Message 001

Communication from the Commission - TRIS/(2025) 0241

Directive (EU) 2015/1535

Notification: 2025/0049/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: 20250241.EN

1. MSG 001 IND 2025 0049 FR EN 27-01-2025 FR NOTIF

2. France

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4. 2025/0049/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Draft Decree on the system of prior declaration of the electronic commerce of medicinal products and the creation of a website for the electronic commerce of medicinal products as provided for in Article L. 5125-36 of the Public Health Code.

6. Medicinal product not subject to mandatory medical prescription

7.

8. The draft Decree provides for the arrangements of the procedure for the prior declaration of the electronic commerce of medicinal products via the internet and the opening of a website dedicated to this activity pursuant to Article 89 of the Law of 7 December 2020 on the acceleration and simplification of public action.

It aims in particular to establish a procedure for access to this simplified and facilitated activity, in line with the obligation laid down in Article 85c of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, according to which Member States shall ensure that medicinal products are offered for sale at a distance by means of information society services.

Pursuant to that Decree, a draft Order is also notified in parallel under Directive 2015/1535. It sets out the elements to be included in the prior declaration of the electronic commerce activity of medicinal products via the internet.

9. Directive 2011/62/EU of 8 June 2011 introduced the framework for the distance selling of medicinal products for all Member States of the European Union. However, Member States have a discretionary margin to lay down rules concerning the online sale of medicinal products. In particular, they may impose conditions on that activity, justified by the protection of public health.

In France, the creation of a website for the electronic commerce of medicinal products previously required the prior authorisation of the regional health agency with territorial jurisdiction.

The Law of 7 December 2020 on the acceleration and simplification of public action made it possible to move from a system of prior authorisation to a system of prior declaration to the regional health agency with territorial jurisdiction. This Law has thus allowed the relaxation of the regime of the Public Health Code applicable to the online sale of medicinal products in order to enable greater development of this activity in pharmacies, to make French pharmacies more competitive at the European level and to offer new services to patients, while ensuring the protection of public health. (see below)

The draft Decree specifies the procedures of the prior declaration. It aims, on the one hand, to facilitate the creation and operation of a website for the online sale of non-prescription medicinal products for pharmacies and, on the other hand, to simplify the tasks of regional health agencies (RHAs).

Article 1 of the draft Decree provides that the prior declaration must be addressed to the Director-General of the territorially competent RHA. It lays down a period of 21 days within which the RHA must send an

acknowledgment of receipt of completeness or notify the missing elements in the event of an incomplete application. The pharmacist then has a period of 15 days to complete their file. Within a subsequent period of 21 days, the RHA acknowledges receipt and decides on the completeness of the file. If the file is incomplete at the end of this period, the pharmacist is invited to file a new declaration.

Article 1 also mentions the pharmacist's obligation to inform the council of the pharmacists' association to which he/she belongs about the creation of the website and to send an acknowledgement of receipt of completeness issued by the RHA.

Article 2 of the draft Decree provides that the pharmacist is required to inform without delay the Director-General of the territorially competent RHA and the council of the pharmacists' association to which he/she belongs of any change in the elements identified as significant in the annex to the Order (R. 5125-72 CSP).

Article 3 of the draft Decree provides that in the event of suspension or cessation of operation of his/her website, the pharmacist must inform the Director-General of the territorially competent RHA and the council of the pharmacists' association to which he/she belongs within 7 days (Article R.5125-73 CSP).

Article 4 of the draft Decree provides for the change of terminology following the transition from an authorisation regime to a prior declaration regime. The concept of 'authorised' websites is deleted. The National Pharmacists' Association maintains a list of pharmacy websites that are legally engaged in the electronic commerce of medicines (Article R.5125-74 CSP).

The text thus concerns the online sale of medicinal products and therefore relates to information society services, as it lays down rules on access to information society service activities and on the conditions to be fulfilled by providers of those services.

The measures introduced by this text will apply only to service providers established in France, i.e. pharmacy licence holders or pharmacists that manage pharmacies of mutual insurance associations or mine workers' welfare in France. Therefore, the measures do not need to be notified under Directive 2000/31/EC (e-commerce) as they do not restrict the free movement of information society services from another Member State.

10. References to basic texts:

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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