



Notification Number: 2016/411/F

Order on the technical rules applicable to electronic commerce websites trading medicinal products referred to in Article L. 5125-39 of the Public Health Code

Date received : 04/08/2016

End of Standstill : 07/11/2016

Issue of comments by : Commission

Message

Message 002

Communication from the Commission - TRIS/(2016) 02423

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0411/F

No abre el plazo - Nezaħajuje 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 késéset - Ma' jiftaħ 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: 201602423.EN)

1. Structured Information Line

MSG 002 IND 2016 0411 F EN 04-08-2016 F NOTIF

2. Member State

F

3. Department Responsible

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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.

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4. Notification Number

2016/0411/F - SERV60

5. Title

Order on the technical rules applicable to electronic commerce websites trading medicinal products referred to in Article L. 5125-39 of the Public Health Code

6. Products Concerned

Dispensing medicinal products via electronic means

7. Notification Under Another Act

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8. Main Content

The Order on the technical rules applicable to electronic commerce websites trading medicinal products is intended to establish a number of rules contributing towards ensuring quality dispensing. These rules concern:

- associated functions intended to contribute towards quality dispensing: in particular, a specific tab for sales of medicinal products and an icon enabling the user to print out their exchanges with pharmacists, a prohibition on subcontracting Internet sales activity, and hyperlinks to the websites of pharmaceutical undertakings;
- the presentation of products online: in particular, a prohibition on posting any information sheets about the medicinal products on the website, other than the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL);
- the protection of health data.

9. Brief Statement of Grounds

The Order has been created in order to ensure that websites selling medicinal products online are able to offer safe, high-quality dispensing of medicinal products.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Article L. 5125-5 of the Public Health Code

11. Invocation of the Emergency Procedure

No

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 has no significant impact on international trade.

SPS aspect

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

European Commission

Contact point Directive (EU) 2015/1535

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