

FRENCH REPUBLIC

Ministry of Health
Youth, Sport and Associations

NOR :[...]

DECREE

**on the application of a security device on the exterior packaging of medicine, and amending
the Public Health Code (regulatory provisions)**

The Prime Minister,

On the report of the Minister for Health, Youth, Sport and Associations,

Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, and in particular Notification No ...;

Having regard to the Public Health Code;

Having heard the Council of State (Social section),

HEREBY DECREES

Article 1

Chapter I of Title II of Book I of the fifth part of the Public Health Code is amended as follows:

I - The following paragraph 4 is added to Article R. 5121-203:

"4. The exterior packaging of the medicine shall bear a security device that makes it possible to detect immediately any opening or attempted opening."

II - An Article R.5121-204, worded as follows, is inserted:

"*Article R. 5121-204.* The head pharmacist of the establishment who is responsible for attaching the device provided for in Article R.5121-203(4) shall attest to having done so by means of a declaration to the Director-General of the French Agency for the Safety of Health Products, indicating the device used. If the establishment is located in another State signatory to the Agreement on the European Economic Area, the declaration shall be made by the qualified person referred to in Article 48 of Directive 2001/83/EC of the European Parliament and of the Council."

Article 2

The Minister for Health, Youth, Sport and Associations shall be responsible for the implementation of this Decree, which shall be published in the Official Gazette of the French Republic.

Done at Paris, on [...]

By the Prime Minister

The Minister for Health, Youth, Sport and Associations