



Notification Number: 1990/274/F

## Notice to manufacturers concerning the registration of a proprietary medical product for self administration.

Date received : 07/09/1990

End of Standstill : 19/12/1990

### 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/60155/2  
DIRECTIVES 83/189/EEC AND 88/182/EEC  
TRANSLATION OF TELEX 001  
NOTIFICATION 90/0274/F

- 3B2 : 9001170.EN

#### 1. Structured Information Line

TLX 002 IND- 90 0274 F-- EN ----- 900907 --- ---

#### 2. Member State

France

#### 3. Department Responsible

Commissioner for standardization, 32 rue Guersant,  
75017 Paris SGCI, 216 rue de l'Université, 75007 Paris

#### 3. Originating Department

Ministry for Solidarity, Health and Social Security,  
Pharmaceuticals and Medical Directorate, 1 Place de Fontenoy,  
75350 Paris 07 SP



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**4. Notification Number**

90/0274/F

**5. Title**

Notice to manufacturers concerning the registration of a proprietary medical product for self administration.

**6. Products Concerned**

Proprietary pharmaceutical products for self administration.

**7. Notification Under Another Act**

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**8. Main Content**

Conditions attached to the preparation of a file requesting an authorization to market proprietary medical products for self administration.

Conditions attached: Characteristics required by self administration such as the choice of active principles having a high effectiveness/safety ratio, indications, dose rate, packaging and information. Endorsed for self administration in the ENT - Stomatology and broncho-pulmonary fields.

**9. Brief Statement of Grounds**

Updating of the procedure involved in preparing a file for a marketing authorization for proprietary medicinal products for self administration.

**10. Reference Documents - Basic Texts**

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**11. Invocation of the Emergency Procedure**

No

**12. Grounds for the Emergency**

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D. WILLIAMSON  
COMEUR  
NNNN