



Notification Number: 2013/555/F

**Pro Pharmacopoeia technical notes submitted for public inquiry Nos 1246 to 1253. No 1246: Spironolactone capsules (0.5 mg to 25 mg); No 1247: Drinkable Glycerol solution at 0.644 g/ml; No 1248: Rue for homeopathic preparations, Ruta graveolens for homeopathic preparations (rev.); No 1249: Ammonium carbonate for homeopathic preparations, Ammonii carbonas for homeopathic preparations (rev.); No 1250: Walnut for homeopathic preparations, Juglans regia for homeopathic preparations (rev.); No 1251: Giant puffball for homeopathic preparations, Bovista gigantea for homeopathic preparations (rev.); No 1252: Ash for homeopathic preparations, Fraxinus excelsior for homeopathic preparations (rev.); No 1253: Common mullein for homeopathic preparations, Verbascum thapsus for homeopathic preparations (rev.).**

Date received : 08/10/2013

End of Standstill : 09/01/2014

Issue of comments by : Germany

## Message

### Message 002

Communication from the Commission - TRIS/(2013) 02588

Directive 98/34/EC

Translation of the message 001

Notification: 2013/0555/F

No abre el plazo - Nezhajuje 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 - Nao 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: 201302588.EN)



## 1. Structured Information Line

MSG 002 IND 2013 0555 F EN 08-10-2013 F NOTIF

## 2. Member State

F

## 3. Department Responsible

Délégué interministériel aux normes – SQUALPI – 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

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  
pharmacopeefrançaise@ansm.sante.fr  
tél. 01 55 87 36 85 – fax. 01 55 87 41 32

## 4. Notification Number

2013/0555/F - C30P

## 5. Title

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## 6. Products Concerned

Draft monographs

## 7. Notification Under Another Act

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## 8. Main Content

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



French Republic with the following wording: "Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, and in particular notification No ..."

**9. Brief Statement of Grounds**

Pro Pharmacopoeia technical notes submitted for public inquiry.

**10. Reference Documents - Basic Texts**

No basic texts 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 not a technical provision or a conformity assessment procedure.

SPS aspect

No - the draft is not a sanitary or phytosanitary measure.

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European Commission

Contact point Directive 98/34

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**EUROPEAN COMMISSION**  
GROWTH DIRECTORATE-GENERAL

**Single Market for goods**  
Prevention of Technical Barriers