

Feedback from MedTech Denmark regarding the revision of the EU Public Procurement Directive (Directive 2014/24/EU)

The public healthcare system is by far the MedTech industry's most important – and in practice only – customer on the Danish market. Denmark has a tax-funded, public healthcare system, and the private market for healthcare services and medical devices is very limited. This means that access to the public market is decisive for Danish and international companies supplying medical devices in Denmark.

Public procurement is conducted through tender procedures. Consequently, the EU Public Procurement Directive, which in Denmark is implemented through the Public Procurement Act, constitutes one of the most central framework conditions for the medical technology industry. The Directive regulates the processes that contracting authorities must follow and aims to ensure transparency, equal treatment and effective competition in the internal market.

Directive 2014/24/EU is now facing a revision. MedTech Denmark considers this revision an important opportunity to strengthen the framework for value-creating, innovation-promoting and sustainable public procurement of medical devices – to the benefit of patients, healthcare professionals and society as a whole.

The challenge is not the directive – but its practical application

MedTech Denmark's fundamental assessment is that neither the Public Procurement Directive nor the Danish Public Procurement Act in themselves constitute the primary barrier to a well-functioning market for medical devices.

The challenges increasingly arise from procurement practices and from the way contracting authorities:

- draft tender documents
- define contractual terms
- apply award criteria
- implement framework agreements

In particular, within consumables, smaller equipment, assistive devices and welfare technology, non-binding framework agreements are often tendered with an estimated consumption over the contract period. In practice, this means that winning a framework agreement often merely functions as a "license to sell" – without any real guarantee of sales.

Estimated consumption is often based solely on historical data, which may be misleading and does not consider:

- changes in treatment methods
- technological development
- demographic shifts
- political priorities

The lack of volume commitments and reliable forecasts creates significant uncertainty for suppliers. This uncertainty propagates throughout the entire value chain and makes it difficult:

- to plan production
- to enter into agreements with subcontractors
- to offer competitive prices

As a result, Denmark increasingly appears as a less attractive market for suppliers of medical devices – to the detriment of innovation, security of supply and long-term cost efficiency in the healthcare system.

It is important to emphasize that these challenges cannot be resolved solely through a revision of the Public Procurement Directive, as the directive is fundamentally a procedural instrument and, as a general rule, does not regulate contract content. Nevertheless, there are several areas where the directive can be adjusted to support more balanced and value-creating procurement practices.

Proposals for improvements in a revision of the Public Procurement Directive

Introduction of a general clause against manifestly unbalanced contractual terms

MedTech Denmark proposes the introduction of a form of general clause in the Public Procurement Directive that can limit the use of manifestly unreasonable and unbalanced contractual terms.

Such a clause could:

- set limits on the use of non-binding framework agreements without reliable forecasts
- prevent the systematic transfer of disproportionate risk to the supplier
- strengthen the principle of proportionality in contract design

This would represent a departure from the Directive's current character as a procedural directive, but it is considered necessary to counteract inappropriate practices that undermine the Directive's overall objectives.

Strengthening and harmonization of award criteria

Public procurement of medical devices should to a much greater extent reflect the total value created by technology.

MedTech Denmark therefore recommends:

- an obligation, when procuring medical devices, to give weight to:
 - patient benefits
 - clinical performance
 - impact on workflows
 - total economic consequences for the healthcare system and society

In addition, a common European understanding of “the most economically advantageous tender” (best price-quality ratio) should be introduced so that:

- value creation is understood consistently across Member States
- innovation and quality are not systematically displaced by the lowest price

This would support the transition towards more value-based procurement and ensure more consistent market conditions across the EU.

Mandatory market dialogues

Early and structured dialogue with the market is crucial when procuring complex medical technology.

MedTech Denmark proposes:

- mandatory market dialogues prior to the tendering of medical technology
- requirements for genuine involvement of clinicians and healthcare professionals in the dialogue

This would:

- improve the quality of technical specifications
- reduce the risk of failed tenders
- ensure that procured solutions match clinical needs

Reduction of administrative burdens – particularly for SMEs

The medical technology industry largely consists of small and medium-sized enterprises. Administrative burdens disproportionately affect these companies.

Therefore, it is proposed to:

- harmonize documentation requirements across all Member States (e.g. a common EU service certificate)
- significantly simplify and reduce the ESPD

- introduce maximum time limits for contracting authorities to create a more balanced process
- require the mandatory use of lots in large procurements to ensure SME access

This is particularly relevant in Denmark, which – despite its size – is among the EU countries conducting the largest number of large, centralized procurements, often without subdivision into lots.

Sustainability in a European perspective

Sustainability should be strengthened in public procurement, but in a way that supports the internal market.

MedTech Denmark recommends:

- the use of European-recognized eco-labels (e.g. the EU Ecolabel) rather than national labels
- limiting national minimum requirements that go beyond EU legislation
- granting contracting authorities' clear legal authority to require sustainable energy sources in production

This would allow contracting authorities to prioritize climate and environmental considerations without creating legal uncertainty regarding the subject matter of the contract.

“Made in Europe” is not the right approach

MedTech Denmark shares MedTech Europe's assessment that protectionist “Buy European” approaches are not an appropriate solution.

Medical technology is characterized by:

- complex, global supply chains
- highly specialized components
- international division of labor

A European preference scheme risks:

- limiting patient access
- increasing costs
- hampering innovation

Instead, the EU should focus on:

- regulatory modernization
- strengthening research, innovation and skills
- value-based market access
- supply chain resilience

Any discussion of European preference schemes should take place in close dialogue with industry and with patients' interests as the primary consideration.

This discussion should also be seen in light of the EU's experience with the International Procurement Instrument (IPI). Medical devices were the first sector to be directly affected by the application of the IPI, and this has illustrated the significant practical and legal complexities associated with preference-based procurement measures in a highly globalized and regulated sector.

The implementation of the IPI in the medical technology area has raised concerns regarding increased administrative burdens, legal uncertainty and potential disruptions to procurement processes, without demonstrably improving market access or supply security. These experiences underline the risks of extending "Made in Europe" or similar preference schemes to medical devices and reinforce the need for proportionate, predictable and value-based procurement frameworks developed in close dialogue with industry and with patients' interests as the primary consideration.

National gold-plating undermines the internal market

Although the internal market functions relatively well for goods, capital and labor, there are significant challenges across horizontal EU legislation.

Directives in areas such as sustainability and digitalization are implemented:

- differently
- at different times
- with national additional requirements

A clear example is the Packaging Directive, where:

- national registration schemes
- varying cost structures
create significant barriers – particularly for SMEs – even when products are CE-marked.

This fragments the market and runs counter to the objectives of EU legislation.

Concluding remarks

The revision of the EU Public Procurement Directive (Directive 2014/24/EU) represents a strategically and politically important window to modernize the framework for public procurement and ensure that the procurement system more effectively supports the Union's overarching objectives in health, innovation, sustainability and industrial competitiveness.

If the revision focuses solely on procedural regulation and technical adjustments, the EU risks maintaining a procurement regime that in practice counteracts political ambitions for value-based healthcare, security of supply and technological development. Conversely, the revision offers a genuine opportunity to make public procurement an active and legitimate policy instrument – within the framework of the fundamental principles of public procurement law.

Public procurement constitutes a substantial share of total public expenditure in the EU and is therefore one of the most powerful policy instruments available to decision-makers. The Public Procurement Directive should thus better support value-based procurement, where contract awards are based on the best price-quality ratio, understood broadly and consistently across Member States.

This entails a clearer recognition that contracting authorities, when procuring medical devices, may legitimately – and in relevant cases should – take into account patient-related benefits, clinical performance, workflows and total economic effects, provided that these criteria have a clear and objective link to the subject matter of the contract and are applied in accordance with the principles of equal treatment, transparency and proportionality.

At the same time, the revision should address the structural challenges in current procurement practices that weaken Europe's security of supply and investment incentives. The widespread use of non-binding framework agreements without a reliable indication of expected volumes leads to a one-sided allocation of risk to suppliers, which may ultimately result in higher prices, reduced competition and increased vulnerability in supply chains.

A clarification in the directive – for example in the form of general frameworks or considerations counteracting manifestly unbalanced contractual terms – could enhance predictability for economic operators without altering the Directive's fundamental nature as a procedural instrument.

Furthermore, the revision represents an important opportunity to reduce unnecessary administrative burdens and strengthen access to public procurement for small and medium-sized enterprises. More harmonized application of documentation requirements, significant simplification of the ESPD and more balanced procedural obligations between contracting authorities and tenderers would be consistent with the principle of proportionality and the Directive's objective of promoting effective competition and genuine market access across Member States. Likewise, a more consistent use of subdivision into lots could contribute to broader participation and enhanced competition.

MedTech Denmark view the revision of the Public Procurement Directive as a crucial opportunity to create a more future-proof procurement regime that places patients' needs at the centre, promotes quality, innovation and sustainability in practice, and at the same time strengthens Europe's industrial and healthcare resilience.

MedTech Denmark look forward to an open and constructive dialogue with the European Commission, the European Parliament and the Member States to ensure a public procurement framework that both respects the fundamental principles of EU law and safeguards the internal market – while actively supporting the Union's political ambitions in the fields of health and innovation.



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