Press Release
27 November 2025 08:45:00 CET

I-Tech strongly rejects the European Commission's proposed non-renewal of Medetomidine under the EU Biocidal Products Regulation (BPR)

I-Tech AB (publ), developer of the innovative antifouling technology Selektope®, announces that the European Commission has drafted an implementation act proposing the non-renewal of the approval of Medetomidine (Selektope®) under the European Union (EU) Biocidal Products Regulation (BPR).

The draft implementation act, which is yet to be published, will be discussed at the 90th Standing Committee on Biocidal Products (SCBP) meeting taking place on 10 December.

I-Tech firmly disagrees with the European Commission's proposal for the non-renewal of Medetomidine - a view supported and shared by a broad coalition of stakeholders - and continues to engage in close dialogue with the European Commission and the EU Member States represented in the SCBP.

According to an extensive, independent socio-economic analysis, a non-renewal scenario would have a disproportionate negative impact on the European economy, the environment, and society. Instead, a renewal of Medetomidine's approval under derogation criteria in the EU BPR regulation is entirely justified.

In response to the proposal, I-Tech is calling on the European Commission to urgently review the EU's renewal and risk assessment and management process for Medetomidine and is calling on EU Member States to not support the current non-renewal proposal.

Markus Jönsson, CEO of I-Tech, says: *"a proposal from the European Commission for the non-renewal of Medetomidine is disappointing. Despite receiving detailed rebuttals and scientific evidence from I-Tech and other stakeholders, the discussion risk proceeding on flawed analysis and misleading scientific conclusions, including:*

- *Pharmaceutical effects of Medetomidine from its use as a sedative have been incorrectly labelled as "endocrine disrupting", despite having no relevance to its antifouling application.*
- *The Analysis of Alternatives (AoA) conducted by Norway contains several obvious errors but was accepted by the Biocidal Product Committee (BPC) without correcting errors.*

This approach by the European Commission risks stifling innovation in the field of marine antifouling, undermining the competitiveness of European shipyards and marine coating manufacturers, and compromising EU climate and sustainability objectives."

When the AoA was published, many external stakeholders highlighted the flaws in Norway's approach during a public consultation phase in 2024. However, no corrective measures have been taken to update the material supporting a decision to date.

Even more alarming for the Maritime industry is that the flawed AoA for Medetomidine is creating a negative precedent. It is now being cited as evidence for further exclusion of other active substances from the EU market.

I-Tech believes that a coordinated re-evaluation of the entire antifouling biocide portfolio should be undertaken, instead of the current fragmented, substance-by-substance approach to reviewing. This approach would ensure consistency, transparency, and the inclusion of all relevant stakeholders in shaping Europe's antifouling biocide toolbox.

I-Tech is also urging the European Commission to undertake a rigorous, science-based and performance-oriented reassessment that takes full account of Selektope®'s unique, low-impact mode of action and demonstrated environmental benefits.

Despite holding full approval under the EU BPR since 2016, a lack of regulatory product category leadership, combined with Member State approval bottlenecks have prevented Selektope®-based antifouling products from reaching the EU market. As such, only 2% of I-Tech's net sales of Selektope® for the year-to-date 2025 came from customers within the EU.

Meanwhile, Asian markets including South Korea, Japan, and China have embraced Selektope®, giving their shipyards a clear competitive advantage through state-of-the-art, fuel-saving coating systems.

Markus Jönsson concludes: *"Member States now have an opportunity to demonstrate their support for innovation, sustainability and the future competitiveness of EU's maritime industry by rejecting the Commission's proposed non-renewal of Medetomidine and call for a coordinated re-evaluation of the entire toolbox in the anti-fouling biocide group."*

I-Tech expects voting on the implementation act to occur sometime in the first half of 2026.

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About I-Tech AB
I-Tech is a biotechnology company that has developed the antifouling technology Selektope®, an active substance that prevents barnacle attachment on submerged surfaces such as ships and boat hulls. By increasing the anti-barnacle performance in marine paint systems (e.g. antifouling coatings), fuel and maintenance costs are reduced ang vessel energy efficiency improved. I-Tech has obtained the necessary regulatory approvals for Selektope® and has several of the world's largest manufacturers of marine antifouling coatings as customers. The company's share is listed for trading on Nasdaq First North Growth Market in Stockholm. The Company's Certified Adviser is DNB Carnegie Investment Bank AB. For more information visit our website www.i-tech.se.

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This information is information that I-tech is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-11-27 08:45 CET.

Attachments

I-Tech strongly rejects the European Commission’s proposed non-renewal of Medetomidine under the EU Biocidal Products Regulation (BPR)