



Notification Number: 2010/540/F

**Technical notes pro pharmacopoeia subject to public inquiry
(texts appended hereto) No. 1223: Fringe tree
PPH/Chionanthus virginiana PPH PPH (Ver. 10) No. 1224:
Bushmaster snake PPH/Lachesis mutus PPH No. 1225:
Plant-based aqueous distillates and aromatic waters (Ver. 10)
No. 1226: Glycerine wax No. 1227: Gelatine capsules of
amiodarone hydrochloride (10mg to 200 mg)**

Date received : 04/08/2010

End of Standstill : 05/11/2010

Issue of comments by : Germany

Message

Message 002

Communication from the Commission - SG(2010) D/52012

Directive 98/34/EC

Translation of the message 001

Notification: 2010/0540/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: 201002012.EN)

1. Structured Information Line

MSG 002 IND 2010 0540 F EN 04-08-2010 F NOTIF

2. Member State

F

3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot –
75572 PARIS Cedex 12



d9834.france@finances.gouv.fr
tél : 01 53 44 98 24 – fax : 01 53 44 98 88

3. Originating Department

Agence française de Sécurité Sanitaire des Produits de Sante –
DLC/Unité Pharmacopée – 143-147, boulevard Anatole France –
F-93285 SAINT-DENIS CEDEX
pharmacopeefrançaise@afssaps.sante.fr
tél. 01 55 87 41 41 – fax. 01 55 87 41 32

4. Notification Number

2010/0540/F - C30P

5. Title

Technical notes pro pharmacopoeia subject to public inquiry
(texts appended hereto)

No. 1223: Fringe tree PPH/*Chionanthus virginiana* PPH PPH (Ver. 10)
No. 1224: Bushmaster snake PPH/*Lachesis mutus* PPH
No. 1225: Plant-based aqueous distillates and aromatic waters (Ver. 10)
No. 1226: Glycerine wax
No. 1227: Gelatine capsules of amiodarone hydrochloride (10mg to 200 mg)

6. Products Concerned

Draft monographs

7. Notification Under Another Act

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8. Main Content

French pharmacopoeia, 10th edition; the texts 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 rules relating to information society services, in particular notification No. ...".

9. Brief Statement of Grounds

Pro Pharmacopoeia technical notes submitted for public inquiry prior to publication in the Official Journal of the French Republic.

10. Reference Documents - Basic Texts

There is no reference text.



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 relevance

No - The draft is not a technical regulation or a conformity assessment.

SPS relevance

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

Catherine Day
Secrétaire général
Commission européenne

Point de contact Directive 98/34
Fax: (32-2) 296 76 60
email: dir83-189-central@ec.europa.eu

sent to :

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli



Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen
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European Free Trade Association
Mr. Robert Murphy

AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena
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NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

EFTA Surveillance Authority
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