Message 001

Communication from the Commission - TRIS/(2026) 1539

Directive (EU) 2015/1535

Notification: 2026/0286/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: 20261539.EN

1. MSG 001 IND 2026 0286 BE EN 10-06-2026 BE NOTIF

2. Belgium

3A. SPF Economie, PME, Classes moyennes et Energie
Direction générale Qualité et Sécurité - Service Bureau de Liaison - BELNotif
NG III – 2ème étage
Boulevard du Roi Albert II, 16
B - 1000 Bruxelles
be.belnotif@economie.fgov.be

3B. Agence fédérale des médicaments et produits de santé
Avenue Galilée 5/03
1210 Bruxelles
Division législation et contentieux
ius@fagg-afmps.be
+32 2 528 40 00

4. 2026/0286/BE - C10P - Pharmaceuticals

5. Royal Decree implementing the Law of 29 February 2024 relating to raw materials used by pharmacists

6. Raw materials used by pharmacists to prepare magistral and officinal preparations

7.

8. The draft implements the Law of 29 February 2024 on raw materials used by retail pharmacists. The draft aims to regulate the raw materials, i.e. active substances and excipients, intended for use by pharmacists in officinal or magistral preparations. The draft sets out the procedures for the approval of monographs and the way in which a raw material can be manufactured, marketed and used, as well as the obligations of the various market players, namely the manufacturer, the distributor and the pharmacist.

9. The draft redefines, clarifies and harmonises requirements, quality and control standards to provide patients, at the end of the process, with raw materials of the highest possible quality, on the basis of which the pharmacist will prepare a magistral or officinal preparation for them.

9a. The notified measure pursues one or more objectives of general interest recognised by Union law, in particular the protection of public health, patient safety and the proper functioning of the market. It aims to prevent identified risks relating, in particular, to the quality, safety, availability or appropriate use of the products concerned.
The measure is capable of achieving the intended objective, as it sets out the procedure for the approval of internal monographs, which are used as analytical references for the authorisation of raw materials, regulates the authorisation of raw materials, and provides a framework for manufacturing and distribution activities through the granting of specific authorisations. The draft Royal Decree also contains requirements relating to the placing on the market of raw materials (labelling and notification of placing on the market and unavailability) and certain requirements applicable to pharmacists. The provisions set out are quite similar to existing provisions for medicinal products for human use at European level.
The measure is necessary and replaces and updates the current legislative framework on raw materials. No other measures are applicable to raw materials. In-house monographs should be approved and the raw materials used by pharmacists should be authorised, as should the manufacture and distribution of the raw materials. The quality, safety and efficacy of the raw materials cannot be guaranteed by means of less stringent measures.
Finally, the measure does not impose an excessive burden. The raw materials and market players must be authorised and comply with standard good practice rules for manufacturing and distribution. Market players established in other Member States may have their authorisation recognised.

9b. The proportionality assessment shall be based on an overall analysis based in particular on:
• monitoring and surveillance of the raw materials market by the competent authority;
• consultation with the relevant stakeholders.
These elements made it possible to identify the risk, assess the effectiveness of the proposed measure and examine possible alternatives.

9c. As part of the preparations for the measure, appropriate consultations took place with the relevant market players and competent services, taking into account the existing regulatory framework.
The measure was also examined in the light of the objectives of Directive (EU) 2015/1535 and the TRIS notification procedure, in order to ensure transparency and facilitate effective dialogue with the Commission and the other Member States.

10. References to the basic texts:

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