Message 001

Communication from the Commission - TRIS/(2025) 2499

Directive (EU) 2015/1535

Notification: 2025/0514/FR

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: 20252499.EN

1. MSG 001 IND 2025 0514 FR EN 10-09-2025 FR NOTIF

2. France

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4. 2025/0514/FR - C00P - PHARMACEUTICAL AND COSMETICS

5. Decree on package leaflets and labelling rules for certain veterinary medicinal products

6. Veterinary medicinal products

7.

8. The draft Decree aims to adapt French law to the provisions of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products.

In particular, the text specifies the rules relating to the labelling notices applicable to certain veterinary medicinal products:
-Veterinary medicinal products registered in accordance with a national procedure and intended exclusively for pet animals, as referred to in Article 5(6) of Regulation (EU) 2019/6
-Homeopathic veterinary medicinal products registered in accordance with Article 86 of Regulation (EU) 2019/6
-Veterinary medicinal products outside the scope of Regulation (EU) 2019/6

Some of the provisions of the draft text were already notified (2024/130/FR). However, amendments have been made to the draft text and result in a new notification pursuant to the third subparagraph of Article 5(1) of Directive (EU) 2015/1535, as well as technical regulations within the meaning of that Directive.

9. French law needs to be adapted to the provisions of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products.

On the other hand, the draft Decree specifies the labelling and package leaflet rules applicable to certain veterinary medicinal products, pursuant to Regulation (EU) 2019/6. These provisions promote the proper use of these medicinal products by facilitating their identification and information to the consumer and thus meet the objective of safeguarding public health.

Firstly, Article 1 of the draft decree lays down the labelling and package leaflet rules applicable to veterinary medicinal products intended exclusively for companion animals mentioned in Article L. 5141-5-1 of the Public Health Code:
-The new Article R.5141-61-6 specifies the labelling rules for primary packaging;
— The new Article R.5141-61-7 specifies the labelling rules for outer packaging;
-The new Article R.5141-61-8 specifies the notice rules.

Secondly, Article 2 of the draft decree reinstates Article R. 5142-71 in the Public Health Code in order to specify the rules for the labelling of the primary packaging of registered homeopathic veterinary medicinal products.

Thirdly, Article 3 of the draft Decree amends Article R. 5142-72 of the Public Health Code in order to specify the rules for the labelling of the outer packaging and package leaflet of registered homeopathic veterinary medicinal products, in accordance with Article 16 of Regulation (EU) 2019/6 as regards the package leaflet of these medicinal products.

Fourthly, Article 4 of the draft Decree replaces the provisions of Article R. 5141-123-8 of the Public Health Code with regard to the labelling and package leaflet of the veterinary medicinal product which benefits from a parallel trade authorisation.

Fifth, Article 5 of the draft Decree lays down the labelling rules for the veterinary medicinal products referred to in Article L. 5142-1-2 of the Public Health Code (veterinary medicinal products not falling within the scope of Regulation (EU) 2019/6 of 11 December 2018, excluding extemporaneous preparations):
-The new Article R.5142-89 specifies the labelling rules for primary packaging;
— The new Article R.5142-90 specifies the labelling rules for outer packaging.

10. References to basic texts: The basic texts were forwarded with an earlier notification:
2024/0130/FR

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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