



Notification Number: 2016/6/F

Pro Pharmacopoeia technical notes submitted for public inquiry Nos 1263, 1264, 1265 and 1266

Date received : 05/01/2016

End of Standstill : 06/04/2016

Issue of comments by : Germany

Message

Message 002

Communication from the Commission - TRIS/(2016) 00030

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0006/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: 201600030.EN)

1. Structured Information Line

MSG 002 IND 2016 0006 F EN 05-01-2016 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Agence nationale de sécurité du médicament et des produits de santé –

Direction des contrôles/Pôle Standardisation, Pharmacopée, Normalisation– 143-147, boulevard Anatole

France – F-93285 SAINT-DENIS CEDEX



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4. Notification Number

2016/0006/F - C00P

5. Title

Pro Pharmacopoeia technical notes submitted for public inquiry Nos 1263, 1264, 1265 and 1266

6. Products Concerned

Draft monograph

7. Notification Under Another Act

-

8. Main Content

- No 1263 Gelatine capsules of amiodarone hydrochloride (5 mg to 200 mg) (rev.)
- No 1264 Common sage PPH, Salvia officinalis PPH (rev.)
- No 1265 Fringe tree PPH, Chionanthus virginiana PPH (rev.)
- No 1266 Colocynth PPH, PPH Colocynthis (rev.).

9. Brief Statement of Grounds

The text (French Pharmacopoeia, 11th edition) will be published by way of an order in the Official Journal of the French Republic.

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 provision nor a conformity assessment procedure.

SPS aspect

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

European Commission

Contact point Directive (EU) 2015/1535

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