MedTech Europe
from diagnosis to cure

Carbon Border Adjustment Mechanism:

Response to EC Public Consultation on the Extension of CBAM to Downstream Products, Anti-Circumvention Measures and Rules for the Electricity Sector

Brussels, 25 August 2025

EXECUTIVE SUMMARY

Global carbon pricing next to boosting more renewable energies and energy efficiency is key for combating climate change. It levels the playing field, rewards innovation and drives emission reductions cost effectively.

MedTech Europe shares the general motivation of preventing carbon leakage in support of fair carbon pricing as long as global climate ambitions differ. At the same time, we have seen several instances where well-intentioned horizontal legislation, such as the EU Deforestation Regulation or Carbon Border Adjustment Mechanism, introduce significant data collection and reporting requirements with associated costs for medical technology manufacturers, which make us challenge the robustness of CBAM for the medical technology sector from an economic, environmental and social sustainability perspective. We are also concerned with conflicts with the sector specific regulatory system established by Regulations (EU) 2017/745 on Medical Devices (MDR) and 2017/746 on in-vitro Diagnostic Medical Devices (IVDR) as CBAM related supplier switches trigger certain MDR/IVDR requalification and regulatory re-approval obligations.

At this stage, MedTech Europe has no evidence of carbon leakage in the MedTech Sector in Europe due to difference in global carbon cost that would in our view justify the inclusion of medical technologies or steel and aluminium intense components used in the manufacturing and assembly of medical technologies in Europe, in the scope of an extended CBAM. We very much appreciate the current efforts towards simplification, which should be maintained and strengthened, including the de minimis threshold and use of default values for emission calculation. However, we still observe significant challenges regarding the technical feasibility of implementing CBAM on highly complex products, such as medical technologies and their supply chains that can be up to 30 tiers from materials to the final device. It is not uncommon for routinely used devices to have hundreds and thousands of different components, including iron-, steel and aluminium intense components.

Contrary to the ambition of CBAM to level the global playing field, extending CBAM to medical technology components could even stimulate a risk of "manufacturing" leakage from the EU to non-EU countries as the sourcing of global components would become more expensive for manufacturing operations in Europe, considering that global markets do not compensate for higher manufacturing costs occurring in Europe. The medical technology sector has a positive trade balance of 11 bn EUR and offers more than two million different medical technologies to prevent disease, diagnose, treat and cure patients.[1]

EU internally, additional CBAM costs cannot be passed on in this sector due to fixed reimbursement and public tendering, rendering carbon border adjustment in our view economically unsustainable at EU MedTech company level.

Manufacturing leakage to non-EU regions would also run counter the EU's wider environmental protection objectives considering that other geographical jurisdictions generally apply lower environmental standards than the EU.

[1] MedTech Europe Facts and Figures 2024

In conclusion:

- The additional administrative burden and cost associated with an extended CBAM scope to steel and aluminium intense products in healthcare, the potential negative implications on the overall attractiveness of Europe for MedTech manufacturing and the subsequent negative implications on the environment as well as on the availability of medical technologies for patients, in our view run counter the EU Commission's sustainable prosperity and competitiveness goals.
- Medical devices and in vitro diagnostic medical devices (IVDs) as regulated under the sector specific MD and IVD Regulations and iron-, steel and aluminium-intensive components used therein should not fall within an extended CBAM scope. The 50-tons exemption suggested via the recently adopted Omnibus Regulation for current goods needs to be maintained.
- We consider other tools than CBAM, such as the upcoming EU Strategy for global climate and clean energy transition as a vehicle for reinforcing climate diplomacy on global carbon pricing, incentives for healthcare decarbonisation across the EU Multiannual Financial Framework and well coordinated value-based public procurement, better suited to support Europe's medical technology sector in its global decarbonisation efforts and a successful implementation of EU climate goals.

We thank the European Commission for the possibility to contribute to the call for evidence and public consultation on this critical topic and provide further MedTech specific background information in this paper.

MedTech specific comments on the suggested CBAM scope extension and anti-circumvention measures

- ### Definition of "steel and aluminium intensive downstream products" and practical implications for European medical technology manufacturers

In 2023, as part of the European Green Deal, the EU introduced the Carbon Border Adjustment Mechanism (CBAM) as a climate instrument to prevent carbon leakage. CBAM currently covers cement, iron and steel, aluminium, fertilisers, electricity, and hydrogen, with the aim of ensuring that imports face the same carbon cost as EU production under the EU Emissions Trading System (EU ETS1). In the Steel and Metals Action Plan the Commission committed to presenting a legislative proposal by the end of 2025, extending the scope of CBAM to certain steel and aluminium-intensive downstream products and including additional anti-circumvention measures.

Iron, steel and aluminium intense downstream products in the MedTech sector and its supply chain include for example the following, to name but a few:

- Oscilloscopes, spectrum analysers and other instruments and apparatus for measuring or checking electrical quantities, excluding meters of heading
- Instruments and apparatus for measuring or detecting alpha, beta, gamma, X-ray, cosmic or other ionising radiation
- Instruments and apparatus for physical or chemical analysis
- Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electromedical apparatus and sight-testing instruments
- Lenses, prisms, mirrors and other optical elements
- Electrical parts of machinery or apparatus
- Semiconductor devices
- Electronic integrated circuits
- Printed circuits

- Machinery parts, not containing electrical connectors, insulators, coils, contacts or other electrical features
- Centrifuges, including centrifugal dryers; filtering or purifying machinery and apparatus, for liquids or gase
- Refrigerators, freezers and other refrigerating or freezing equipment, electric or other; heat pumps other than air-conditioning machines of heading
- Surgical steel trays and surgical instruments, such as scalpels, forceps, scissors or retractors
- Orthopaedic appliances and implants, such as bone screws, plates, and rods
- MRI-compatible surgical tools – although MRIs require non-magnetic materials, certain non-ferromagnetic stainless steels and aluminium tools are used during MRI-guided surgery
- Dental tools – dental probes, drills, and pliers
- Wheelchairs
- Hospital beds
- Prosthetic limbs
- Sterilisation trays
- Endoscopic equipment – some parts (like tube tips or internal shafts)
- Stethoscopes

With respect to medical technologies and steel and aluminium-intense components used therein, we confirm the relevance of addressing scope 3 emissions in MedTech's decarbonisation journey. We fully support global carbon pricing, more renewable energies and energy efficiency as key decarbonisation levers in the MedTech sector and its value chain.

Administrative burden, economic and technical feasibility

However, CBAM introduces extensive data collection and reporting requirements for medical technologies, which generate significant costs that can outweigh the decarbonisation incentive that CBAM aims to generate. Based on data prior to the revision and introduction of the new 50t threshold, the cost of reporting (FTEs required to collect data from suppliers, IT systems etc.) for example can be 100 times higher than the actual carbon tax, meaning that for 100 EUR paid as carbon price an investment of 100 000 EUR in reporting was needed in certain cases.

Extending the scope to medical technologies and steel and aluminium-intense components used therein will exponentially increase complexity, administrative data collection and reporting burden and associated costs, which risks disadvantaging European medical technology manufacturers in export markets that do not enact similar carbon pricing ambitions and do not compensate for CBAM costs. The medical technology (MedTech) sector exhibits significant trade intensity, with a significant surplus in international trade. Europe, in particular, has a positive trade balance in medical devices, with a surplus of €11 billion in 2023, and the US, China, Japan, and Mexico are key trading partners.

Within the EU, national reimbursement rules fix prices paid for medical technologies that are procured publicly so that increased costs stemming from the implementation of CBAM cannot be unilaterally passed on.

CBAM in its present form already is a considerable administrative burden when it comes to the determination of carbon weight, its price and origin etc.

The deadline of reporting the end of the month after the quarter has demonstrated to be a constraint considering the high variety of different moving parts and the dependence of medical technology manufactures on the providing of timely, accurate and complete information in order to fulfil their own (extensive) CBAM information

requirements. More time for data gathering will be essential. The lack of data, their quality, accurateness and representativeness, such as for above mentioned determination of carbon weight, its price or origin etc, remains of serious concern. Too often, manufacturers rely on estimated industry averages by the Commission as real world data is simply not available. Expanding CBAM to cover downstream goods, such as medical devices with PCBs or cables containing aluminium or steel, would add significant complexity. Suppliers often source metals from multiple countries, including those without traceability requirements, making consistent emissions tracking extremely difficult and time-consuming.

Besides, a large number of CBAM reports have been submitted to competent authorities due to the 150 EUR de minimis threshold. This issue will be compounded by the introduction of additional reports if CBAM is expanded, leading to even more backlog and administrative burden for competent authorities and reporting entities. Consequently, an expansion is only practical if the proposed 50 tonne threshold, among other simplifications, is finally adopted. This will eliminate reports which do not further the goal for which CBAM was created, while still capturing significant carbon emissions embedded in the products of the most consequential importers. Additionally, the stated objectives of an extended CBAM could be more effectively and proportionately achieved through existing mechanisms.

CBAM risks to patient access and innovation

Increasing the cost or complexity of importing these components could have real consequences: delays in production or imports, increased cost to health systems, and reduced access to critical technologies. Materials and/or suppliers of materials, such as iron, steel or aluminium, cannot be easily changed based on carbon intensity or emission reporting in the highly regulated medical technologies sector, since supplier qualification is governed by strict quality, safety, and patient care standards. Such changes can represent a “significant change” that triggers lengthy requalification processes and in many cases regulatory re-approvals under the sector specific regulatory system set by Regulations (EU) 2017/745 on Medical Devices (MDR) and 2017/746 on in-vitro Diagnostic Medical Devices (IVDR). As a consequence, access to medical technologies for patients and healthcare professionals can face delays and at worst prevent patients access to life saving and life sustaining medical products.

However, considering the strategic relevance of medical technologies for public health, policies should support patient access, affordability, and innovation. As currently designed, CBAM will not drive decarbonisation in MedTech the way it might in more commodity-based sectors.

Risks of circumvention and resource shuffling: CBAM for electricity as a good

The current approach of emissions reporting under the Commission Implementing Regulation (EU) 2023/1773 consists of measuring *actual* embedded emissions of imported products by tracing them back to the individual manufacturing plants where they were produced. This makes reporting very accurate and relevant for own decarbonisation pathways of downstream manufacturers, such as MedTech that use CBAM basic goods, such as iron, steel or aluminium.

At the same time, there is indeed a risk that CBAM in its present form unintentionally creates an incentive for resource shuffling, whereby currently covered CBAM goods produced in low-carbon production facilities in non-EU countries are redirected to European customers while high-carbon sales continue or even increase in non-EU markets, which would undermine its own environmental effectiveness while benefiting producers who can reallocate clean and less clean production between the EU market and non-EU markets. Assessing the appropriateness of currently applied **default values** on electricity seems a tangible way forward to us.

Conclusion

To move beyond CBAM as "a paperwork exercise" with limited added value, a global (not only EU-wide) effort to determine carbon pricing should be pursued in the interest of competitiveness, market access as well as human and planetary health. Other tools, such as incentives for healthcare decarbonisation across the EU Multiannual Financial Framework, well coordinated value-based public procurement and the upcoming EU Strategy for global climate and clean energy transition, are in our view better suited to support Europe's medical technology sector in its global decarbonisation efforts and a successful implementation of EU climate goals.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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