KN2026/00808 – Baxter AB remissvar *2026-05-06*

Baxter AB has reviewed the memorandum *"Tillsyn enligt EU:s f gasförordning i fråga om elektriska brytare, desfluran och märkning av dosinhalatorer."*

Baxter AB supports the objective of reducing emissions of fluorinated greenhouse gases and acknowledges that Regulation (EU) 2024/573 significantly restricts the use of desflurane. As clarified by the European Commission, the Regulation does not impose a total prohibition but permits the continued use of desflurane where the treating physician, exercising professional clinical judgment, determines that alternative anesthetics are not suitable due to the patient's specific medical needs. Such use does not require prior authorization.

Baxter AB notes that the memorandum proposes assigning responsibility for the supervision of desflurane use to Läkemedelsverket, and introduces a legal basis for the authority to adopt provisions on fees related to supervisory and control activities.

Baxter AB recognizes that Member States may introduce fees to cover the costs of regulatory monitoring, control, and market surveillance. Such administrative fees are a common feature of supervisory systems and may be justified where they are clearly linked to the performance of specific regulatory functions.

At the same time, Baxter AB emphasizes the importance of distinguishing between taxes, general contributions, and administrative fees. While fees for supervisory activities may be justified, measures that are, in practice, closely linked to, or triggered by, the use of a medicinal product give rise to distinct legal and proportionality considerations.

In this context, Baxter AB is concerned that fees introduced within the framework of supervision of desflurane use, depending on their design and application, could effectively function as a charge on the use of desflurane. Given that such use is already highly restricted and limited to exceptional cases where it is clinically justified, this may result in disproportionate effects.

Moreover, any financial burden associated with the use of desflurane risks indirectly influencing clinical decision-making. Under Regulation (EU) 2024/573, in particular Article 13(8), treatment decisions must remain based solely on the physician's clinical judgment and considerations of patient safety. Measures that create economic disincentives in this context risk undermining this principle.

In addition, if supervisory fees were structured in a manner that effectively targets the use of a medicinal product with a valid marketing authorization, this would raise concerns regarding proportionality, potential discriminatory effects, and the absence of a clear legal basis in the Regulation (EU) 2024/573 for such an approach.

In light of the above, Baxter AB considers that the use of desflurane in accordance with Article 13(8) of Regulation (EU) 2024/573, namely, where clinically justified on the basis of the patient's individual needs - should not be subject to fees that are directly or indirectly linked to its use.

Baxter AB has no further comments.