



Notification Number: 2002/374/E

Draft Royal Decree regulating plant medicines.

Date received : 23/09/2002
End of Standstill : 24/12/2002
Issue of comments by : Commission, France

Message

Message 002

Communication from the Commission - SG(2002) D/51874
Directive 98/34/EC
Translation of the message 001
Notification: 2002/374/E

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200201874.EN)

1. Structured Information Line

MSG 002 IND 2002 0374 E EN 24-12-2002 23-09-2002 E NOTIF 24-12-2002

2. Member State

Spain

3. Department Responsible

SUBDIRECCION GENERAL DE ASUNTOS INDUSTRIALES, ENERGETICOS,
TRANSPORTES, COMUNICACIONES Y MEDIO AMBIENTE.
DIRECCION GENERAL DE COORDINACION DEL MERCADO INTERIOR Y OTRAS
POLITICAS COMUNITARIAS.
SECRETARIA DE ESTADO PARA ASUNTOS EUROPEOS.
MINISTERIO DE ASUNTOS EXTERIORES.
C/ PADILLA, 46. PLANTA 2ª .DESPACHO 6218. (28006 MADRID).
TELEFONOS:91 379 84 64, 91 379 83 87 Y 91 379 83 98
FAX: 91 479 84 01
DIRECCION CORREO ELECTRONICO: d83-189@ue.mae.es

3. Originating Department

AGENCIA ESPAÑOLA DEL MEDICAMENTO. MINISTERIO DE SANIDAD Y CONSUMO. PASEO DEL PRADO
, 18-20. 28071. TELEFONO. 91.5.96 16 27 FAX 91. 5.96 44 22



4. Notification Number

2002/374/E - C00P

5. Title

Draft Royal Decree regulating plant medicines.

6. Products Concerned

Plants and plant mixtures, in addition to preparations obtained from plants in the form of extracts, lyophilizates, distillates, tinctures, cooked products or any other galenical preparation with a therapeutic, diagnostic or preventative use.

7. Notification Under Another Act

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8. Main Content

Draft Royal Decree regulating plant medicines, which shall follow the system for pharmaceutical specialities, laboratory preparations, magistral formulae or those specific to traditional plant medicines as appropriate, with the specifications laid down in this standard. The Ministry of Health and Consumer Affairs shall draw up a list of plants whose sale to the public shall be restricted or prohibited due to their toxicity; plants that are traditionally considered to have medicinal properties, where no specific reference is made to their therapeutic, diagnostic and preventative properties, may be freely sold to the public. Their sale on rounds shall remain prohibited.

9. Brief Statement of Grounds

To update the regulation on medicines made from plant species, taking into account the progressive increase in the use of plant products and possible risks to health arising from the uncontrolled consumption of these. This is notified pursuant to the procedure laid down in Directive 98/34/EC, in accordance with the provisions of Royal Decree No 1337 of 31 July 1999, regulating the provision of information in the field of technical standards and regulations, and rules and regulations relating to information society services.

10. Reference Documents - Basic Texts

This Royal Decree, which has the status of legislation on pharmaceutical products, pursuant to Article 2(1) of Law No 25 of 20 December 1990, on Medicines, implements Article 42 of the aforementioned Law, deriving its legal status from the same article.

11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

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13. Confidentiality



NO

14. Fiscal measures

NO

David O'Sullivan
Secretary-General
European Commission

sent to:

Bundesministerium für Wirtschaft Referat VD2
Frau Christina Jäckel

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau Brigitte WIKGOLM

Department of Trade and Industry - Standards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

Délégation Interministérielle aux Normes
Mme Piau

EC

.

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

ELOT
Mr E. Melagrakis

Erhvervs- og Boligstyrelsen
Lene Hald Nielsen

European Free Trade Association

.

Institut Belge de Normalisation
Mme F. Hombert

Instituto Português da Qualidade
Sra. Candida Pires

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium



Mme Kerstin Carlsson

Min. de Asuntos Exteriores
Esther Perez Pelaez

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën Belastingdienst - Douane / CDIU
De Heer IJ.G. van der Heide

Ministero dell'Industria, del commercio e dell'artigianato
Signor P. Cavanna

Ministère des Affaires Economiques
Mme Descamps

NSAI
Mr Tony Losty

National Agency for Enterprise & Housing
Laila Østergren

SPERATI Marie
.

Service de l'Energie de l'Etat
Mr J.-P. Hoffmann

sent to :

Department of Trade and Industry - Standards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EC
.

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Mr. Gunnar Thor PETURSSON

ELOT
Mr E. Melagrakis

European Free Trade Association
.

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Kommerskollegium



Mme Kerstin Carlsson

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financien Belastingdienst - Douane / CDIU
De Heer IJ.G. van der Heide

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
Denis Colfer

Représentation Permanente du Royaume-Uni
.

Undersecretariat of Foreign Trade General Directorate of Standardisation
Saadettin DOGAN