

FRENCH REPUBLIC

Ministry for Health and Prevention

Order 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:

The Minister for Health and Prevention,

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 French Public Health Code, in particular Article R. 5125-71 thereof;

Having regard to Decree No xxx-2022 of dd/mm/yyyy on the prior declaration system for a website for the online sale of products;

Having regard to notification No xxxx/xxx/F of dd/mm/yyyy to the European Commission pursuant to [Directive];

Having regard to the opinion of the Competition Authority, dated xx/xx/xxxx,

Hereby decrees:

Article 1 – The documents to be included in the 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 R. 5125-71 are defined in the Annex to this Order.

Article 2 – This Order shall enter into force on dd/mm/yyyy.

Article 3 – The Minister for Health and Prevention shall be responsible for the execution of this Order, which shall be published in the Official Journal of the French Republic.

Done at

Geneviève Darrieussec

ANNEX

Documents to be included in the prior declaration <small>*significant elements, any modification of which must be notified in accordance with Article 2 of Decree No xxx-2022 of dd.mm.yyyy on the prior system of declaration of a website for the online sale of medicinal products</small>	Response elements and/or specific reference available for consultation (page No, annex No...)
I – PHARMACY INFORMATION	
<u>Information for the applicant :</u> Civility, first name and last name of the applicant E-mail Telephone number	Public Health Code: - Article L. 5125-33 - Article L. 5125-35 - Article L. 5125-37
<u>Information on the pharmacy:</u> Name of the pharmacy Licence number SIRET number Title, First name(s) and Surname(s) of the pharmacist(s) who own(s) or manage(s) the pharmacy Full postal address of the pharmacy Phone number / email Date of submission of the prior declaration Letter of application co-signed by the pharmacist(s) who own(s) or manage(s) the pharmacy If the pharmacy is managed by a company: a copy of the articles of association of the company	
II – INFORMATION RELATING TO THE PHARMACIST(S) RESPONSIBLE FOR THE ELECTRONIC COMMERCE OF MEDICINAL PRODUCTS	
Copy of the certificate(s) of registration with the council of the pharmacists' association of the pharmacist(s) who own(s) or manage(s) the pharmacy*	Article L. 5125-33 of the Public Health Code
List and qualification of the pharmacist(s) responsible for the electronic commerce of medicinal products in the pharmacy (owner, assistant or substitute)*	Article L. 5125-33 of the Public Health Code
III – INFORMATION RELATING TO THE ELECTRONIC COMMERCE OF MEDICINAL PRODUCTS IN THE PHARMACY	
Description of the organisation of the electronic commerce of medicinal products in the pharmacy*	Point 8.6.1 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version)
Description of the conditions for setting up the pharmacy, in particular concerning the premise or area dedicated to the electronic commerce of medicinal products*	Articles R. 5125-8 and R. 5125-9 of the Public Health Code
V - WEBSITE	
V-1 - Administrative identifier of the website	
Screenshot(s) of the website page mentioning:	Article 19 of Law No 2004-575 of 21 June 2004 on

Documents to be included in the prior declaration <small>*significant elements, any modification of which must be notified in accordance with Article 2 of Decree No xxx-2022 of dd.mm.yyyy on the prior system of declaration of a website for the online sale of medicinal products</small>	Response elements and/or specific reference available for consultation (page No, annex No...)
<ul style="list-style-type: none"> - The URL of the site*, - Information on the pharmacist(s) who own(s) or manage(s) the pharmacy selling medicinal products, - information concerning the pharmacy. 	<p>confidence in the digital economy</p> <p>Point 1 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p>
<p>Screenshot with the contact details and hyperlinks to the websites of the health authorities (ANSM, Ministry of Health) and the council of the pharmacists' association, as well as the common European logo (present only on the parts of the website offering medicinal products)</p>	<p>- Article R. 5125-70 of the Public Health Code</p> <p>Point 1 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p>
V-2 - Technical rules of the website	
<p>Copy of the form relating to the processing of personal data carried out in the context of the website contained in the declarant's register of personal data processing activities*</p>	<p>Point 3 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p>
<p>Screenshot of the message informing the patient about the processing of their personal data and their rights</p>	<p>Point 3 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p> <p>Articles 12 to 14 of the General Data Protection Regulation.</p>
<p>Declaration on honour by the pharmacist who owns or manages the pharmacy regarding the administration (including content management) of the website for the electronic commerce of medicinal products has not been subcontracted to a third party outside the pharmacy**</p> <p>**except for the design and technical maintenance of the website</p>	<p>Point 1 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p>
<p>Copy of the contract with the service provider that designs and/or provides technical maintenance of the website and a copy of the "health data host" certification *</p>	<p>Point 3 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code</p> <p>Article L. 1111-8 of the Public Health Code</p>
VI - ORDERING PROCESS	
VI-1 - Presentation of the medicinal product	
<p>Screenshot of the specific electronic commerce</p>	<p>Point 1 of the Annex to the Order of 28 November</p>

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tab for medicinal products, with the date of updating	2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code
Screenshot showing an example of the presentation of a medicinal product	Point 2 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code
Description of the procedures for verifying the mandatory consultation by the patient of the package leaflet of the medicinal product to place the order	Point 8.1 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version)
VI-2 - Patient data	
Description of the conditions for creating and securing the patient account and screenshot of the information requested from the patient at registration	Point 1 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code
Screenshot of the health questionnaire and description of the information and update requirements	Point 8.1 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version)
VI-3 - Dispensation	
Description and screenshot of the exchange arrangements between the pharmacist and the patient	Point 8.1 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version)
Description and screenshot of the means of alerting the pharmacist or of blocking in case the exemption dose indicated for the active substance ordered is exceeded	Point 8.2 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version) Point 1 of the Annex to the Order of 28 November 2016 on the technical rules applicable to websites for the electronic commerce of medicinal products provided for in Article L. 5125-39 of the Public Health Code
VI-4 - Order preparation and delivery	

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Description of the preparation and delivery conditions in compliance with the SmPC (special storage conditions) and transport conditions, in particular for temperature-sensitive products	Articles R. 5125-47 to R. 5125-49 of the Public Health Code Point 8.6 of the Order of 28 November 2016 on good practice in the dispensing of medicinal products in pharmacies, pharmacies of mutual insurance associations or mine workers' welfare, referred to in Article L. 5125-5 of the Public Health Code (consolidated version)

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