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CLIMA.C.1/AK

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Subject: Open Letter on the restrictions on the use of desflurane

Dear Mr Marin and other co-signatories,

Thank you for your letter and for raising your concerns regarding the upcoming restriction on desflurane as outlined in Article 13(8) of the F-Gas Regulation (Regulation (EU) 2024/573). As DG Climate Action, Unit C1 is responsible for the F-Gas Regulation, I am responding on behalf of all addressees of your email.

First, let me acknowledge the importance of stakeholder participation in designing new policies, particularly where healthcare and environmental considerations intersect. Extensive consultations were held on this topic with the stakeholder community during the preparation of the impact assessment, including the feedback received through the "Have your Say" better regulation tool ([1]).

Article 13(8) of the F-Gas Regulation was especially designed to strike the balance by restricting routine use of desflurane due to its high climate impact, while ensuring continued access in all situations where it is necessary from a medical point of view. The exception stated in this Article allowing use of desflurane where strictly required and no other anaesthetic can be used on medical grounds, means that anaesthetists may continue to use desflurane when, in their professional judgment, no other anaesthetic can be used because of a patient's specific medical needs.

([1]) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12479-Review-of-EU-rules-on-fluorinated-greenhouse-gases/feedback_en?p_id=30057883&page=1

Your letter refers to the national decommissioning of desflurane by the NHS in the UK, where desflurane can no longer be used except for a specific set of procedures, while pointing out that also in these cases anaesthetists should continue to decide on a case-by-case basis the best anaesthesia approach for these procedures given that these procedures are also routinely, and successfully, performed without the use of desflurane. The F-gas Regulation gives anaesthetists a similar choice based on medical grounds and allows to do so also for other medical conditions than the ones you mention in your letter. Hence the Regulation does not limit access to the best medical treatments.

Regarding the administrative feasibility, it is important to note that a prior authorisation is not required. Rather, the healthcare institutions must document the medical justification – typically this could be done through existing clinical records – and be prepared to present such documentation upon request by national authorities or the European Commission. The administrative effort for complying with the measure is therefore considered rather low for the medical practitioner and the health care institution.

Also, we would like to clarify that the F-Gas Regulation is an important part of the EU's broader climate policy aimed at reducing emissions of potent greenhouse gases. The global warming potential (GWP) of desflurane is significantly higher than that of other commonly used anaesthetics. The fact that desflurane is a short-lived gas, as you point out, means that its climate impact in the short term is rather underestimated by the fact that the metric GWP over a 100 years was used. This metric is generally used in climate policies to compare the impact of different greenhouse gases over time. If one uses a metric that looks at the short-term impacts, then the impact of desflurane on global warming would increase in relative terms ([2]).

As you correctly point out, a reduction of desflurane will result in a quick win for the climate. Annual emission savings in the EU from anaesthetic agents are estimated to be at least 1 million tonnes CO_2 equivalents using the GWP 100 metric ([3]).

([2]) An atmospheric lifetime shorter than 100 years will mean that the climate impact is underestimated by the GWP based on 100 years. This is evident when the GWP(20 years) is referred to, which is 7020 by the 6th Assessment Report of the International Panel of Climate Change (IPCC) vs 2590 for the GWP(100years).

([3]) P. 30 of "Commission Staff working document, Impact Assessment report Accompanying the Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014", available at: https://climate.ec.europa.eu/document/download/9013881e-8d5d-429e-9112-c908f127c833_en?filename=f-gases_impact_assessment_en.pdf

Consequently, the Commission considers that the desflurane restriction is a proportionate and evidence-based measure that supports climate objectives while fully preserving the ability of clinicians to act in the best interests of their patients.

Yours sincerely,

[e-signed]
Tom VAN IERLAND
Head of Unit