FRENCH REPUBLIC

Ministry of Labour, Health, Solidarity
and Family

Decree

laying down various implementing measures for Act No. 2023-1250 of 26 December 2023 on the financing of social security for 2024 on combating shortages of medicinal products

NOR: xxx

Groups concerned: *National Agency for the Safety of Medicinal Products and Health Products, holders of marketing authorisations, pharmaceutical undertakings 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.*

Subject: *Provisions implementing the Social Security Financing Act 2024. The Decree lays down the conditions under which the Minister responsible for health, exceptionally and temporarily, authorises by Decree the production of special officinal preparations defined in point 3 of Article L. 5121-1 of the Public Health Code to deal with the stock shortages of a medicinal product of major therapeutic interest or the cessation of its marketing or to deal with a threat or a serious health crisis. The text also provides for the types of animal 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 Public Health Code. The text also details the adversarial procedure at the end of which the Agency may take these measures. Finally, the decree lays down the conditions for implementing the obligation, set out in Article L. 5124-6 of the Public Health Code, for undertakings 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 undertakings holding or operating marketing authorisations to grant, free of charge and 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.*

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

Application: *The Decree is adopted pursuant to point 3 of Article L. 5121-1, Article L. 5121-33-3 and Article L. 5124-6 of the Public Health Code, as amended by 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,

On the report of the Minister for Labour, Health, Solidarity and Family,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, as amended by Directive 2004/27/EC of 31 March 2004 on the Community code relating to medicinal products for human use, in particular Articles 5 and 81 thereof;

Having regard to Directive (EU) no. 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down an information procedure in the field of technical regulations and of rules on Information Society services;

Having regard to the Public Health Code, in particular Articles L.5121-31, L.5121-33-3 and L.5124-6 thereof;

Having regard to Act No. 2023-1250 of 26 December 2023 on the financing of social security for 2024;

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

Having heard the Council of State (social division),

Hereby decrees:

Article 1

I. Chapter I of Title II of Book I of Part Five of the Public Health Code is amended as follows:

1 Section 19 becomes Section 20, comprising Article R. 5121-222, which becomes Article R. 5121-223;

2 It is re-established by a Section 19 worded as follows:

'Section 19:

'Special officinal preparations

'*Article R. 5121-222.* – For the purposes of applying the second paragraph of point 3 of Article L. 5121-1, the Minister responsible for health authorises, by decree, the production of special officinal preparations, after obtaining the opinion of the Director-General of the National Agency for the Safety of Medicinal Products and Health Products.

'The Order shall cease to apply automatically on the date on which the medicinal product concerned is made available, as published on the Agency's website. ';

II. After Article R. 5124-49-6, Articles R. 5124-49-7 and R. 5124-49-8 are inserted, worded as follows:

'*Article R. 5124-49-7.* – The animal health measures taken by the Director-General of the National Agency for the Safety of Medicines and Health Products to ensure the supply of a medicinal product of major therapeutic interest, pursuant to Article L. 5121-33-3, shall relate to the adaptation of distribution, the import of medicinal alternatives or any other measure having equivalent effect.

'The decision of the Director-General of the Agency shall specify the time limit within which marketing authorisation holders and pharmaceutical companies operating these medicinal products must comply with the prescribed animal health measures and the procedures for the lifting of the measures. ';

'Article *R. 5124-49-8.* – I. – The declaration of the suspension or discontinuation of the marketing of a medicinal product of major therapeutic interest referred to in Article L. 5124-

6(II) shall be drawn up in accordance with the guidelines laid down by decision of the Director-General of the National Agency for the Safety of Medicinal Products and Health Products. That statement shall mention, in particular, the foreseeable effects on patients, in view of the loss of volume represented by the suspension or cessation of the marketing of the proprietary medicinal product on the French market and the therapeutic alternatives available on the market after the suspension or cessation of marketing.

‘Within two months of receipt of the declaration referred to in the preceding paragraph, the Director-General of the Agency shall inform the marketing authorisation holder of the obligation incumbent on him to seek a pharmaceutical company to ensure the effective resumption of the operation of the medicinal product. The Director-General of the Agency shall set the date of implementation of the obligation and invite the marketing authorisation holder to submit its comments within a time limit to be set by the Director-General of the Agency.

‘II. – For the purpose of informing pharmaceutical companies, the marketing authorisation holder shall publish a declaration of its intention to grant the operation or transfer the marketing authorisation for the medicinal product concerned on a dedicated web page on its website and communicate the electronic link to that web page to the National Agency for the Safety of Medicinal Products and Health Products.

‘The Agency shall publish the list of electronic links communicated to it.

‘III. – 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 the guidelines laid down by decision of the Director-General of the National Agency for the Safety of Medicinal Products and Health Products.

‘The Director-General of the Agency may request from the marketing authorisation holder additional information to that contained in the report.

‘IV. – Within one month of receipt of the report referred to in III, if the National Agency for the Safety of Medicinal Products and Health Products considers that the need cannot be met on a permanent basis, it may request the marketing authorisation holder to grant free of charge the manufacture and use of the medicinal product under the conditions laid down in point 3 of point II of Article L. 5124-6.

‘Within one month of receipt of such request, the marketing authorisation holder shall concession the operation and manufacture of the medicinal product under the above conditions and shall inform the Director-General of the State Agency for the Safety of Medicinal Products and Health Products thereof. Upon receipt of this information, the Director-General of the Agency shall forward to the pharmaceutical establishment owned by a legal person governed by public law, which he shall designate, a copy of the marketing authorisation file for the medicinal product concerned. This information shall be published by the Agency on its website.

‘The concession of operation and manufacture shall not affect the obligations of the holder of the marketing authorisation.

‘The operating and manufacturing concession shall be tacitly renewed at the end of each two-year period in the absence of a decision to the contrary by the Director General of the Agency.

‘In accordance with Article L. 5124-6(II), the Director-General of the Agency may authorise the holder of the marketing authorisation to terminate that concession early, provided that an undertaking markets on the French market a medicinal product, the active ingredient of which is identical to that of the medicinal product which has been the subject of the concession, under conditions which make it possible to cover the need on a lasting basis.

‘V. – Pursuant to the I of Article L. 5124-6 providing that the cessation of marketing cannot take place before the end of the period necessary to put in place the alternative solutions to cover the need previously satisfied by the laboratory, the holder or the operator shall make every effort to cover the national need until the product is made available by a purchaser. ”.

Article 2

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:

Minister of Labour, Health, Solidarity and Family:

Catherine VAUTRIN