



Notification Number: 1999/21/F

Technical and organisational criteria for the security of order papers used by doctors for prescriptions.

Date received : 13/01/1999

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Issue of comments by : Commission

Message

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EUROPEAN FREE TRADE ASSOCIATION SURVEILLANCE AUTHORITY

EUROPEAN FREE TRADE ASSOCIATION
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TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (99) D/50109/2



DIRECTIVE 98/34/EC
TRANSLATION OF TELEX 001
NOTIFICATION 99/0021/F

- 3B1 : 9900109.EN

1. Structured Information Line

TLX 002 IND- 99 0021 F-- EN ----- 990113 --- ---

2. Member State

France

3. Department Responsible

Secrétariat Général du Comité Interministériel pour les
Questions de Coopération Economique Européenne
2, Bd Diderot
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3. Originating Department

Secrétariat d'Etat à la Santé et à l'Action Sociale Direction
Générale de la Santé
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F-75350 PARIS 07 SP

4. Notification Number

99/0021/F

5. Title

Technical and organisational criteria for the security of
order papers used by doctors for prescriptions.

6. Products Concerned

Medical prescription papers.

7. Notification Under Another Act

No

8. Main Content

Technical criteria defining the characteristics of security
prescriptions and the organisational procedures to be
implemented by publishers, stationers, printers and
transporters in order that prescribers (doctors, midwives,
dental surgeons, vets) may be supplied in security with
prescription papers with the following characteristics:
watermarked paper without brighteners, with micro letters,
pre-printed in blue, numbered by batch.



9. Brief Statement of Grounds

The Minister responsible for Health has decided to make the paper used for medical prescriptions unfalsifiable, or very difficult to falsify, in order that they may offer sufficient guarantees in the face of the misuse for fraudulent purposes of prescriptions made out on these papers, particularly in the case of prescriptions for the main analgesics (stupefacients and certain psychotropic products with analgesic properties).

10. Reference Documents - Basic Texts

Draft Decree on poisonous substances, the prescription and provision of medicinal products classed as stupefacients or subject to the regulations on stupefacients and the organisation of drug dependence evaluation, amending the Public Health Code.

Standard NF EN ISO 536

Standard NFQ 03-015

Standard ISO 8402.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

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