

FRENCH REPUBLIC

Ministry of Health, Families, Autonomy
and Persons with Disabilities

Decree

**laying down various measures for the implementation of Law No 2025-199 of 28
February 2025
on the financing of social security for 2025
relating to addressing shortages in medicinal products**

NOR: XXX

Public concerned: National Agency for Medicines and Health Products Safety, marketing authorisation holders, pharmaceutical companies marketing a medicinal product.

Subject: Provisions implementing the Social Security Financing Act 2025.

The decree sets out the conditions under which the Director General of the National Agency for Medicines and Health Products Safety may, in order to promote an adequate and continuous supply to the national market, authorise the marketing authorisation holder or the pharmaceutical company marketing a medicinal product of major therapeutic interest that is out of stock or at risk of being out of stock to temporarily build up a safety stock at a level below that required under ordinary law.

The decree defines the content and conditions for drawing up and updating shortage management plans pursuant to Article L. 5121-31 of the Public Health Code. It also lays down the conditions under which such plans may be subject to enhanced requirements.

The text specifies the conditions under which the Director-General of the Agency may reduce the period of publicity for decisions imposing financial penalties to less than one year.

Entry into force: The text shall enter into force on the day after its publication.

Application: The decree is adopted pursuant to Articles L.5121-29, L. 5121-31 and L. 5471-1 of the Public Health Code, in the version resulting from Article 75 of Law No 2025-199 of 28 February 2025 on the financing of social security for 2025. The decree, as well as the provisions of the Public Health Code that it creates, may be consulted on the Légifrance website (<http://www.legifrance.gouv.fr>).

The Prime Minister,

Based on the report of the Minister of Labour, Health, Solidarity and Families,

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the Public Health Code, in particular Articles L. 5111-4, L. 5121-29, L. 5121-31 and L. 5471-1 ;

Having regard to notification No 2024/XXX/FR of XXX addressed to the European Commission;

Having heard the Council of State (social division),

THE FOLLOWING IS DECREED:

Article 1

Section IV of Chapter IV of Title II of Book I of the fifth part of the Public Health Code is amended as follows:

(1) In Article R. 5124-49-4 a point VI is added, worded as follows:

‘VI – In order to promote the appropriate and continuous supply to the national market of medicinal products included on the list provided for in Article L. 5121-30 of the Public Health Code, the Director-General of the National Agency for the Safety of Medicines and Health Products may, on a temporary basis, decide of his own motion or at the request of a marketing authorisation holder or a pharmaceutical company operating a proprietary medicinal product, to authorise the establishment of a safety stock at a level lower than that required under II, III or IV of this Article, on the following grounds:’

‘(1) the occurrence of an event having the characteristics of force majeure;’

‘(2) An exceptional situation, duly justified by objective and sufficient evidence, in particular of an epidemiological nature or to compensate for the stock-out of a therapeutic alternative.’

‘The decision of the Director-General of the Agency shall be taken for a maximum period of six months, which may be renewed if the situation persists.’

‘Silence maintained by the Director-General of the Agency for more than two months from the presentation of a request to modify the safety stock threshold by the marketing authorisation holders and the pharmaceutical companies providing a medicinal product constitutes a decision of rejection.’

‘Except in an emergency, marketing authorisation holders and pharmaceutical companies providing the medicinal products concerned must be able to present their observations to the Director-General of the Agency before the implementation of an ex officio modification of the safety stock threshold mentioned in VI of this Article.’

(2) Article R 5124-49-5 of the Public Health Code is replaced by the following provisions:

‘Article R.5124-49-5 – I.- For the medicinal products of major therapeutic interest referred to in Article L. 5111-4, marketing authorisation holders and pharmaceutical companies operating medicinal products shall, under their responsibility, draw up the shortage management plans referred to in Article L.’5121-31

‘These plans shall include the following:’

‘(1) General information on the proprietary medicinal product, in particular the full name, the international non-proprietary name, the ATC code, the list of presentations marketed, the type of marketing authorisation procedure, the contact details of the operator, the list of manufacturers of the active ingredient and the finished product and their location, the distribution channel(s) in France, in the other countries of the European Union in which the medicinal product is distributed and the marketing of the medicinal product outside the European Union;’

‘(2) The clinical criticality of the proprietary medicinal product based on information on its use, including documented use outside a marketing authorisation, sales volumes and market share among similar or comparable specialities, the existence of therapeutic or non-therapeutic alternatives and the impact on the patient in the event of a disruption or risk of a disruption of supply;’

‘The methodology for assessing the clinical criticality of the proprietary medicinal product will be specified by decision of the Director-General of the Agency and published on its website.’

‘(3) Identification and analysis of vulnerabilities in the supply chain of the speciality concerned, in particular those linked to the manufacturing, packaging and distribution cycles which may lead to a risk of stock-outs;’

‘(4) The preventive measures implemented to mitigate or remedy each vulnerability identified in (2) and (3), including the creation of security stocks for the domestic market as defined in Article R. 5124-49-4 ;’

‘(5) The management measures provided for in the event of a risk of stock-outs or stock-outs of the proprietary medicinal product to prevent or limit the impact for patients. These measures must be planned sufficiently in advance so that they can be implemented as quickly as possible when needed;’

‘(6) The history of stock-outs and tensions and changes to the shortage management plan for the speciality.’

‘The detailed content of the above sections shall be determined by guidelines laid down by decision of the Director-General of the National Agency for the Safety of Medicines and Health Products.’

‘II.-Marketing authorisation holders and pharmaceutical companies providing medicinal products shall update these shortage management plans as and when necessary.’

‘III.- The shortage management plans shall be sent each year to the National Agency for the Safety of Medicines and Health Products in accordance with the terms and conditions defined by decision of the Director-General of the Agency and shall be sent thereto, at any time, upon its request.’

‘IV.- The Director-General of the National Agency for the Safety of Medicines and Health Products may subject to increased formalisation and documentation requirements relating to the information listed in I, the shortage management plans for medicinal products of major therapeutic interest that have been subject to risks of regular shortages or stock-outs in the two previous calendar years. ’

Article 2

To the title II of book IV of the fifth part of the Public Health Code, a Chapter VI is inserted as follows:

‘Chapter VI: Publication of penalties imposed by the National Agency for the Safety of Medicines and Health Products (Article R. 5421-2)

In accordance with IV of Article L. 5471-1, financial penalty decisions issued under Article L. 5423-9 of the Public Health Code for amounts less than EUR10,000 remain available for a period of six months from their date of publication on the website of the French National Agency for Medicines and Health Products Safety.’

Article 3

The Ministry of Labour, Health, Solidarity and Family shall implement this Decree, which shall be published in the Official Journal of the French Republic.

Done on:

By the Prime Minister:

S. LECORNU

The Minister for Health, Families, Independence and People with Disabilities:

S. RIST