



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Uimhir an Fhógra : 2019/0525/F (France)

Decree on intense pulsed light depilation processes for aesthetic purposes

An dáta ar a bhfuarthas é/í : 25/10/2019

Deireadh leis an Tréimhse Neamhghníomhaíochta : 27/01/2020

Message

Message 002

Communication from the Commission - TRIS/(2019) 02975

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2019/0525/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201902975.EN)

1. MSG 002 IND 2019 0525 F EN 25-10-2019 F NOTIF

2. F

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4. 2019/0525/F - S00S

5. Decree on intense pulsed light depilation processes for aesthetic purposes



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6. Intense pulsed light depilation processes for aesthetic purposes

7. -

8. The draft Decree aims to regulate the practice of intense pulsed light depilation in the context of aesthetic services provided by doctors, medical assistants or beauticians, particularly with regard to:

- the type of device that can be used;
- the conditions of use of intense pulsed light (IPL) equipment;
- information and warnings for users and purchasers of IPL depilation devices;
- reporting adverse events.

9. The purpose of the draft Decree is to change the current French system, which restricts the practice of pulsed light depilation processes to doctors, while at the same time limiting the risk of burns, and the risks - little understood - of malignant transformations of lesions due to the radiation and the removal of cancerous lesions.

From now on, this service may be provided by any doctor, any medical assistant practising under the responsibility of a doctor, or any beautician providing depilation services to consumers using this type of device. The changes to the system are the result of strong demand from various economic actors, mainly beauty institutes, in the context of an opinion of the National Agency for Food, Environmental and Occupational Health & Safety (ANSES) that has made it possible to consider lifting the medical monopoly on these services.

The draft Decree has therefore been drafted in compliance with the recommendations made by ANSES in its December 2016 report on the health risks associated with the use of devices employing physical agents intended for the practice of processes for aesthetic purposes.

The draft Decree provides that, before any initial pulsed light depilation service is provided, the consumer is to be informed of the contraindications applicable to intense pulsed light depilation and advised to seek their doctor's advice.

It also provides that any undesirable event occurring during or after a depilation process may be declared by the professional or the consumer themselves.

Consequently, the regulations on pulsed light depilation are necessary, appropriate and proportionate in terms of the public health objectives pursued. This regulatory change will lead to a significant opening of the market as the provision of these services has hitherto been restricted to doctors; beauticians will now also be permitted to provide them.

The draft text does not cover devices sold directly to the general public.

10. Reference(s) to basic text(s): - Article L412-1 of the French Consumer Code;

- Article L1151-2 of the French Public Health Code;

- ANSES collective expert appraisal report of December 2016: The health risks of the use of devices for aesthetic procedures implementing physical agents

11. No

12. -



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13. No

14. No

15. -

16. TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

European Commission

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