Message 001

Communication from the Commission - TRIS/(2025) 3687

Directive (EU) 2015/1535

Notification: 2025/0768/BE

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: 20253687.EN

1. MSG 001 IND 2025 0768 BE EN 18-12-2025 BE NOTIF

2. Belgium

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4. 2025/0768/BE - C10P - Pharmaceuticals

5. Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool

6. the following medicinal products for human use authorised or imported in parallel into Belgium:
- subject to prescription
- reimbursable
- other medicinal products (not subject to prescription, non-reimbursable) that share the same ATC5 code

7.

8. The measure provides for the creation of a stock monitoring system offering a comprehensive and in-depth view of the availability of a series of medicinal products authorised on the Belgian market. This scheme will make it possible to anticipate shortages, through increased transparency of stocks and better understanding of demand, while ensuring optimal monitoring of unavailability in order to ensure continuity of care and strengthen the availability of medicinal products.
This will be achieved through the compulsory disclosure of a series of data by the stakeholders referred to in the text. In all, there are three distinct obligations, all of which apply to the various stakeholders, data and frequencies.

9. The envisaged measure pursues a public health objective in that it aims to strengthen the fight against shortages of medicinal products in Belgium, both preventively, before they occur, and reactively, when they are already present. These shortages have adverse consequences for patients (stress, treatment errors, therapy changes, less effective or more expensive treatments, worsening of symptoms) and for society (increased pressure on health services, increased costs for social security).
The measure selects precisely those medicinal products that should be subject to mandatory data reporting, according to an approach based on the risk to public health; while all shortages have a detrimental effect on patients, it has been decided to limit the scope to prescription and/or reimbursable medicinal products (as well as products sharing the same ATC code, as these could be used as alternatives) due to the more problematic consequences in the event of shortages.
The daily communication frequency is necessary as the prevention/management of shortages depends on access to current data in order to enable a rapid response should the need arise. The AFMPS is aware of the workload for stakeholders, so communication will be automatic, via a machine-to-machine IT platform.
The measure therefore pursues a public health objective, through compulsory disclosure suited to the needs of the administration in the context of the prevention and management of shortages of medicinal products.
As regards the medicinal products concerned, the stakeholders concerned, the communication frequencies and the communication methods, the measure is appropriate for the objective pursued and does not go beyond what is necessary to achieve it.

10. References to basic texts: There are no basic texts

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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