

Message 001

Communication from the Commission - TRIS/(2025) 3809

Directive (EU) 2015/1535

Notification: 2025/0795/FR

Notification of a draft text from a Member State

Notification – Notificación – 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 - Nezahtuje 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 jiftaħ 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: 20253809.EN

1. MSG 001 IND 2025 0795 FR EN 31-12-2025 FR NOTIF

2. France

3A. Ministère de l'économie, des finances et de la souveraineté industrielle et numérique

Direction générale des entreprises

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3B. Ministère de la santé, des familles, de l'autonomie et des personnes handicapées

Direction générale de la santé

Sous-direction politique des produits de santé et qualité des pratiques et des soins (PP)

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4. 2025/0795/FR - C10P - Pharmaceuticals

5. Decree laying down various implementing measures for Law No 2025-199 of 28 February 2025 on the financing of social security for 2025, related to addressing shortages of medicinal products.

6. Pharmaceutical products

7.

8. The draft decree is issued pursuant to Article 75 of Law No 2025-199 of 28 February 2025 on social security financing for 2025 (LFSS for 2025).

It sets out, at regulatory level, a number of measures to combat shortages of medicinal products:

- the conditions under which the Director General (DG) of the French National Agency for Medicines and Health Products Safety (ANSM) may authorise pharmaceutical companies temporarily to build up a lower level of buffer stock for medicinal products of major therapeutic interest (MITM) that are out of stock or at risk of being out of stock;
- the conditions for drawing up and updating plans for the management of shortages (SMPs);

It first specifies the conditions under which the Director General of the French National Agency for Medicines and Health Products Safety (ANSM) may, in order to promote an appropriate and continuous supply to the national market, authorise the marketing authorisation holder (MAH) or the pharmaceutical company operating a MITM that is out of stock or at risk of being out of stock temporarily to build up a reduced level buffer stock.

It then defines the conditions for drawing up and updating SMPs, which were previously governed by a model established by decision of the Director General of the ANSM. It also provides for the possibility for the Director General of the ANSM to impose stricter requirements on SMPs for medicinal products that have regularly been subject to risks of shortages or actual shortages over the past two years.

9. The draft decree forms part of the measures to combat medicinal product shortages with a view to enabling better anticipation and management of such shortages, as well as ensuring continuity of patient treatment.

The Director General of the ANSM may now authorise, on an exceptional and temporary basis, pharmaceutical companies to build up a buffer stock at a level lower than the level normally required for medicinal products of major therapeutic interest (MITM) in cases of force majeure or in other exceptional circumstances, duly justified by objective and sufficient evidence. This derogation from ordinary law is intended to promote an adequate and continuous supply to the domestic market. This measure supplements those relating to the creation of buffer stocks of medicinal products and in particular MITMs which had been notified under notification No 2020/599/F.

To address the public health challenge posed by constraints in the supply of medicinal products, it is further proposed to clarify the conditions for the preparation and updating of plans for the management of shortages. These SMPs are developed for all MITMs in order to identify the risks of unavailability and

provide solutions with the aim of ensuring the continuity of treatment for the patients concerned. The decree specifies the main elements expected in the SMPs, which have so far been laid down by decision of the Director-General of the ANSM, and leaves it up to the Director-General of the ANSM to make these SMPs subject to enhanced requirements, for medicinal products that are regularly in a situation of risk of shortages or actual shortages.

The introduction of such measures meets the real public health challenge and will enable the health agency (ANSM) to manage shortages more efficiently and properly. The possibility of exemptions in exceptional circumstances, such as force majeure, allows the principle of proportionality to be respected. The aim is to ensure a continuous supply to patients, even in situations of severe supply pressure.

These enacting terms are also proportionate:

- The reduction in the level of the buffer stock level is authorised only on an exceptional and temporary basis, at the request of the pharmaceutical company, for a maximum period of six months and renewable only if the situation persists. Thus, the authorisation by the Director General of the ANSM to hold stock levels below those required by common law will cease at the end of the six-month period. This arrangement is not intended to reduce the storage requirement but to ensure the supply of medicinal products in specific situations.

- The decree specifies the main elements expected from pharmaceutical laboratories in their plans for the management of shortages. Until now, these elements were determined only by decision of the Director General of the ANSM. The precision of the expectations in the law provides laboratories with greater predictability and remains a guarantee of stability. The Agency's Director-General may also impose stricter requirements as regards the plans for the management of shortages for medicines that have been subject to risks of shortages or actual shortages in the last two years. This measure helps to anticipate shortages of medical products that are often in high demand.

10. References to basic texts: There are no basic texts

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

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European Commission

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