Notification Number: 2018/611/F

Pro Pharmacopoeia technical notes Nos 1273, 1274, 1275

Date received	:	12/12/2018
End of Standstill	:	13/03/2019
Issue of comments by	:	Germany

Message

Message 002

Communication from the Commission - TRIS/(2018) 03402
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2018/0611/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 - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201803402.EN)

1. Structured Information Line
MSG 002 IND 2018 0611 F EN 12-12-2018 F NOTIF

2. Member State
F

3. Department Responsible
Direction générale des entreprises – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13
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3. Originating Department
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4. Notification Number
2018/0611/F - C00P

5. Title
Pro Pharmacopoeia technical notes Nos 1273, 1274, 1275

6. Products Concerned
Draft monographs for pharmaceutical products

7. Notification Under Another Act
-

8. Main Content
It is proposed that the following monographs be revised in order to improve techniques or specifications in relation to the quality of substances authorised on the market:

- No 1273: Rye ergot for homeopathic preparations, Secale cornutum for homeopathic preparations, New monograph

- No 1274: Formic acid for homeopathic preparations, Formicum acidum for homeopathic preparations (rev.)

- No 1275: Homeopathic preparations. Further specifications from the French Pharamcopoeia Authority (rev).

9. Brief Statement of Grounds
The texts, implemented in the 11th edition of the French Pharmacopoeia, will be published by way of a decision of the Director-General of the French National Agency for the Safety of Medicines and Health Products after they have been submitted for public inquiry.

10. Reference Documents - Basic Texts
No basic text(s) available

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 is neither a technical regulation nor a conformity assessment procedure.

SPS aspect

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

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European Commission

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