



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 201

Communication from the Commission - TRIS/(2024) 1640

Directive (EU) 2015/1535

Notification: 2024/0037/AT

Forwarding of the response of the Member State notifying a draft (Austria) to comments (5.2) of European Commission.

MSG: 20241640.EN

1. MSG 201 IND 2024 0037 AT EN 25-04-2024 24-06-2024 AT ANSWER 25-04-2024

2. Austria

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4. 2024/0037/AT - C10P - Pharmaceuticals

5.

6. Regarding Notification 2024/37/AT:

Austria is aware of the importance of the European solidarity mechanism. For this reason, a corresponding derogation has now been included in the Ordinance, according to which it is permissible to fall below the stock levels if this is necessary to fulfil the solidarity mechanism.

As regards the Commission's concern to ensure a sufficient transitional period (*vacatio legis*) in the event of a revision of the annex, it is noted that, from Austria's perspective, this already follows from the principle of proportionality. In any event, a corresponding passage has been included in the explanatory notes for clarification.

The assumption that marketing authorisation holders already hold stocks corresponding to three months' requirements is based on communications from industry representatives. As part of a questionnaire survey carried out in autumn 2022, these representatives stated that companies have stocks of three to four months' supply per product. Due to the delayed entry into force (ten months after announcement), no impact on the other EU markets is expected.

European Commission

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