Message 001

Communication from the Commission - TRIS/(2025) 3698

Directive (EU) 2015/1535

Notification: 2025/0771/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: 20253698.EN

1. MSG 001 IND 2025 0771 BE EN 18-12-2025 BE NOTIF

2. Belgium

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4. 2025/0771/BE - C10P - Pharmaceuticals

5. Draft law containing various provisions concerning medicinal products and health products

6. The draft law aims to amend various laws under the jurisdiction of the FAMHP, mainly in matters of medicinal products, health products, medical devices, blood, human bodily material and health professions.

7.

8. The draft law introduces amendments to several laws in order to update, clarify or harmonise the rules applicable to medicinal products, health products, medical devices, blood and human bodily material.

The main areas are:

- Medicinal products for human use:
° Removal of the mandatory reference to the Therapeutic Magistral Form (TMF), which becomes a professional recommendation and no longer a legal obligation.
° Strengthening of measures against medicinal product shortages: the minister or their delegate may take preventive and corrective measures (redistribution of stocks, priority for hospitals, limitation of distribution, etc.) in the event of a proven or imminent shortage.
° Clarification and extension of the possibilities for hospital pharmacists to dispense medicinal products to outpatients in certain cases.
° Harmonisation of rules relating to the control of medicinal products by laboratories, by removing the notion of an "approved" laboratory in favour of a manufacturing authorisation, in accordance with European standards.

- Blood and blood products:
° Replacement of the mandatory cardiovascular examination during blood donation with a brief clinical examination, and adaptation of the maximum volumes collected to increase available stocks.

- Experiments on human subjects:
° Administrative simplification for non-commercial sponsors and alignment of definitions with clinical trial legislation.
° Removal of certain quantitative criteria for the approval of ethics committees, which have become obsolete with the evolution of the European framework.

- Medical devices and in vitro diagnostic devices:
° Extension of procedural deadlines for informal appeals and elimination of the mandatory hearing of the applicant, for greater flexibility and efficiency.

- Veterinary medicinal products:
° Harmonisation with European Regulation 2019/6, reintegration of certain omitted provisions, and allocation of additional powers to the King to set practical arrangements.
- Raw materials used by pharmacists:
° Strengthening the role of the Commission for medicinal products for human use in the evaluation of applications for authorisation of raw materials, and adaptation of procedures for the drafting and publication

of analytical references.
- Healthcare professions:
° Clarification of the rules relating to the temporary closure of pharmacies and the dispensing of automated medicinal preparations to people living in communities.

All of these amendments aim to strengthen the safety, availability and quality of medicinal products and health products, simplify administrative procedures, harmonise national legislation with European standards and address current challenges in the health sector.

Various extracts from this project have already been the subject of a TRIS notification by means of notification 2025/0405/B.

9. The explanatory memorandum, detailed in the brief, justifies the main amendments:

- Therapeutic Magistral Form (TMF): The transfer of TMF management to the pharmacists' sector aligns with European practice and allows TMF to be considered as a recommendation, not as an obligation, thus promoting self-monitoring and adaptation to needs in the field.

- Combating medicinal product shortages: Existing measures were deemed insufficient since they only allowed action after a shortage had been identified. The preliminary draft allows for preventive and proportionate interventions, such as the redistribution of stocks or the limitation of distribution, in order to guarantee access to essential medicinal products and protect public health.

- Control of medicinal products: The elimination of the concept of approved laboratory aims to harmonise Belgian legislation with European requirements, by subjecting all relevant laboratories to a manufacturing authorisation that simplifies and modernises the regulatory framework.

- Blood and blood products: The brief clinical examination replaces the mandatory cardiovascular examination, which is considered unreliable and unnecessary according to the latest scientific knowledge and European recommendations. The increase in the maximum volume collected is also justified by the need to increase blood stocks.

- Experiments and clinical trials: The amendments aim to simplify procedures for non-commercial promoters, align definitions and remove outdated criteria, while maintaining a high level of protection for participants.

- Medical devices: The lengthening of procedural deadlines and the elimination of the applicant's hearing are intended to make procedures more flexible and adapted to the increasing complexity of cases.

- Veterinary medicinal products: The adjustments made serve to correct oversights in the transposition of the European regulation and give the King the power to set certain practical modalities, for better adaptation to the realities of the sector.

- Raw materials: The increased involvement of the Commission for Medicinal Products for Human Use in the evaluation of raw materials ensures better consideration of clinical and public health aspects.

- Healthcare professional: The clarifications made to the rules for the temporary closure of pharmacies and the dispensing of medicinal preparations respond to logistical needs and exceptional situations encountered in the field.

Each change is thus motivated by the desire to ensure the safety, availability and quality of care, to simplify administrative procedures, to harmonise legislation with European standards and to meet the concrete needs of professionals and patients.

10. References to basic texts: The basic texts were forwarded with an earlier notification: 2025/0405/BE

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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