

FRENCH REPUBLIC

Ministry of Health and Access to Care

Decree No 20XX-XXXX of DATE on the system of prior declaration of the electronic commerce of medicinal products and the creation of a website for the electronic commerce of medicinal products as provided for in Article L. 5125-36 of the Public Health Code

NOR:

Target audience: *Pharmacists who own pharmacies, regional health agencies, the Pharmacists' Association.*

Purpose: *This draft Decree, adopted pursuant to Article L. 5125-41 of the Public Health Code, specifies the procedures for the prior declaration of the electronic commerce of medicinal products via the internet and the opening of a website dedicated to this activity pursuant to Article 89 of the Law of 7 December 2020 on the accelerating and simplification of public action.*

Entry into force: *This Decree shall enter into force three months after its publication in the Official Journal of the French Republic.*

Explanatory note: *This Decree provides for the abolition of the detailed rules relating to the procedures for the prior authorisation by regional health agencies of the electronic commerce of medicinal products carried out by a pharmacist and the opening of a site dedicated to that activity and replaces them with new rules relating to the system of prior declaration to regional health agencies.*

References: *The provisions of the Public Health Code as amended by this Decree may be consulted, in the wording resulting from this amendment, on the Légifrance website (<http://www.legifrance.gouv.fr>).*

The Prime Minister,

The report of the Minister for Health and Access to Care;

Having regard to 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, in particular Article 85c thereof;

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 Civil Code, in particular Article 1 thereof;

Having regard to the Public Health Code, particularly Articles L. 5125-33 and L. 5125-41 thereof;

Having regard to notification No xxxx/xxx/F addressed on dd/mm/yyyy to the European Commission under 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 Opinion No 24-A-02 of the Competition Authority dated 23/05/2024 on draft decrees and orders relating to the system of prior declaration of an activity and a website for the electronic commerce of medicinal products;

Having heard the Council of State (social division),

HEREBY DECREES:

Article 1

Article R. 5125-71 of the Public Health Code is replaced by:

‘ I.- The prior declaration of the electronic commerce of medicinal products and the creation of a website for the electronic commerce of medicinal products provided for in Article L. 5125-36 shall be sent by the pharmacists referred to in the third paragraph of Article L. 5125-33 to the Director-General of the regional health agency in whose territorial jurisdiction the pharmacy is located, by any means capable of acknowledging receipt thereof.

The prior declaration shall contain the elements provided for by order of the Minister responsible for health.

II.- The electronic commerce of medicinal products and the creation of a website for the electronic commerce of medicinal products provided for in Article L. 5125-36 may begin as soon as an acknowledgement of receipt of completeness of the declaration is sent by the regional health agency within 21 days of receipt of the prior declaration.

In the event that within the same period, the prior declaration is incomplete, the regional health agency shall notify the pharmacist of an acknowledgement of receipt of the incomplete declaration and a list of the missing elements. The pharmacist shall complete his/her file within 15 days of receipt of this notification, by any means capable of acknowledging receipt.

The regional health agency acknowledges receipt of the additional documents by any means capable of acknowledging receipt and decides on the completeness of the file within 21 days

of receipt. In the event of a complete application, it shall send an acknowledgement of receipt of completeness. In the event of an incomplete declaration, a notification of incompleteness shall be sent to the pharmacist. A new declaration must be sent.

III.- No later than seven days after the actual opening to the public of his/her website for the electronic commerce of medicinal products, the pharmacist shall inform the council of the pharmacists' association to which he/she belongs of the creation of the website for the electronic commerce of medicinal products and send it a copy of the acknowledgement of receipt of completeness of his/her prior declaration.'

Article 2

Article R. 5125-72 of the Public Health Code is replaced by:

' Any change in the elements identified as significant in the annex to the Order referred to in Article R. 5125-71 of the prior declaration shall be notified by pharmacists, without delay, by any means capable of acknowledging receipt, to the Director-General of the territorially competent regional health agency and to the council of the pharmacists' association to which they belong.'

Article 3

In Article R. 5125-73, the words 'without delay' is replaced by the words 'within 7 days'.

Article 4

In Article R. 5125-74, the word 'authorised' are replaced by the words 'legally engaged in the electronic commerce of medicinal products'.

Article 5

The provisions of this Order shall enter into force 3 months after the publication of this Decree in the Official Journal of the French Republic.

Article 6

The Minister for Health and Access to Care is responsible for the execution of this Decree, which will be published in the Official Journal of the French Republic.

Done on:

Michel Barnier

By the Prime Minister:

The Minister for Health and Access to Care

Geneviève Darrieussecq