



Notification Number: 1990/226/F

Notice to manufacturers regarding applications for authorization to market herbal medicines (1990).

Date received : 08/08/1990

End of Standstill : 14/11/1990

Message

25681 UKECBR B
26730 IVERN B
206 2260426 01 RPGR
226236 GSI GR
ATT. MR. MITROPOULOS
219621 ELOT GR
ATT. MR. MELAGRAKIS
8813148 DIHQ
ATT. MR. J. WALKER
32501 OLAS EI
ATT. MR. J. NULTY
COPY : III/B/2 - PRE 68

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (90) D/50984/2
DIRECTIVES 83/189/EEC AND 88/182/EEC
TRANSLATION OF TELEX 001
NOTIFICATION 90/0226/F

- 3B2 : 9000999.EN

1. Structured Information Line

TLX 002 IND- 90 0226 F-- EN ----- 900808 --- ---

2. Member State

France

3. Department Responsible

Standardization Directorate-32, rue Guersant-75017 Paris
and SGCI-216, Rue de l'Universite-75700 Paris

3. Originating Department

Ministry of Solidarity, Health and Social Protection-Pharmacy and Drugs Directorate, 1, Place de Fontenoy-75350
Paris07SP



4. Notification Number

90/0226/F

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5. Title

Notice to manufacturers regarding applications for authorization to market herbal medicines (1990).

6. Products Concerned

Files on applications for authorization to market herbal medicines (174herbs).

7. Notification Under Another Act

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8. Main Content

Procedure for the compilation of files for recording herbal medicines. Updating of the previous notice published in 1986, the addendum to the notice published in 1988 and the notice on pharmaceutical specialities based on laxative drugs published in 1987.

9. Brief Statement of Grounds

To enable companies not to have to repeat toxicological and/or clinical tests on herbs whose non-toxicity and activity have been established.

10. Reference Documents - Basic Texts

Notice to manufacturers concerning requests for authorization to market herbal specialities (Official Bulletin No86/20A-Ministry of Social Affairs and Employment).

- Addendum to notice86/20A published in Official Bulletin No20 (1988)

- Notice to manufacturers of 3June1987 concerning specialities based on laxative drugs

- EEC guideline: Quality of herbal remedies

- Notice to applicants for marketing authorizaiton 1989 (EEC).

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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D. WILLIAMSON
COMEUR



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

NNNN