



Notification Number: 2016/410/F

## Order on best practices in the dispensing of medicinal products in retail pharmacies, cooperative pharmacies and emergency pharmacies for the mining industry, as mentioned in Article L. 5121-5 of the Public Health Code.

Date received : 04/08/2016

End of Standstill : 07/11/2016

### Message

Message 002

Communication from the Commission - TRIS/(2016) 02420

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0410/F

No abre el plazo - Nezaahajuje 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' 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: 201602420.EN)

#### 1. Structured Information Line

MSG 002 IND 2016 0410 F EN 04-08-2016 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

Direction générale des entreprises – SQUALPI – Bureau de la réglementation des produits - 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 du médicament (PP2).

14, avenue Duquesne - 75350 PARIS 07 SP

emilie.bouttier@sante.gouv.fr

tél : 01.40.56.78.13 – fax : 01.40.56.47.92

#### **4. Notification Number**

2016/0410/F - C00P

#### **5. Title**

Order on best practices in the dispensing of medicinal products in retail pharmacies, cooperative pharmacies and emergency pharmacies for the mining industry, as mentioned in Article L. 5121-5 of the Public Health Code.

#### **6. Products Concerned**

Dispensing of medicinal products

#### **7. Notification Under Another Act**

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#### **8. Main Content**

This order on best practices in the dispensing of medicinal products in retail pharmacies is intended to clarify the various steps in the dispensing process, especially to define the pharmaceutical analysis of orders or in relation to requests for optional prescriptions and pharmaceutical advice, and to provide for a pharmaceutical opinion to be drawn up when the pharmacist identifies a problem compromising the effectiveness or safety of the treatment.

This order also makes it possible to introduce the notions of a quality system and risk management in the context of dispensing, and to specify certain additional rules applicable to the electronic trade in medicinal products, such as the necessity for interactive exchange and the establishment of an online questionnaire.

#### **9. Brief Statement of Grounds**

This draft Order is intended to increase the safety of the dispensing process, whether over the counter or via electronic means. Quality dispensing constitutes a significant public health challenge, as it contributes to optimising the effectiveness of treatments and reducing the risks of medicine-related patient harm.

#### **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**

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**13. Confidentiality**

No

**14. Fiscal measures**

No

**15. Impact assessment**

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**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.

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European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: [grow-dir83-189-central@ec.europa.eu](mailto:grow-dir83-189-central@ec.europa.eu)