

# Decrees, orders, circulars

## GENERAL TEXTS

### MINISTRY OF LABOUR, HEALTH AND SOLIDARITY

#### Decree no. 2024-490 of 29 May 2024 on the sale of devices containing injectable hyaluronic acid

NOR: TSSP2406007D

**Target audience:** pharmacists, doctors, dental surgeons, patients, industrialists.

**Subject:** sale of devices containing injectable hyaluronic acid.

**Entry into force:** the Decree shall enter into force one month after its publication.

**Notice:** the Decree stipulates that the supply of injectable hyaluronic acid-based medical devices and products, in light of their serious risks to human health, is subject to a medical prescription.

**References:** the Decree and the provisions of the Public Health Code which it amends may be consulted, in the version resulting from this amendment, on the Légifrance website (<https://www.legifrance.gouv.fr>).

The Prime Minister,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

Having regard to Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices;

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 (codification);

Having regard to the Public Health Code, in particular Article L. 5211-6 thereof;

Having regard to notification No 2023/619/FR sent to the European Commission on 3 November 2023; Having heard the Council of State (social division),

Hereby decrees:

**Article 1.** - Chapter I of Title I of Book II of Part Five of the Public Health Code is supplemented by a section 12 as follows:

#### ‘ Section 12

#### ‘ **Devices subject to certain conditions of sale, resale or use**

‘ Article R. 5211-72. – May only be made available free of charge or in return for payment to doctors for their professional use and, on their prescription, to their patients:

‘1. Injectable medical devices, irrespective of the mode of introduction, including intradermal, containing hyaluronic acid;

‘2. Injectable products, irrespective of the mode of introduction, including intradermal, having no intended medical purpose, referred to in Annex XVI(3) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, containing hyaluronic acid.

‘ Article R. 5211-73. – The devices referred to in Article R. 5211-72(1) may also be made available, under the same conditions, to dental surgeons and their patients.’ **Article 2.** - This Decree shall enter into force one month after its publication.

**Article 3.** - The Minister for Labour, Health and Solidarity, and the Minister attached to the Minister for Labour, Health and Solidarity, responsible for Health and Prevention, shall each be responsible for the implementation of this Decree, which will be published in the *Official Journal* of the French Republic.

Dated 29 May 2024

GABRIEL ATTAL

*By the Prime Minister*  
*The Minister for Labour, Health and Solidarity*

CATHERINE VAUTRIN

*The Minister attached to the Minister*  
*for Labour, Health and Solidarity*  
*responsible for Health and Prevention,*

*FREDERIC VALLETOUX*