Message 001

Communication from the Commission - TRIS/(2025) 2145

Directive (EU) 2015/1535

Notification: 2025/0437/BG

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: 20252145.EN

1. MSG 001 IND 2025 0437 BG EN 12-08-2025 BG NOTIF

2. Bulgaria

3A. Министерство на икономиката и индустрията,
дирекция "Европейски въпроси и законодателство на ЕС за стоки и услуги",
ул. "Славянска" № 8
1000 София
Tel.: +359 2 940 7336; +359 2 940 75 22
+359 2 940 7565
email: infopointBG@mi.government.bg

3B. Министерство на здравеопазването,
дирекция "Лекарствена политика"
пл. "Св. Неделя" № 5
1000 София
Тел.: +359 2 930 1243
email: mbotusharov@mh.government.bg

4. 2025/0437/BG - C10P - Pharmaceuticals

5. Draft Law amending and supplementing the Law on Medicinal Products for Human Use

6. Medicinal products for human use

7.

8. The reasons for the preparation of this draft law are mainly aimed at enhancing the current regulatory framework in the field of medicinal products through its improvement.
Conceptually, this draft law proposes measures to address shortages or unavailability of medicines by refining the obligations of all actors in the drug supply chain and creating additional obligations for them, changes to the calculation algorithm set out in the Specialized Electronic Tracking and Analysis System (SETAS), as well as changes to the penalty provisions of the law. Provision is also made for simplified arrangements for the supply of medicinal products subject to parallel import on the Bulgarian market, allowing holders of authorisations for parallel import to obtain authorizations under an accelerated procedure.
Another important change that is proposed with this draft law relates to the parallel import authorisation regime. It shall be possible to list in a single authorisation all the Member States from which the medicinal product concerned is to be imported. It is proposed that the authorisation for parallel imports be granted for a period of five years. Upon expiry of this term, the authorisation may be renewed, and thereafter shall be valid for an indefinite period.
Next, a change is proposed whereby, in cases of established shortage of a specific medicinal product, a shortened administrative procedure for issuing a parallel import license should be applied.
A significant change that is proposed to be adopted is a change in the algorithm for calculating the shortage of medicinal products available on prescription for which information is reported to SETAS.
It is proposed that the calculations be made taking into account 100 % of the quantities needed to meet the health needs of the population over a period of one month, instead of the current 65 %. This figure will be calculated on the basis of the average monthly consumption of the relevant medicinal product for the previous 12 months, starting from the day of the analysis for the finding of the shortage. Currently, the period for which this average monthly consumption is calculated is 6 months.
It is provided that SETAS, in addition to the current information provided for by law, shall also contain information on registered requests to marketing authorisation holders and wholesale authorisation holders of a medicinal product, respectively to parallel import authorisation holders. It is also proposed to contain information on registered refusals to supply prescription-only medicinal products in response to requests.
It is proposed that SETAS provide a facility for holders of a marketing authorisation for medicinal products to obtain information on stocks in the warehouses of holders of a wholesale distribution authorisation for medicinal products of prescription medicinal products.
A significant change proposed by the draft is the possibility for the Minister of Health, exceptionally and for reasons related to the protection of the health of the population, to prohibit by order the export of medicinal products from the territory of the Republic of Bulgaria. The order is to be issued on the basis of an analysis by the Ministry of Health showing that there are insufficient quantities of medicinal products available to meet the needs of the population.
Changes are also envisaged in the provisions on administrative criminal proceedings of the law, in view of the proposals made above.
The expected outcome of the adoption of the project is related to the improvement of the current regulatory framework in the field of medicinal products, which will ensure the security of the drug supply process and

limit the cases of unavailability or shortages of medicinal products critical to the population.

9. The reasons for the preparation of this draft law are mainly aimed at enhancing the current regulatory framework in the field of medicinal products through its improvement. This is necessary in order to cope in the future with cases of unavailability or shortages in pharmacies of medicinal products critical to the population. The unavailability or shortages of vital medicinal products available on prescription is a very serious problem, both at international and national level.
With regard to the objectives set by this draft law, it should be noted first of all as the main and highest priority objective – to fully meet the needs of Bulgarian patients with medicinal products available on prescription by overcoming their unavailability and shortages and avoiding such problems in the future. This objective is intended to be achieved through the above proposals for changes to the legislation governing these processes.
The proposed changes in the area of retail trade in medicinal products are aimed at preventing unregulated practices that could lead to shortages or unavailability of medicinal products. The latter will be achieved by filling the existing gap in the law and avoiding conflicting interpretation of its provisions. The changes in the law are aimed at preventing the practice of dispensing medicinal products under a prescription regime without presenting a prescription. Through the proposals for measures to reduce the administrative burden, the draft aims to improve the country's regulatory policy and ease the administrative procedures for the exercise of rights and legitimate interests of citizens and legal entities.
The expected outcome of the adoption of the project is related to the improvement of the current regulatory framework in the field of medicinal products, which will ensure the security of the drug supply process and limit the cases of unavailability or shortages of medicinal products critical to the population. Another expected outcome is the achievement of more transparency and traceability in the processes for the supply of medicinal products between the different actors and meeting the needs of Bulgarian citizens. Appropriate penalties for violation of the law have been introduced as safeguards for the achievement of these outcomes.

10. References of the Basic Texts: 2023/0711/BG,2018/0227/BG

Basic texts have been forwarded within the framework of previous notifications:
2023/0711/BG
2018/0227/BG

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu