



Notification Number: 2005/520/F

**Technical notes Pro Pharmacopoeia subject to public inquiry**  
**Technical notes Pro Pharmacopoeia (texts attached) No 1084 :**  
**Black henbane (leaf) No 1085 : Common ash (bark) No 1086 :**  
**1% iodine alcohol No 1087 : Sodium bicarbonate capsule (0.25**  
**- 0.5 - 1 g) No 1088 : Sodium chloride capsule (0.5 - 1 g) No**  
**1089 : Zinc oxide paste No 1090 : Colloidal silver ointment No**  
**1091 : 10% or 20% campher ointment No 1092 : Zinc oxide**  
**ointment No 1093 : Simplified preparation of ethanol solutions**  
**with a suitable content No 1094 : Placebo syrup for**  
**therapeutic use No 1095 : Strong 1% iodine iodo-iodide**  
**solution (Lugol) No 1096 : Picric acid PPH (10th revision) No**  
**1097 : Angostura PPH (10th revision) No 1098 : Giant reed**  
**PPH (10th revision) No 1099 : Dusty miller PPH (TNPP 1016**  
**revision) No 1100 : Common plantain PPH (10th revision) No**  
**1101 : Birdsfoot trefoil PPH (10th revision) No 1102 : Yellow**  
**sweetclover PPH (10th revision) No 1103 : Butcher's broom**  
**PPH (10th revision) No 1104 : Curly dock PPH (10th revision)**  
**No 1105 : Saw palmetto PPH (10th revision) No 1106 : Figwort**  
**PPH (10th revision) No 1107 : Senna PPH (10th revision) No**  
**1108 : Black elderberry PPH (10th revision) 7. - 8. Quality**  
**requirements for the products referred to in paragraph 6 and**  
**the related legislation. 9. Protection of Public Health 10.**  
**French Pharmacopoeia - 10th edition. The texts shall be**  
**published in the Official Gazette of the French Republic with**  
**the 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..." ". 11. NO 12. - 13. NO 14. NO 15. - 1**

Date received : 27/09/2005



End of Standstill : 29/12/2005

## Message

### Message 002

Communication from the Commission - SG(2005) D/52288

Directive 98/34/EC

Translation of the message 001

Notification: 2005/0520/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 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.

(MSG: 200502288.EN)

#### 1. Structured Information Line

MSG 002 IND 2005 0520 F EN 29-12-2005 28-09-2005 F NOTIF 29-12-2005

#### 2. Member State

France

#### 3. Department Responsible

Délégué interministériel aux normes - SQUALPI -12 rue Villiot - 75572 PARIS CÉDEX 12

suzanne.piau@industrie.gouv.fr ou syrte@industrie.gouv.fr

tél : 01 53 44 97 04 - fax : 01 53 44 98 88

#### 3. Originating Department

AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES PRODUITS DE SANTÉ - DLC/Unité pharmacopée - 143-147, boulevard Anatole France - F-93285 SAINT-DENIS CEDEX

#### 4. Notification Number

2005/0520/F - C30P

#### 5. Title

Technical notes Pro Pharmacopoeia subject to public inquiry

Technical notes Pro Pharmacopoeia (texts attached)

No 1084 : Black henbane (leaf)

No 1085 : Common ash (bark)

No 1086 : 1% iodine alcohol



No 1087 : Sodium bicarbonate capsule (0.25 - 0.5 - 1 g)  
No 1088 : Sodium chloride capsule (0.5 - 1 g)  
No 1089 : Zinc oxide paste  
No 1090 : Colloidal silver ointment  
No 1091 : 10% or 20% campher ointment  
No 1092 : Zinc oxide ointment  
No 1093 : Simplified preparation of ethanol solutions with a suitable content  
No 1094 : Placebo syrup for therapeutic use  
No 1095 : Strong 1% iodine iodo-iodide solution (Lugol)  
No 1096 : Picric acid PPH (10th revision)  
No 1097 : Angostura PPH (10th revision)  
No 1098 : Giant reed PPH (10th revision)  
No 1099 : Dusty miller PPH (TNPP 1016 revision)  
No 1100 : Common plantain PPH (10th revision)  
No 1101 : Birdsfoot trefoil PPH (10th revision)  
No 1102 : Yellow sweetclover PPH (10th revision)  
No 1103 : Butcher's broom PPH (10th revision)  
No 1104 : Curly dock PPH (10th revision)  
No 1105 : Saw palmetto PPH (10th revision)  
No 1106 : Figwort PPH (10th revision)  
No 1107 : Senna PPH (10th revision)  
No 1108 : Black elderberry PPH (10th revision)

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

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## **8. Main Content**

Quality requirements for the products referred to in paragraph 6 and the related legislation.

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

Protection of Public Health

## **10. Reference Documents - Basic Texts**

French Pharmacopoeia - 10th edition. The texts shall be published in the Official Gazette of the French Republic with the 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..." "

## **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**

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David O'Sullivan  
General Secretary  
European Commission

Contact point Directive 98/34  
Fax: (32-2) 296 76 60  
email: Dir83-189-central@cec.eu.int

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sent to :

Department of Trade and Industry STRD2  
Mr Philip Plumb

EFTA Surveillance Authority  
Mr. Gunnar Thor PETURSSON

European Free Trade Association  
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Hungarian Notification Centre Ministry of economy & transport  
Mr Zsolt Fazekas

Kauppa-ja teollisuusministeri  
Ms. Leila Orava

NSAI  
Mr Tony Losty

Représentation Permanente de l'Irlande  
Denis Colfer

Représentation Permanente du Royaume-Uni



EUROPEAN COMMISSION  
GROWTH DIRECTORATE-GENERAL

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

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Undersecretariat of Foreign Trade General Directorate of Standardisation  
Mr Mehmet COMERT