

FRENCH REPUBLIC

Ministry of Health and Prevention

Decree

on the supply of injectable hyaluronic acid

NOR:

Notice: Supervision of the supply of injectable hyaluronic acid-based medical devices and products, in light of their serious risks to human health, in order to make them subject to prescription and to prohibit their sale on the internet.

The Prime Minister,

On the report of the Minister of Health and Prevention,

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 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 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety;

Having regard to the Customs Code, particularly Article 38 thereof;

Having regard to the Public Health Code, in particular Articles L. 5211-6, L. 4141-1 and L. 4161-1 thereof;

Having heard the Council of State (social division),

Hereby decrees:

Article 1

I. – Hyaluronic acid injections, including intradermal devices and irrespective of the mode of introduction, may only be performed by doctors and dental surgeons.

II. – Injectable hyaluronic acid-based medical devices, including intradermal devices, irrespective of the mode of introduction, may only be delivered to doctors and dental surgeons for their professional use or, on their prescription, to a patient.

III. – Injectable hyaluronic acid-based products, including intradermal products, irrespective of the mode of introduction, having no intended medical purpose referred to in Article 1(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 may only be issued to doctors for professional use or, on prescription, to a patient.

IV. – The online sale of the devices referred to in II and III, and their importation in the context of an online sale, shall be prohibited, except for the health professionals mentioned in I.

Article 2

The Minister for the Economy, Finance and Industrial and Digital Sovereignty and the Minister for Health and Prevention are responsible for the implementation of this decree, which will be published in the *Official Journal* of the French Republic.

Dated

By the Prime Minister:

The Minister for Economy, Finance and Industrial and Digital Sovereignty,

Bruno LE MAIRE

The Minister for Health and Prevention,

Aurélien ROUSSEAU