



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2024/0037/AT (Austria)

Ordinance of the Federal Minister for Social Affairs, Health, Care and Consumer Protection concerning the stockpiling of proprietary medicinal products for human use

Date received : 24/01/2024

End of Standstill : 25/04/2024 (closed)

Message

Message 001

Communication from the Commission - TRIS/(2024) 0212

Directive (EU) 2015/1535

Notification: 2024/0037/AT

Notification of a draft text from a Member State

Notification – Notificación – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20240212.EN

1. MSG 001 IND 2024 0037 AT EN 24-01-2024 AT NOTIF

2. Austria

3A. Bundesministerium für Arbeit und Wirtschaft

Abteilung V/8

A-1010 Wien, Stubenring 1

Telefon +43-1/71100-808805

E-Mail: not9834@bmaw.gv.at

3B. Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz

VI - Humanmedizinrecht und Gesundheitstelematik

A/4 - Abteilung für Rechtsangelegenheiten Arzneimittel, Medizinprodukte, Apotheken, Krankenanstalten, übertragbare Krankheiten

A-1030 Wien, Radetzkystraße 2



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4. 2024/0037/AT - C10P - Pharmaceuticals

5. Ordinance of the Federal Minister for Social Affairs, Health, Care and Consumer Protection concerning the stockpiling of proprietary medicinal products for human use

6. Medicinal products

7.

8. Stockpiling defined proprietary medicinal products for human use in Austria is intended to prevent shortages of medicinal products caused by supply bottlenecks and to safeguard the supply of medicinal products in Austria.

The main aspects of the draft legislation are an obligation imposed on marketing authorisation holders to stockpile proprietary medicinal products for human use and obligations imposed on marketing authorisation holders to provide notification to the Federal Office for Safety in Health Care.

9. Supply bottlenecks and shortages of medicinal products, in particular with respect to proprietary medicinal products for human use that require a prescription, are a global problem that has been repeatedly encountered in the past and became increasingly apparent again in light of the COVID-19 pandemic and the related delays in the supply chain. In addition, the situation has been exacerbated by an exceptionally high wave of infection (European/global) in the 2022/23 winter season.

10. Reference to the basic texts: No basic text available

11. No

12.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu