Message 001

Communication from the Commission - TRIS/(2025) 1429

Directive (EU) 2015/1535

Notification: 2025/0276/NL

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – 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 késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx 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: 20251429.EN

1. MSG 001 IND 2025 0276 NL EN 03-06-2025 NL NOTIF

2. Netherlands

3A. Centrale dienst voor In- en Uitvoer, Douane Groningen. cdiu.notificaties@douane.nl

3B. De Directie Wetgeving en Juridische Zaken van het Ministerie van Volksgezondheid, Welzijn en Sport.

4. 2025/0276/NL - C10P - Pharmaceuticals

5. Regulation of the Minister for Health, Welfare and Sport, of date TBC, No TBC, amending the Medicines Act Regulation in connection with delivery on doctor's certificate and shortage decisions (Chain ID 27698)

6. Medicinal products as referred to in Directive 2001/83/EC.

7.

8. The amendment to the Medicines Act Regulation relates to the way in which the Health Care and Youth

Inspectorate [Inspectie Gezondheid en Jeugd, IGJ] may permit the introduction of a medicinal product from another Member State or a country with a mutual recognition agreement in the Netherlands in the event of a shortage affecting the delivery of a medicinal product for which a marketing authorisation has not been granted, due to a special need of a patient. The amending regulation is a continuation of existing law, but includes a modernisation of the wording of the article to better align with practice, and to align with the new basis in Article 40 of the Medicines Act.

Making medicinal products available on the basis of this regulation does not affect the professional assessment made by physicians when prescribing. Physicians remain responsible for issuing prescriptions for medicinal products and always do so on their own initiative and for each patient individually.

Mutual recognition is not relevant to this provision, since this concerns (part of) the national implementation of an exception on the basis of Article 5 of Directive 2001/83/EC. This exception is without prejudice to the recognition of prescriptions from prescribers from other EU Member States or to the rights and obligations of marketing authorisation holders of medicinal products as referred to in the aforementioned Directive.

9. In view of a recent court ruling on the relationship between the Medicines Act Regulation and the basis for this regulation in Article 40 of the Medicines Act, the Act will be amended on this point and the regulation also needs to be updated. With the exception of a few details, no substantive changes are envisaged compared to the existing regime. With the entry into force of this amending regulation, administrative burdens will be avoided and patients would not be left without medicines in the event of a shortage of medicines to the extent that exemptions at individual level would not be acceptable due to the time involved.

This notification is made as a precaution because it cannot be excluded that the scheme does not contain technical requirements, although it is not intended to lay down technical requirements. The regulation, like its predecessor, lays down the conditions for prescribers, manufacturers, wholesalers and pharmacists to apply for an exemption in the event of a shortage of medicinal products (which cannot be solved by other means) in order to import into the Netherlands and distribute medicinal products for which no marketing authorisation has been granted in the Netherlands, but which have been granted one in another country, for a limited period of time. The conditions laid down do not go beyond what is necessary because, on the one hand, they ensure that the market in medicinal products is not distorted, or as little as possible, and, on the other hand, patient safety and thus public health are safeguarded. That exemption is also non-discriminatory as it may be invoked by any person authorised to deal with medicinal products. The possibility of granting an exemption does not go beyond what is necessary to protect the interests of public health: in times of (major) shortages it is imperative that medicinal products for which a Dutch marketing authorisation has been granted may be brought to the Dutch national territory to prevent (large numbers of) patients from being left without medicines. This is the least restrictive means of achieving this objective, since the exemption may only be used if it is established that no adequate medicinal alternative exists (such as a similar medicinal product). In addition, the exemption is always temporary and, before the exemption is granted, other ways of mitigating the shortage of medicinal products will be considered, such as using magistral preparations, where appropriate.

10. Numbers or titles of basic texts:

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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