MEDICO INDUSTRIEN
MEDTECH DENMARK

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Medtech Denmark's response to 'Nordic Criteria for more Sustainable Packaging'

Medtech Denmark has received the consultation material regarding the Nordic Criteria for more Sustainable Packaging and has the following remarks:

General considerations

Medtech Denmark appreciates the Nordics' exciting initiative on sustainable packaging that aligns with The Danish Regions Procurement Strategy 2020-2025 and the recent governmental agreement on a National Strategy for Reduction of CO_2-emission by 70%.

In compliance with this, the member companies of Medtech Denmark are very dedicated in their focus on sustainability.

The medtech industry supports a public procurement of medical devices to be focusing on sustainability in a balanced and proportionate way, creating the greatest value for patients, regions, and communities.

Requirements to sustainable medical device packaging should be set with the correct timing to allow suppliers to adapt gradually to a balanced development of a more sustainable European device market. Discrepancies in market maturities in individual European countries can prove very difficult for a medtech supplier to adapt to.

The deployment of decision-making tools to organize and prioritize supplier compliance to specifications within sustainability can prove to be a proper starting point for driving a pan-European development.

However, from a supplier perspective, a high degree of recognizability and standardization of such requirements will be a prerequisite.

Moreover, deployment of decision-making tools to rank supplier compliance will most likely be very complicated to develop, as the medtech market is extremely diversified and granulated. Any tool to serve tenders will evidently be quite complex.

Optimized sustainability of packaging requires investments.

Material changes, development of new packaging solutions, modified sterilization procedures and redesign of new product protection systems can be very costly for suppliers. Even more costly is the associated recertification of the product-packaging solution, which will often be needed in case of sterilized products.

A worst-case scenario can lead to products being phased out due to excessive cost of compliance to new sustainable demands. This will inevitably lead to a reduction in the availability of innovative medical devices that create value for patients, health care and the economy.

Additionally, focus on criteria for an enhanced sustainability profile for the medtech device including its packaging solution will drive the development costs for pursuing this focus, leaving less resources to R&D on the basic healthcare profile of the product.

Sustainability in products and processes is a concern to all, but the realistic approach to more sustainable medtech products need to be accompanied by enlarged purchasing budgets to accommodate the financing of the associated development costs mentioned above.

Increased sustainability requirements can therefore hardly be achieved without an increase in procurement budget.

A successful development towards more sustainable medtech product supplies will be conditional on the timing of initiatives between the Nordics and the rest of Europe, to create a harmonized EU development and additionally be conditional on the coherence between specific requirements and additional product unit cost.

Balanced use of quality, price, and sustainability

A balanced deployment of criteria for unit price, for quality and for sustainability is imperative to the medtech suppliers.

The suppliers' prime objective is to develop safe products that serve their stated purpose for the benefit of patients and users. This purpose will always come first, and therefore quality, functionality and patient safety and healthcare value will always be the most important priorities for the industry. These come before other criteria, such as price and sustainability.

The primary purpose of medical devices is not sustainability, but patient health, patient safety and comfort.

Therefore, we agree in what is clearly stated under 'Guide to the Use of The Criteria' that the use of the criteria must never be at the expense of patient safety, the regulatory requirements according to the CE mark and the associated standards.

When sustainability requirements are incorporated into tenders and additional costs for packaging optimization are included, there is a risk that the ratio (unit price)/ (value creation) will change in a negative way making the product appear more expensive to supply a given value.

It is therefore essential that sustainability requirements are not incorporated in such a way that this ratio is twisted negatively leading to patients and clinicians potentially receiving lower clinical value per unit price.

In addition, it is very important that the product assessment reveals real world sustainability data when assessing the scoring points. If these criteria are not properly met, unit price will inevitably come out with the highest scoring in the tenders because there will be an insufficient variation in sustainability criteria.

This is already a well-known issue in terms of quality criteria, which is why tenders often end up being decided on price. This issue can be overcome by defining quality and sustainability criteria as minimum requirements and not competition requirements.

Hence, competition requirements should only be deployed in areas where a large variety of suppliers can actually comply to the enhanced demand for quality or sustainability.

Need for joint European initiative

It is commendable that the Nordic countries are leading the way, but the medtech industry is global and Europe is a unified market in relation to CE marking, chemical legislation, and packaging legislation.

Consequently, Medtech Denmark strongly calls for the Nordics to engage in dialogue with the rest of the EU to shape the entire European market. It is rewarding that the Nordics are collaborating with other European countries, for instance the Netherlands, in this project, and it is positive that the initiators are seeking inputs to the model from Medtech Europe and the other medical device industry associations in the Nordic countries.

For many members of Medtech Denmark, the Nordic region remains a relatively small market. It is therefore a very difficult task for suppliers to change the packaging solution for products to be supplied in such a limited market compared to the EU market.

It is a prerequisite for suppliers on the Danish market that packaging solutions to serve this market can also be applied as a competitive advantage on other markets. Investments in better sustainability must be addressed as an investment that can strengthen the global competitive edge of the product. Common European market must be regarded as the minimum market size.

Consequently, Medtech Denmark calls on the Nordic countries to work for the EU Commission to create common European criteria for packaging that can be used transnationally for the purchase of medical devices. The Commission has developed so-called green procurement criteria for several product areas.

Medtech Denmark has additional comments on the draft submitted by the Nordics on criteria for more sustainable packaging. These follow the chronology of the draft:

Remarks on 'Guide to the Use of the Criteria'

The use of basic, advanced, and spearhead criteria as minimum or competition requirements

The Nordics clearly state that the gradual implementation of new packaging requirements will take into account the maturity of the market in specific product areas and with an emphasis on conduction early market dialogues.

Medtech Denmark agrees, that a specific review before every call for tenders based on an early market dialogue, preferable through both written consultations and dialogue meetings, is essential to assess the level of availability of a given product area and thus also to decide whether minimum or competition requirements are the most appropriate approach in the given call for tenders.

Likewise, we agree that a close dialogue with relevant suppliers to come up with a thorough market analysis will determine when it is appropriate to move up the 'ladder', so that what was previously 'advanced' becomes the new 'basic'.

If the market is not mature or in situations where market players are at very different levels, the use of

minimum requirements should be exercised with restraint to ensure that the essential competition can continue in the tender.

If the bar is set too high too quickly, there is a risk that suppliers will be discouraged from bidding in tenders and that innovative products that score high on clinical value will not be considered. This will not be beneficial to the healthcare sector, as it will harm competition in the tender and reduce product availability.

Remarks on 'Process Guide and Decision Tree'

The Nordics claim that 'the gross list of criteria presented in section 3 is generic to packaging materials of all types of healthcare products'. Medtech Denmark wishes to challenge this statement.

It is important to take into account that the medical device market is not a single market but consists of a huge number of submarkets ranging from low-risk products to high-risk products. Packaging differs greatly from one market to another, and it is important that this is reflected in the tender requirements.

The large variety of product and solutions makes it difficult to do any comparison when it comes to assessing and scoring each product. Every product has its specific and unique packaging solution which makes any comparison very complicated. This can easily form the basis for misleading comparisons.

In the case of products where there are both a single-use and multiple-use solutions, it may be difficult to compare the packaging solutions. The two solutions will offer different value in the handling and re-sterilization, which is associated with different environmental outcomes.

If single-use product can reduce climate impact by not having to be re-sterilized using energy and water and staff resources to re-sterilize, this can in some cases be more sustainable when looking at the entire value chain, even though the sum of the entire packaging may amount to a higher weight than the multiple-use alternative.

Similarly, tenders should not only look at the weight of the packaging. Use of regenerated material will often be inferior in strength compared to virgin material, thus demanding for more material usage (thickness) to provide a similar physical protection as the virgin alternative.

Sterile products often contain multilayer sterile barriers which bring up the weight of the packaging.

It should also be borne in mind that the requirements for more sustainable packaging are very complicated and almost inconsistent in case of cross-sectorial procurements, as the associated deliveries and packaging solutions are different when serving the patients individually in the municipalities as compared to the inventory supplies in the regions and at hospitals.

In addition, it must be taken into consideration, that private homes do not recycle to the same extent as the centralized packaging handling at hospitals.

Finally, purchasers should be aware that packaging solutions highly depend on the supply logistics.

Logistics originate from the forecast being made by the hospitals. An insufficient forecast of demand will lead to a reorder of equipment. A small number of items will often be sent by deploying packaging solutions with the tertiary packaging being determined by the third-party logistics operator.

Tertiary packaging can often form a disproportionate part of the packaging solution for shipments of single device deliveries.

Additionally, it must be born in mind that the enhanced packaging criteria in the MDR challenge the possibilities for a supply of a limited number of items per shipment as the packaging system forms an integrated part of the product/packaging solution. This regulatory constraint does not align with the general picture of orders demanding a limited number of items.

Need for consistency in case of breach of contract

If requirements are made in the tender to supply a more sustainable packaging, the procuring and contraction partner must be required to monitor the compliance of the tenderer with the requirements.

The contracting partner must allocate the necessary resources to verify whether the requirements are met and in full compliance. Otherwise, there is a risk of a bias in the market, where suppliers lose out on being thorough and orderly in favor of suppliers who claim to meet requirements without actually doing so.

It is stated by the Nordics that the tenderer should 'consider if it is possible to include development and improvement of the requirements to sustainability during the contract period'.

In addition, it is essential that the contracting partner monitors compliance within the given timeframe from the start of the contract. If suppliers can avoid meeting the criteria during the contracting period as promised, contractual provisions must be set to counteract this. A supplier must not be enabled to promise future enhanced sustainability of the product without actually delivering this. A time limit and a consequence if a supplier fails to meet the requirements must be installed in any contract.

Remarks on 'Reduce Material Consumption'

Medtech Denmark calls for further guidance on how to weight the packaging, especially in cases where the packaging consists of more than one material.

Use of metal, no. 1.4 p. 7

Metal is often used in multilayer polymer-based materials to obtain certain barrier effects. Moreover, RFID devices (Radio Frequency ID) are often built in as an integrated part of the packaging to facilitate tracking and tracing of the supply. RFID devices contain metal. For these reasons prohibiting the use of metal can compromise both the packaging system and the tracking system.

Remarks on 'Design for Recycling'

Use of polymer multilayer materials, no. 2.1 p. 8

Producers of medtech devices must operate in alignment with the Packaging & Packaging Waste Directive in which it is compulsory to minimize the packaging solution. Deployment of multilayer polymers contribute to build in several functional attributes in a very compact manner to ensure optimized product protection from e.g. contamination. For this reason, restrictions on the usage of multilayers

based on complex polymers as EVA and Nylon may compromise the intended product protection.

Biobased material, no. 2.2 p. 9

Medtech Denmark considers it unclear why non-PE biobased materials (LDPE, HDPE, LLDPE), PP and PET are not allowed.

In addition, we suggest a clarification on what is meant by 'certificate of origin'? A definition of this could usefully be added to the definition list, Appendix B on p. 17.

Multilayer packaging, no. 2.2 p. 9

Medtech Denmark is questioning why multilayer packaging is not allowed. In most cases, it is easy to separate polymers from carton and paper. Carton provides physical protection whereas paper allows product information to be written while polymers and laminates hereof provide transparent visibility and sterile barriers.

RecyClass, no. 2.3 p. 10

Medtech Denmark is calling for more information to be added about RecyClass. This can also usefully be added to the definition list, Appendix B on page 17.

Requirements regarding temperature (60 C) and labelling, no. 2.5 p. 11

A general requirement that labels must be detachable at a maximum temperature of 60 degrees C can in some cases be inconsistent with the fact that both some sterilization processes and some transport modalities operate at temperatures above this limit.

Remarks on 'Recycled or Sustainably Sourced Materials'

Requirements regarding FSC-certified fiber-based material, no. 3.2 p. 13

Requirements to the amount of FSC-certified fiber-based materials used in the packaging solution represent a supplementary cost for the producer of the medical device, as this calls for a FSC-certification of the company. This extra cost will primarily be put on the product price.

Specifically remarks regarding sterile products

In the case of sterile products, sterile packaging is regulatory considered as part of the product. It should therefore be ensured that the plastics mentioned can withstand the usual sterilization methods.

As mentioned previously, changing the sterile primary packaging will require a recertification of the product. This is extremely expensive and time consuming.

Changing the packaging size is another cost driver as this requires the installation of a new UDI (Unique Device Identification) and consequently a new registration in EUDAMED (European medtech database).

Consequently, in the case of sterile products in particular, care should be taken to not applying

minimum requirements in tenders.

Remarks on 'Appendix A Scoring Model'

The Nordics introduce a scoring model being divided into three main categories, 'Plastic material', 'Cellulose based material' and 'Metal'. This distinction of material categories must be regarded as being much to simplified and hence without practical usability.

In case tenders should be based on scoring models, the highly diversified medtech market requires a much more detailed and granulated model providing a much more detailed analysis of different product propositions. Scoring models should therefore be sufficiently fine-meshed and observe the many quality levels of materials (e.g. plastics and laminate quality) in order to display a true weighting between packaging alternatives.

For example, as mentioned, the scoring model should take into account that packaging solutions which rely on recycled/regenerated material typically weigh more than packaging solutions based on virgin material. This relationship is not currently reflected in the scoring model on page 14.

The choice of material is also strongly influenced by the demands for JHT (Journey Hazard test) to be met.

Admittedly, this may cause huge considerations to come up with a model being robust to serve this variety of products but less than this will inevitably cause major flaws in the actual scoring and ranking of products.

Finally, Medtech Denmark seeks an explanation as to why the draft includes a scoring model for 3.1 'Reduce Material Consumption', but not for 3.2 'Design for Recycling' or 3.3 'Recycled or Sustainably Sourced Materials'.

Purchasers should balance supplier requirements with their own internal handling capabilities

It is essential that the requirements placed on suppliers for more sustainable packaging are accompanied proportionality by assessing the actual quality and capacity of the healthcare sector's internal processing of used packaging and process actions when deploying the product.

It must be a prerequisite that the internal handling and disposal of used packaging and the processes involving the deployment of the product are at a level that justifies the demands for sustainability of the product. Failing to comply with this will lead to an over expenditure in which product qualities being paid for will not come into use. The healthcare system will purchase – and pay extra for – product characteristics which they will not really be able to use in the internal packaging handling.

This applies, as mentioned earlier, in supply forecasting. Inferior forecasting is inconsistent with the sustainability targets. Requiring the delivery of many small orders represent a large climate impact and also a major additional cost for suppliers.

It is essential that the internal packaging handling is in line with the requirements for sorting and disposal in the factions required of the supplier. Of equal importance, the healthcare sector must ensure that their contract with external operators, receiving and processing used packaging to regenerate and

utilize disposed material, comply with the same set of sustainability and documentation requirements

as the original medtech manufacturers are exposed to.

Finally, it might be considered to which extent the health sector sustainability standards can best be accommodated by introducing supplier packaging management system by which the healthcare sector pays the suppliers to handle their own packaging.

Internal healthcare sector dialogue

The work resort and work division within the healthcare sector between environmental officers, procurement officers and clinicians can make it difficult to meet fair and proportionate packaging requirements that can actually come into practice and usefulness during the busy everyday life of healthcare.

It is crucial that the necessary competences prevail by introducing a close dialogue between the three resort areas to accomplish a common understanding of the best possible way to achieve a higher level of sustainability under everyday working conditions. .

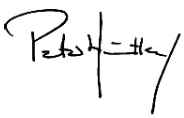
Final remarks

Despite the many reservations mentioned, Medtech Denmark finds that the Nordics' initiative towards an increased sustainability is exciting and necessary.

Consequently, we will offer our support to the future endeavor to put more emphasis on sustainability. As we see the Nordics' initiative, some further development will be needed to turn the Nordic Criteria for more Sustainable Packaging into an operative guideline for procurement officers in the Nordic countries.

Furthermore, as mentioned this development should provide a proper timing to secure compliance with the European development.

Best regards,



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