Notification Number: 2015/56/F

Decree relating to procedures for the application of Article L. 4362-10-1 and the wording and information that should feature on websites for the distance sale of corrective lenses and contact lenses

Date received : 05/02/2015

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Issue of comments by : Commission

Message

Message 002

Communication from the Commission - TRIS/(2015) 00307

Directive 98/34/EC

Translation of the message 001

Notification: 2015/0056/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: 201500307.EN)

1. Structured Information Line

MSG 002 IND 2015 0056 F EN 05-02-2015 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère des Affaires Sociales, de la Santé et des droits des femmes Direction Générale de l'Offre de Soins Sous-Direction des Ressources Humaines du Système de Santé Bureau Exercice, Déontologie et Développement professionnel continu (RH2) 14 avenue Duquesne 75007 PARIS Tel. 01.40.56.48.37 Fax. 01.40.56.42.46 guy.boudet@sante.gouv.fr

4. Notification Number

2015/0056/F - SERV20

5. Title

Decree relating to procedures for the application of Article L. 4362-10-1 and the wording and information that should feature on websites for the distance sale of corrective lenses and contact lenses

6. Products Concerned

Distance sales of corrective lenses for ametropia, and corrective contact lenses

7. Notification Under Another Act

8. Main Content

The purpose of Article 1 of this draft decree is to specify the essential wording that should feature on websites for the distance sale of corrective lenses and contact lenses. The chosen wording is not exhaustive and is intended to provide the patient with clear information regarding products distributed via these websites. The products in question are effectively medical devices intended to correct visual problems and deficiencies. Article 2 provides for the procedures whereby dispensing opticians may provide advice or useful information to patients making use of the services offered by these websites. This advice must be free, relevant, targeted, appropriate and individualised.

9. Brief Statement of Grounds

This draft decree is intended to supplement the legislative mechanism resulting from Law No 2014-344 of 17 March 2014 on consumer affairs. The purpose of one of the provisions of this law is to address the infringement proceedings (2005/70) launched against France by the European Commission regarding online sales of corrective lenses. The Commission reproached France for its lack of precision regarding the legality of online sales of optical products and glasses, that was liable to constitute an obstacle to Article 39 of the TEC and Article 3(2) of Directive 2000/31/EC. In order to clarify the French legislation, a new Article L. 4362-10-1 was therefore integrated into the French Public Health Code, the purpose of which was to give explicit recognition to the online sale of optical products and glasses, thereby complying with European Union law. This provision refers responsibility for specifying the wording that should feature on the websites, as well as the procedures for providing advice, to the relevant regulatory authority. In this regard, the draft decree lists the wording deemed essential to the desired objective, i.e. providing the patient with the best possible information when making their online purchase. The procedures relating to advice provided remotely by the dispensing optician specify the

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free and individualised nature of this advice, as well as the times when patients will be able to receive it. 10. Reference Documents - Basic Texts References to basic texts: Article L. 4362-10-1 of the French Public Health Code 11. Invocation of the Emergency Procedure 12. Grounds for the Emergency 13. Confidentiality No 14. Fiscal measures No 15. Impact assessment 16. TBT and SPS aspects TBT aspect No - the draft is not a technical provision or a conformity assessment procedure. SPS aspect No - the draft is neither a sanitary nor a phytosanitary measure. ***** **European Commission** Contact point Directive 98/34