Message 001

Communication from the Commission - TRIS/(2025) 2030

Directive (EU) 2015/1535

Notification: 2025/0412/RO

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: 20252030.EN

1. MSG 001 IND 2025 0412 RO EN 30-07-2025 RO NOTIF

2. Romania

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4. 2025/0412/RO - C10P - Pharmaceuticals

5. Draft Order amending and supplementing the Sanitary Veterinary Rule regarding the procedure for placing on the market and using reagents and diagnostic kits for veterinary use

6. Reagents and diagnostic kits for veterinary use

7.

8. The proposed amendments and additions consist of:
- clarification of the scope through the exclusion of veterinary rapid diagnostic tests and those tested by the European reference laboratories in accordance with the provisions of the European regulations in force;
- updated definitions for: ‘manufacturing authorisation’, ‘provisional authorisation for use’, ‘competent national reference laboratory’ and ‘diagnostic kit for veterinary use’;
- amendment of the deadlines for: notifying amendments to the documentation on the basis of which the manufacturing authorisation was issued, completing technical documentation submitted in support of marketing authorisation applications, issuing marketing authorisations and notifying trade in reagents and diagnostic kits for veterinary use;
- additions to the provisions regarding the advertising of reagents and diagnostic kits for veterinary use;
- the addition to Article 21 of a derogation from the provisions of paragraph (2)(c) thereof to the effect that, if the epidemiological situation so requires, the National Sanitary Veterinary and Food Safety Authority may, at the request of the laboratories of the sanitary veterinary and food safety directorates of the counties and of the municipality of Bucharest, issue provisional authorisations for use exclusively for those reagents and diagnostic kits for veterinary use necessary for the diagnosis of list A/emerging diseases;
- amendment of Annex 9 on the deadlines for carrying out the procedure for issuing the marketing authorisation.

9. Having regard to:
- the current epidemiological situation in Romania regarding the spread of peste des petits ruminants in animals;
- the authorisation and designation of county veterinary health and food safety laboratories for the diagnosis of peste des petits ruminants using immunoenzymatic methods, in accordance with the provisions of Order No 205/2007 approving national reference laboratories and their tasks, as subsequently amended and supplemented;
- the proposal submitted by the Institute for Diagnosis and Animal Health (IDAH) to amend Order No 81/2008 approving the Sanitary Veterinary Rule regarding the procedure for placing on the market and using reagents and diagnostic kits for veterinary use;
- the fact that no diagnostic set/kit for testing for peste des petits ruminants using the immunoenzymatic method is currently authorised in Romania; Article 21 of Order No 81/2008 should be amended so that diagnostic sets/kits for List A/emerging diseases that are not authorised for marketing can benefit from a provisional authorisation for use by county veterinary and food safety laboratories designated for the diagnosis of peste des petits ruminants, until the authorisation procedure for placing them on the market has been completed.

10. Reference(s) to basic text(s):

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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