# Decrees, orders, circulars

## GENERAL TEXTS

### MINISTRY OF LABOUR, HEALTH, SOLIDARITY AND FAMILIES

### Decree No. 2025-760 of 4 August 2025 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

NOR: *TSSP2513470D*

***Groups concerned:*** *French National Agency for the Safety of Medicinal Products and Health Products, holders of marketing authorisations, pharmaceutical companies operating a medicinal product of major therapeutic interest, pharmaceutical establishments owned by a legal person governed by public law, pharmacies holding the authorisation referred to in the second paragraph of Article L. 5125-1-1 of the French Public Health Code.* ***Subject:*** *The Decree sets out the conditions under which the Minister for Health may, on an exceptional and temporary basis, authorise by order the production of special officinal preparations as defined in point 3 of Article L. 5121-1 of the French Public Health Code.*

*The text also provides for the types of public health measures that the Agency may take in order to ensure an appropriate and continuous supply by the holders and operators of marketing authorisations, pursuant to Article L. 5121-33-3 of the French Public Health Code.*

*Finally, the Decree lays down the conditions for implementing the obligation, set out in Article L. 5124-6 of the French Public Health Code, for companies holding or operating marketing authorisations stopping the marketing of medicinal products of major therapeutic interest, which are no longer the subject of patent protection, to use all their means to find a buyer. It specifies the conditions under which the Agency may request companies holding or operating marketing authorisations to grant, free of charge and for a temporary period, to a public pharmaceutical structure the manufacture and use of the medicinal product in order to allow continuity of supply to the French market.*

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

***Application:*** *the 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.*

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 French Public Health Code;

Having regard to Act No. 2023-1250 of 26 December 2023 on the financing of social security for 2024, notably Articles 71, 72 and 77 thereof;

Having regard to notification No. 2025/0138/FR of 12 March 2025, addressed to the European Commission; Having heard the Council of State (Social Affairs Section),

Hereby decrees:

**Article 1. –** Chapter I of Title II of Book I of Part Five of the French Public Health Code is amended as follows:

1 After Section 15, a Section 15a is inserted as follows:

*‘Section 15a*

***‘Special public powers of the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products***

‘*Article R. 5121-206-1.* – In the event of a shortage or risk of a shortage in the supply of a medicinal product of major therapeutic interest or a vaccine referred to in *b* of point 6 of Article L. 5121-1, the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products may, by means of a reasoned decision setting out the procedures and time limits for appeal, taken following an adversarial

procedure, take public health measures in the interests of public health with a view to ensuring an adequate and continuous supply by marketing authorisation holders and operators.

‘These measures, which are proportionate to the health risks involved, enable the agency to impose specific conditions, or to restrict or suspend the use, export, wholesale distribution, packaging or holding for sale of the health product in question, as well as to arrange for the importation of alternative treatments.

‘The decision of the agency’s Director-General shall be notified to the addressee and shall specify the time limit within which the addressee must comply with it.

‘Public health measures taken pursuant to Article L. 5121-33-3 shall be lifted immediately once they are no longer necessary. ’.

2 Section 19, which includes Article R. 5121-222, becomes Section 20, including Article R. 5121-225;

3 A section 19 is inserted worded as follows:

*‘Section 19*

***‘Special officinal preparations***

‘*Article R. 5121-222.* – In order to deal with the situations provided for in point 3 of Article L. 5121-1, the Minister responsible for Health, after identifying a need, may authorise, on an exceptional and temporary basis, by order adopted after consulting the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products, the production of special officinal preparations in accordance with the requirements laid down in that article.

‘The order and the monograph of the preparation shall be published on the website of the French National Agency for the Safety of Medicinal Products and Health Products.

‘Pharmacies manufacturing special medicinal preparations shall send to the Director-General of the regional health agency which authorised them pursuant to the second paragraph of Article L. 5125-1-1 and to the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products a monthly assessment of the preparations they have made.

‘*Article R. 5121-223.* – Special officinal preparations are intended for the prescribing doctor’s patients, under the doctor’s responsibility.

‘*Article R. 5121-224.* – The authorisation shall automatically lapse when the conditions set out in point 3 of Article L. 5121-1 are no longer met, on the date specified on the page of the French National Agency for the Safety of Medicinal Products and Health Products’ website dedicated to the availability of health products. ’

**Article 2.** – A Section 8 shall be added to Chapter IV of Title II of Book I of the fifth part of the French Public Health Code, worded as follows:

*‘Section 8*

***‘Suspension and cessation of the marketing of a medicinal product***

‘*Article R. 5124-73-1.* – The notification of the suspension or cessation of the marketing of a medicinal product or a product subject to the provisions of Chapter I of this Title shall be drawn up in accordance with the model established by the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products.

‘Attached are the measures that the pharmaceutical company intends to implement to ensure the effective marketing of the medicinal product for which a discontinuation or suspension is being considered, for the period required to put in place alternative solutions to meet the resulting demand.

‘Where the decision to suspend or cease marketing relates to a medicinal product of major therapeutic interest that is no longer protected by intellectual or industrial property rights, the notification shall set out the foreseeable consequences of this action for patients, having regard in particular to the resulting loss of sales volume on the French market and the available therapeutic alternatives.

‘*Article R. 5124-73-2.* – Within two months of receiving the complete declaration, where the Director-General of the Agency considers that the available therapeutic alternatives are insufficient to meet, on a sustainable basis, the need arising from the cessation or suspension of the marketing of a medicinal product of major therapeutic interest that is no longer protected by intellectual or industrial property rights, he shall inform the marketing authorisation holder that it is their responsibility to search for a pharmaceutical company to ensure the effective resumption of the use of the medicinal product in question and shall invite them to submit their comments within a time limit set by him.

‘*Article R. 5124-73-3.* – The marketing authorisation holder, who is responsible for finding a pharmaceutical company to ensure the effective resumption of the use of a medicinal product pursuant to II of Article L. 5124-6 shall make public their intention to grant the marketing rights or to transfer the marketing authorisation for the

medicinal product concerned by any appropriate means and shall publish this on a dedicated page of their website, the address of which they shall communicate to the French National Agency for the Safety of Medicinal Products and Health Products.

'The Agency shall publish on its website the list of email addresses communicated to it pursuant to this Article.

'*Article R. 5124-73-4.* – The report referred to in the second paragraph of point 3 of II of Article L. 5124-6 shall be drawn up in accordance with a model defined by the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products.

'The Director-General of the Agency may request the marketing authorisation holder to complete the report addressed to him/her within a period to be fixed by the Director-General of the Agency.

'*Article R. 5124-73-5.* – The Director-General of the French National Agency for the Safety of Medicinal Products and Health Products shall, where appropriate, request, by reasoned decision indicating the procedures and time limits for appeal, the marketing authorisation holder to grant free of charge the use and manufacture of the medicinal product in question to a pharmaceutical establishment owned by a legal person governed by public law which it designates, within one month of receipt of the full report.

'The marketing authorisation holder shall have one month from receipt of this request to respond and inform the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products thereof. This information is published on the Agency's website.

'*Article R. 5124-73-6.* – The marketing and manufacturing authorisation may be renewed for a period of two years by a reasoned decision of the Director-General of the French National Agency for the Safety of Medicinal Products and Health Products, setting out the time limits and procedures for appeal, which is notified to the marketing authorisation holder.

'*Article R. 5124-73-7.* – The fact that the authorisation to use and manufacture the medicinal product is granted under the conditions laid down in the last paragraph of Article L. 5124-6 (II) has no bearing on the obligations incumbent on the holder of the marketing authorisation. '.

**Article 3.** – The Minister of Labour, Health, Solidarity and Families, and the Minister attached to the Minister of Labour, Health, Solidarity and Families, with responsibility for Health and Access to Healthcare, are responsible, each in their respective areas, for the implementation of this Decree, which will be published in the Official Journal of the French Republic. Drawn up on 4 August 2025.

FRANÇOIS BAYROU

By the Prime Minister:

*The Minister of Labour, Health, Solidarity and Families,*

CATHERINE VAUTRIN

*The Minister attached to the Minister of Labour, Health, Solidarity and Families, with responsibility for Health and Access to Healthcare.*

YANNICK NEUDER