

Message 001

Communication from the Commission - TRIS/(2025) 1515

Directive (EU) 2015/1535

Notification: 2025/0296/PT

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – 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 késésekét - 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: 20251515.EN

1. MSG 001 IND 2025 0296 PT EN 11-06-2025 PT NOTIF

2. Portugal

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4. 2025/0296/PT - C10P - Pharmaceuticals

5. Regulation setting out the rules for activities relating to medical gases referred to in Article 149 of Decree-Law No 176/2006 of 30 August, as amended.

6. Medical gases

7.

8. This proposal for a regulation is intended to apply to the manufacture, primary or secondary packaging, labelling, information leaflet, technical management, transportation, distribution, marketing, supply and home delivery of the medical gases referred to in Article 149 of Decree-Law No 176/2006 of 30 August, as amended.

9. Article 149(4) of Decree-Law No 176/2006 of 30 August, as amended, provides that the legal basis applicable to the primary or secondary packaging, labelling, information leaflet, technical management, transportation, distribution, marketing, supply and home distribution to patients of medical gases is defined by the regulations issued by INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. [Portuguese Authority for Medicines and Health Products]. (INFARMED, I.P.). The regulation on medical gases was approved by Resolution No 56/CD/2008, of 21 February 2008, of the Executive Board of INFARMED, I.P., which entered into force on 1 March 2008. However, the experience gained in the meantime in the application of the Regulation on Medical Gases recommends the introduction of several amendments to it, and the intention is therefore to adopt a new Regulation on Medical Gases.

10. References of the Basic Texts:

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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