EN
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Answer given by Mr Hoekstra
on behalf of the European Commission
(15.1.2025)

The Commission and the Member States' competent authorities are aware of the temporary constraints to comply with the new labelling requirement in Regulation (EU) 2024/573[1] (the F-gas Regulation) from 1 January 2025 for medicinal products, because of the specific approval procedures related to labels on such products.

To prevent this situation from leading to a disruption of supply and to facilitate a uniform application of the rules in the Member States, the Commission has included recital (7) in the Commission Implementing Regulation 2024/2174[2] on the format of the labels stating that the '*enforcement of the provisions should take into consideration the regulatory processes for changing existing labelling requirements or the process of re-labelling equipment or products already placed on the EU market'*. Moreover, the Commission has explained to the competent authorities in the Member States the elements that are relevant to consider when enforcing this provision in a proportionate manner. Finally, the Commission has included a document and a dedicated code in the customs database TARIC (the integrated Tariff of the European Union) which will temporarily enable smooth import of metered dose inhalers even in the absence of the F-gas labelling and the Commission has informed the customs authorities and the economic operators about this measure.

With these actions, the Commission aims to ensure that the new labelling requirement will not negatively impact the supply of medicines in the EU.

[1] https://eur-lex.europa.eu/eli/reg/2024/00573/oj
[2] https://eur-lex.europa.eu/eli/reg_impl/2024/2174/oj