



Notification Number: 1997/204/F

Additional clause to the French Pharmacopoeia, 10th edition

Date received : 18/04/1997

End of Standstill : 22/07/1997

Message

REP PERMANENTE ROYAUME UNI

REP PERMANENTE IRLANDE

REP PERMANENTE GRECE

MINISTRY OF INDUSTRY, ENERGY & TECHNOLOGY
ATT. MR. Z.P. MAVROUKAS

HELLINIKOS ORG. TYPOPISOES
ATT. MR. MELAGRAKIS

DGS INTERNATIONAL BELGIUM

DEPT. OF TRADE AND INDUSTRY, QUALITY AND EDUCATION DIVISION,
ATT. MRS. B. O'GRADY

INST INDUST RESEARCH.
ATT. MR. J. NULTY

KOMMERSKOLLEGIUM
ATT. MS. KERSTIN CARLSSON

MINISTRY OF TRADE AND INDUSTRY
ATT. MS. TOLONEN

EUROPEAN FREE TRADE ASSOCIATION SURVEILLANCE AUTHORITY

EUROPEAN FREE TRADE ASSOCIATION
ATT. MS. BAKKE-D'ALOYA

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (97) D/50972/2
DIRECTIVES 83/189/EEC, 88/182/EEC AND 94/10/EC
TRANSLATION OF TELEX 001
NOTIFICATION 97/0204/F



- 3B1 : 9700972.EN

1. Structured Information Line

TLX 002 IND- 97 0204 F-- EN ----- 970418 --- ---

2. Member State

France

3. Department Responsible

Ministère de l'Industrie
Délégation interministérielle aux Normes - Bureau de
Normalisation et des Affaires Internationales

3. Originating Department

Agence du médicament

4. Notification Number

97/0204/F

5. Title

Additional clause to the French Pharmacopoeia, 10th edition

6. Products Concerned

Monographs of the French Pharmacopoeia (amendments and additions) (texts enclosed)

Revised monographs:

Hawthorn (flower of)

Pasteur bursa

Erythrosine

Grindelia

Indigotine

Quinoleine yellow

Pollens for allergen products

Sulconazole (nitrate of)

Cina for homeopathic preparations

New monographs:

Mint (leaf of)

Hymenoptera venom for allergen products

Artemisia dracunculus for homeopathic preparations

Asperula odorata for homeopathic preparations

Eucalyptus globulus for homeopathic preparations

Foenum graecum for homeopathic preparations

Galeopsis ochroleuca for homeopathic preparations

Galium aparine for homeopathic preparations

Glechoma hederacea for homeopathic preparations

Jaborandi for homeopathic preparations

7. Notification Under Another Act



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8. Main Content

Quality requirements for the products mentioned in paragraph 6 and related regulations.

9. Brief Statement of Grounds

Protection of Public Health

10. Reference Documents - Basic Texts

French pharmacopoeia, 10th edition. The texts will be published by means of an order in the Official Journal of the French Republic with the note: "Having regard to Directive 83/189/EEC laying down a procedure for the exchange of information in the field of technical standards and regulations, amended by Directives 88/182/EEC and 94/10/EC.". These monographs were the subject of notifications 96/0371/F and 96/0011/F at the time of their publication in a public enquiry.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

D. WILLIAMSON
COMEUR
NNNN