Notification Number: 2013/297/F

Decree relating to the issue of corrective lenses

Date received : 04/06/2013 End of Standstill : 05/09/2013

Message

Message 002

Communication from the Commission - TRIS/(2013) 01420

Directive 98/34/EC

Translation of the message 001 Notification: 2013/0297/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 késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Мääräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201301420.EN)

1. Structured Information Line

MSG 002 IND 2013 0297 F EN 04-06-2013 F NOTIF

2. Member State

F

3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13

d9834.france@finances.gouv.fr

tél: 01 44 97 24 55

3. Originating Department

Ministère des affaires sociales et de la santé.

Direction générale de la santé.

Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.

Bureau des dispositifs médicaux et autres produits de santé (PP3).

14, avenue Duquesne - 75350 PARIS 07 SP

jean.meister@sante.gouv.fr

tél: 01.40.56.44.85 – fax: 01.40.56.47.92

4. Notification Number

2013/0297/F - S00S

5. Title

Decree relating to the issue of corrective lenses

6. Products Concerned

Product: Corrective lenses.

Service: Offering the patient the chance to benefit from the services of a professional able to answer any requests for information or advice (under the scope of the electronic trade of corrective lenses)

7. Notification Under Another Act

_

8. Main Content

The draft decree establishes the rules determining the ways (notably using electronic means) by which corrective lenses can be issued. On the one hand, it subjects the first issue of corrective lenses to the prior verification by the professional that the corrective lenses have been adjusted prior to issue and, on the other hand, it subjects their issue to a valid medical prescription for patients under sixteen. Furthermore, it establishes the conditions for operating a website selling corrective lenses (offering the patient the chance to benefit from the services of a qualified professional able to answer any requests for information and advice given on the website). Finally, it requires service providers established in France to declare their website with the relevant territorial Regional Health Agencies (ARS), which publish the list of declared websites.

9. Brief Statement of Grounds

Whilst awaiting appropriate legislation, this draft decree aims to provide a temporary clarification of the corrective lens issue methods (notably by electronic means) and the requirements with which suppliers involved in this business must comply. The subjecting of the issue of corrective lenses to certain conditions is in the interests of public health and helps ensure greater health protection.

10. Reference Documents - Basic Texts

References to basic texts: Articles L. 4362-1 and L. 5211-5 of the Public Health Code.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

_



EUROPEAN COMMISSION GROWTH DIRECTORATE-GENERAL

Single Market for goods Prevention of Technical Barriers

13. Confidentiality No
14. Fiscal measures No
15. Impact assessment -
16. TBT and SPS aspects TBT aspect
No - the draft has no significant impact on international trade.
SPS aspect
No - the draft has no significant impact on international trade.

European Commission
Contact point Directive 98/34 Fax: +32 229 98043 email: dir83-189-central@ec.europa.eu