Message 001

Communication from the Commission - TRIS/(2025) 0703

Directive (EU) 2015/1535

Notification: 2025/0138/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: 20250703.EN

1. MSG 001 IND 2025 0138 FR EN 12-03-2025 FR NOTIF

2. France

3A. SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits
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3B. Ministère du travail, de la santé, des solidarités et des familles
Direction générale de la santé
Sous-direction politique des produits de santé et qualité des pratiques et des soins (PP)
Bureau du médicament (PP2)
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4. 2025/0138/FR - C00P - PHARMACEUTICAL AND COSMETICS

5. Decree laying down various measures for the implementation of Act No. 2023-1250 of 26 December 2023 on the financing of social security for 2024, relating to addressing shortages of medicinal products

6. Medicinal products

7.

8. The draft decree is adopted pursuant to Articles 71, 72 and 77 of Act No. 2023-1250 of 26 December 2023 on the financing of social security for 2024 (LFSS for 2024).

It sets out at regulatory level the following mechanisms to address shortages of medicinal products: - the special officinal preparations (POS); - the animal health measures that the National Agency for the Safety of Medicines and Health Products (ANSM) may take, in the event of a disruption or risk of a disruption in the supply of a medicinal product of major therapeutic interest (MITM), in order to ensure an appropriate and continuous supply by the holders and operators of marketing authorisations; - the measures to facilitate the resumption of operations in the event of a planned cessation of marketing of mature MITMs, known as the 'Florange measure'.

It first specifies the conditions under which the Minister responsible for health, on an exceptional and temporary basis, authorises by decree the carrying out of POSs to deal with the shortage of stock of an MITM or the cessation of its marketing or to deal with a serious health threat or crisis. The Minister must first obtain the opinion of the Director General (DG) of ANSM. The Order shall cease to have effect automatically on the date on which the medicinal product concerned is made available, as published on the Agency's website.

It then sets out the types of animal health measures that the DG of the ANSM may take in order to ensure an appropriate and continuous supply by marketing authorisation holders and operators, in application of Article L. 5121-33-3 of the Public Health Code. The text also details the adversarial procedure at the end of which the Agency may take these measures.

Finally, the draft text clarifies the conditions for the implementation of the obligation to seek a buyer by the holder of the marketing authorisation stopping the marketing of a mature MITM if the available therapeutic alternatives do not make it possible to cover the need in a sustainable manner. It thus details the procedures for the declaration of foreseeable impacts on the French market by laboratories, the procedures for the publication of the research offer and the model of the report indicating the actions undertaken to search for a buyer, the offers received and, for each of them, the reasons which led them to accept or refuse it. It also determines the conditions under which the Agency may request laboratories to grant free of charge for a temporary period to a public pharmaceutical structure the manufacture and operation of the medicinal product in order to allow continuity of supply to the French market.

9. The draft decree is part of the measures to address stock shortages in order to make it possible to better anticipate and manage them with the objective of ensuring the continuity of patient treatment.

The POS scheme is based on feedback from the production of amoxicillin preparations in the last two winter seasons. The device makes it possible to frame the conditions for the use of POS on an exceptional basis in order to allow for production and dispensing by dispensing pharmacists under homogeneous quality and

safety conditions.

In order to respond to the public health challenge posed by addressing tensions in the supply of medicines, it is then proposed to strengthen the animal health powers of the DG of ANSM in order to enable it to compel pharmaceutical companies to adopt specific measures, which it has been unable to do until now. These measures will concern the adaptation of the distribution channel, the importation of alternative medicinal products or any other measure having equivalent effect. It is important to clarify that they will not seek to block access to the market for medicinal products but to ensure the finest possible coverage of the needs of the population in a context of disruption.

Finally, the Senate report of July 2023 on the shortage of medicinal products and the choices of the French pharmaceutical industry states that, according to the National Academy of Pharmacy, 71% of pharmaceutical companies would question the marketing of some of their medicinal products in France or have already decided to do so. The national trade union representing generics (Gemme) identified ‘nearly 700 pharmaceutical presentations with little or no profitability, the discontinuation of which we envisage in the short or medium term, that is to say approximately 12% of the volumes of generic medicines currently marketed – mainly MITMs’. These figures give an overview of the extent of the trend towards the abandonment of mature products by laboratories. Therefore, in order to ensure the continuity of supply of treatments for patients, it is proposed to empower companies holding or operating marketing authorisations discontinuing the marketing of mature MITMs.

The implementation of such measures responds to a real public health challenge and will allow for the anticipation of measures, more efficient management of shortages by the National Health Agency (ANSM) and, as a last resort, the production of vital medicines, in a short time, in the event of a rupture on French territory.

These enacting terms are also proportionate:
- the POS enacting terms are only triggered once all solutions for addressing shortages using proprietary medicinal products have been implemented and exhausted. Furthermore it is a time-limited measure to compensate for the shortage of a proprietary medicinal product in order to be able to supply patients. Production will cease as soon as the proprietary medicinal product is available again in sufficient quantities to cover national needs. That provision is based on the derogations provided for in Article 5 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use with a view to meeting special needs, due to the unavailability of a medicinal product and in the event of a public health emergency. These POSs are subject to medical prescription after examination of the patient by the prescriber.
- the animal health measures are in no way intended to block access to the market for medicinal products, which is, moreover, in a situation of tension or rupture. In a situation where the availability of products is limited, the objective is to ensure a fairer and finer coverage of the health needs of the population. Moreover, in the case of a measure adversely affecting an undertaking, the procedure will ensure that all the guarantees of legal certainty are provided to the industries concerned. The DG of the ANSM will initiate contradictory proceedings and the decision of the DG of the ANSM will set out the details of lifting the animal health measure.
- the obligation to find a buyer will only apply in rare cases, in the absence of sufficient therapeutic alternatives and after analysis by the ANSM. Finally, this system will cease as soon as the same medicinal

product or a similar medicinal product that allows the need to be covered in a permanent manner is available on the French market. Similarly, the obligation to transfer, free of charge, the manufacture and operation of the medicinal product by the marketing authorisation holder will be imposed only as a last resort, where the marketing authorisation holder is unable to find a pharmaceutical undertaking to ensure the effective resumption of the operation of the medicinal product, and will constitute a temporary measure. As soon as an alternative medicinal product is marketed on the French market and will make it possible to cover the need for medicinal products on a lasting basis, the holder of the marketing authorisation may terminate the concession early.

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

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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