

**FRENCH REPUBLIC**

Ministry of Labour, Health, Solidarity and  
Family

**Decree No. of XXXXX**

**amending Decree No 2022-100 of 31 January 2022 regarding the individual dispensing of certain medicinal products in retail pharmacies**

NOR:

***Groups concerned:** Retail pharmacies, pharmaceutical laboratories, wholesalers and depositories.*

***Purpose:** Amendment to the medicinal products which may be dispensed individually and of the information to be affixed to the new packaging.*

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

***Application:** the Decree is issued pursuant to Article 40 of Law No 2020-105 of 10 February 2020 relating to the fight against waste and in favour of the circular economy*

**The Prime Minister,**

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, with particular reference to Articles L. 5123-8 et L. 5132-42-1 thereof;

Having regard to the notification xxxx to the European Commission pursuant 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 heard the Council of State (social section),

Hereby decrees:

**Article 1**

Subsection 6 of Section 1 of Chapter II of Title III of Book I of the fifth part of the Public Health Code is amended as follows:

1° At the end of Article L. 5132-42-2, a sentence is added, worded as follows: “This list shall specify the form in which they are presented.”;

2° Article L. 5132-42-3 is repealed;

3° Article L.5132-42-6 is amended as follows:

a) In the first sub-paragraph, after the words: "the following information", the words are inserted: "if these do not appear on the primary packaging,";

b) The provisions 1° to 10° shall be replaced by the following provisions:

1° the name of the proprietary pharmaceutical product, the dosage and the pharmaceutical form;

2° Where applicable, an indication of the recipient profiles ("infant", "child" or "adult");

3° The common name(s) where the medicinal product contains a maximum of three active substances;

4° Where applicable, special storage precautions;

5° Expiry date in clear text,

6° The manufacturing batch number

7° The dosage and duration of treatment.'

## **Article 2.**

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.

Signed on

By the Prime Minister:

Minister of Labour, Health, Solidarity and  
Families

Catherine Vautrin

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

Yannick Neuder