, potentially impacting its manufacturing, performance, safety profile, and intended function. In some cases, it may not be feasible to achieve the same level of patient safety or product efficacy after such changes. In other cases, the change affects the manufacturing set up triggering a lengthy process of revalidation and testing. Change in the composition can trigger not only a chemical composition review but also biological evaluation and toxicological risk assessment. Regulatory requirements apply also to the medical device packaging, where changes might require new dose mapping tests to ensure sterility, stability studies for ensuring the shelf life, new transportations studies to confirm the packaging ability to protect the product adequately.

These efforts and constraints must also be acknowledged and considered when evaluating compliance and progress.

Any new or revised sustainability requirements should therefore complement these frameworks and avoid compromising patient safety or device performance. In particular where such compromising could lead to devices being scrapped due to not reaching the user in perfect condition.

We support a phased, evidence-based approach to packaging sustainability aligned with the EU Packaging and Packaging Waste Regulation (PPWR 2025/40) and applied consistently across European markets. Please note that primary packaging is exempted from the recyclability requirements described in this regulation. Primary packaging of medical devices, especially of sterile products, does not only protect the product, but it performs a function beyond acting as a sterile barrier. Limiting the use of multilayer and other polymer materials besides those specified in the table risks intended product protection and performance. Therefore, we suggest to exclude primary packaging from all levels of the criteria.

2. Remark on Use of the Criteria – Spearhead criteria and Innovation clauses

As these Criteria is used when suppliers compete thus being very commercially sensitive, it is very important that suppliers are not permitted to make commitments about future sustainability improvements without presenting realistic targets and actionable plans. While many suppliers have sustainability strategies and plans in place, their ability to deliver on these by the end of the contract period might vary.

3. Material Minimization

Medtech Denmark supports the reduction of packaging material usage wherever feasible. Packaging is engineered to minimize weight and volume while maintaining device protection and compliance with regulatory and logistical requirements.

Ongoing initiatives across our operation include:

- Transition from printed Instructions for Use to electronic IFUs (eIFUs) where regulatory possible as the possibility for using eIFUs currently only applies for devices used by professional users
- Optimization of carton and transport packaging to reduce material intensity; and
- Continuous assessment of packaging designs identify further reduction opportunities without affecting usability or safety.

In regard to Criterion 1.1. reduce material consumption we suggest to exclude this as this could favor manufacturers that started with a bad packaging design over producers that have optimized their packaging design from the beginning.

In regard to Criterion 1.2 Weight and material information, the scoring model should consider that packaging solutions which rely on recycled material generally weigh more than packaging solutions based on virgin material. This relationship is not currently reflected in the scoring model. Without this consideration, weight evaluation can be misleading.

Moreover, the size of the tertiary packaging varies depending on the order quantity, which makes it difficult to specify the weight. If this requirement is to be used, please clarify how suppliers with flexible tertiary packaging sizes should provide this information.

Furthermore, this requirement is not yet commonly seen in tenders and involves significant effort for suppliers to collect data for all products - particularly for consumable products or suppliers with large assortments. We therefore recommend that the basic level remains a competition criterion until this becomes more widely adopted.

In regard to Criterion 1.3 Reduce the climate and environmental impact of packaging by means of a scoring model, we have the following comments: A scoring model is useful, but it must be aligned with harmonized standards and industry practices so as to account for the supplier's sustainability efforts, otherwise the evaluation will be untruthful. There are many other factors that need to be considered when assessing environmental impact, not just material type and weight. Energy source also plays a crucial role during the manufacturing of a product. The same quality of product may have a significant lower impact if it is manufactured by using renewable energy. This is not considered at all in the scoring model and could lead in fact to wrong conclusions.

Furthermore, we have received many comments from companies as to this being a very time-consuming requirement, especially for tenders involving consumable products. We suggest that it applies only to the top 5–10 products (or a similar limited selection) to begin with.

We also recommend extending the submission period, as this criterion requires additional work from suppliers going back to mother companies or other economic operators in the supply chain to be able to complete the tender response, which is already a resource-intensive process without these additional requirements.

In regard to Criterion 1.4 Minimize metal use, the primary packaging for some products has been designed to maintain the humidity of the product while at the same time providing a sterile barrier during the whole shelf life of the product. Considering that, the primary packaging is not primarily designed to be used, consumed and disposed of together with the product, as it primarily functions as a sterile barrier in the traditional sense. Preventing evaporation while allowing minimal preparation for the user requires the critical element of metal in the packaging. Therefore, metal in primary packaging must be excluded from the advance criteria when it's a critical element to minimize evaporation and preserving the sterile barrier.

4. Design for Recyclability

We support the use of mono-materials such as PE, PP, and PET and the reduction of complex composite structures where technically and regulatory feasible. Secondary and tertiary packaging are generally designed for recyclability. Changes to primary packaging for sterile or contact-sensitive products may require design validation and, in some cases, re-certification under MDR as pointed out above.

In regards to Criteria 2.3. regarding substances, it is important to note that MDR acknowledges that the presence of certain hazardous substances does not automatically equate to an unacceptable risk. Instead, MDR requires manufacturers to conduct a thorough scientific risk assessment including toxicological evaluation and biocompatibility testing (e.g., per ISO 10993) to demonstrate that any potential exposure is controlled and that the overall benefit-risk profile for the patient remains positive.

Future criteria should:

- Recognize the differing design and regulatory requirements of sterile versus non-sterile packaging
- Limit the substance requirement to intentionally added substances and respect the specific justification analysis done by the manufacturer under MDR
- Consider the actual recycling infrastructure available in healthcare settings to ensure that design improvements deliver measurable environmental outcomes

5. PVC Phase-out

The industry supports efforts to reduce or eliminate PVC and other non-recyclable polymers from packaging. PVC use in medical device packaging is limited, and substitution programs are ongoing. Where PVC remains necessary, it serves a validated role in ensuring product protection or sterility, and substitution would require regulatory review and potential re-certification.

A phased implementation, allowing time for material validation and supply-chain readiness, will help maintain product availability and compliance.

6. Recycled or Bio-based Content

We support increasing the use of recycled and bio-based materials in packaging where such materials meet all relevant quality, performance, and regulatory requirements.

Current status within the sector includes:

- Tertiary packaging incorporating more than 50 % recycled content;
 - Secondary packaging materials with 15 - 100 % recycled content in active validation;
- and
- **Ongoing assessments of recycled or bio-based plastics for selected primary packaging applications.** However, Primary packaging of medical devices, especially that one of sterile products, does not only protect the product, but it performs a function beyond acting as a sterile barrier. Setting a threshold for recycled fibre content, criterion 3.2., risks bringing the intended product protection and performance in danger. Therefore, primary packaging must be excluded from all levels of the criteria as pointed out before.

As regards

Finally, aesthetic differences in recycled materials (e.g., minor colour variation etc. which do not affect functionality, or compliance should be accepted within sustainable procurement frameworks.

7. Sustainable Sourcing and Certification

Medtech Denmark supports the intent of demonstrating responsible, sustainable sourcing.

However, we do not support making third-party eco-labelling or certification a mandatory requirement where equivalent assurance can be provided through internal supplier-management systems.

Third-party certifications and associated logo requirements become part of the product design. Mandating sustainable-sourcing certification for regulated medical-device packaging would add unnecessary complexity and risk to product supply, particularly in the absence of clearly defined sustainable-design criteria for this category.

Distribution centers within Europe already use FSC-certified tertiary packaging to our knowledge.

For other packaging levels, supplier agreements include sustainability and responsible-sourcing provisions equivalent in intent to third-party certification. This ensures traceability and compliance without creating additional administrative burden or certification costs.

Moreover, no certification scheme has yet defined sustainable medical-device packaging criteria that remain fully compliant with EU MDR 2017/745, ISO 11607, and related standards.

Therefore we recommend that equivalent internal assurance mechanisms should be recognized in lieu of mandatory third-party certification within the Nordic Criteria framework. Also due to the fact that third-party certification can be very expensive for suppliers with large assortments, placing additional financial pressure on suppliers if this requirement is upheld.

RecyClass provides certification based on the current recycling system, penalizing packaging that could be recycled if the current technology was more advanced. Lack of acknowledgment of suppliers' efforts to design for recycling results in penalization simply because the recycling technology is not ready, which we do not think is fair. Recycling requires the involvement of every stakeholder in the supply chain and cannot be tackled by suppliers alone. Therefore, certain parameters such as size should be excluded from the analysis to not penalize recycling efforts in packaging just because the current assessment under the Recyclclass cannot deal with this.

In regard to Criterion 2.5. Labels that do not harm the recyclability of plastic packaging

The criteria refer to the exemption of inner and outer packaging for medical devices, but that only applies to non-sterile packaging definitions (Appendix C) of medical devices. Sterile packaging (primary and secondary packaging) should be included to the exemption in the criterion and added to the table.

In regard to Criterion 2.6. Labelling and information requirements

Information on disposal should be also allowed on other types of physical support, instructions for use, laser printed instead of on a label as it might not be possible to collect regulation and disposal information under one single label. This is very much dependent on the size of the medical device at hand.

8. Implementation and Market Readiness

The stepwise structure of the Nordic Criteria (Basic / Advanced / Spearhead) provides a practical implementation model. To support effective adoption, we recommend:

- Early market engagement prior to tender publication to confirm technical readiness and supplier capacity
- Use of minimum (mandatory) requirements only where broad market capability exists to ensure competition and supply continuity
- Consideration of actual recycling capacity within healthcare institutions to ensure requirements align with waste-handling capabilities.

This approach promotes tangible outcomes while remaining proportionate to the characteristics of medical-device packaging.

9. Clarification on Additional Packaging Requirements

Certain Nordic tenders include additional or multi-layer packaging specifications extending beyond regulatory or clinical safety needs. Such requirements often stem from local hospital logistics practices rather than patient-safety or sustainability objectives.

While these practices may assist internal handling, they can also increase material use and related costs without measurable environmental or clinical benefit.

We recommend reviewing these specifications to ensure alignment with the material minimization principle (Criterion 1.1) and to confirm that any additional packaging serves a demonstrable functional or safety purpose. This matter has been brought to the attention of Danish Regions under discussions of the 'Stamdata' project, facilitated by GS1. Here it has been maintained that Denmark needs an additional layer of packaging for sterile medical devices due to requirements when receiving the products at the regional warehouses. This additional packaging layer is only a requirements in tenders from Denmark and Sweden.

10. Specific comments to Appendix A and C1

Following the manufacturing process, retail boxes are placed inside larger cardboard boxes named shipper boxes for transport. After leaving the manufacturing site, retail boxes can be repacked into other shipper boxes at the distribution centers. In this repacked process, retail boxes can end in the same shipper box with other medical devices. To keep the advantages of the existing transportation synergies and reduce the impact on the environment, we suggest that the transport packaging requirements only apply to the original shipper box packed at the manufacturing site.

Consequences of applying the transportation packaging requirements on transport packaging after leaving the manufacturing site would impose a need for specific shipping flow for products under scope of the specific tender, will diminish the overall efficiency of logistic operations and the ability to utilize transportation synergies. In practice, it would require designated routes, increased number of shipping trucks, additional packaging materials and could potentially result in longer delivery times for the user.

11. Specific comments to Appendix D

Third-generation bioplastic is mentioned, and in stead we suggest having focus on second generation feedstock as this do not compete with food supply in stead of first generation as stated.

12. Recommendations

To ensure consistent and practical implementation, we recommend:

- Align Nordic packaging criteria with the EU PPWR 2025/40 and exclude primary packaging from all levels of the Nordic Criteria
- Consider alignment with most other European countries as regards the mandatory requirements of 3 packaging layers for sterile products to avoid packaging specifications that increase material use without measurable benefit
- Keep the advantages of the existing transportation synergies by only requiring that transport packaging requirements apply to the original shipper box packed at the manufacturing site.
- Apply phased and proportionate timelines based on product risk, technical feasibility, and regulatory obligations
- Allow extended submission periods in the tender procedure to comply with these requirements which are time-consuming
- Maintain structured supplier dialogue before introducing new requirements
- Recognize equivalent internal sourcing systems alongside third-party certification
- Verify that hospital waste-management infrastructure can accommodate recyclability requirements
- Maintain balanced tender evaluation models that consider sustainability together with safety, quality, and cost.

We welcome the Nordic initiative to enhance packaging sustainability and remain committed to continuous improvement in this area.

Kind regards,



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