Notification Number: 2003/227/E

Draft Royal Decree regulating medicinal gases.

Date received	:	27/06/2003
End of Standstill	:	29/09/2003
Issue of comments by	:	Commission,Italy

Message

Message 002

Communication from the Commission - SG(2003) D/51231
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0227/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: 200301231.EN)

1. Structured Information Line
MSG 002 IND 2003 0227 E EN 29-09-2003 27-06-2003 E NOTIF 29-09-2003

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.
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3. Originating Department
AGENCIA ESPAÑOLA DEL MEDICAMENTO. MINISTERIO DE SANIDAD Y CONSUMO. PASEO DEL PRADO , 18-20. 28071. TELEFONO 91.5. 96.41.16 Y 91.5.96.16.69 . FAX 91. 5. 96. 16. 74.

4. Notification Number
2003/0227/E - C10P

5. Title
Draft Royal Decree regulating medicinal gases.

6. Products Concerned
Industrially-manufactured gases classed as medicines, and the pharmaceutical laboratories which, after having been authorised by the Spanish medicines agency (agencia española del medicamento), become holders of the marketing authorisation for medicinal gases, and marketers of medicinal gases.

7. Notification Under Another Act
-

8. Main Content
Key words: Classification of gases as medicines, definition, standard.

The draft Royal Decree regulating medicinal gases consists of three chapters, nine articles, one sole transitional provision, one sole repealing provision and three final provisions.
As reflected in the preamble, it aims to give Article 54(a) of Law 25/90 on Medicines power to implement and refers to gases intended for both human and veterinary use, without distinction.
Chapter I(2) specifies the conditions necessary for a gas to be classed as a medicine, laying down the bases for its authorisation as such.
Chapter II lays down authorisation procedures and general and specific conditions. Chapter III lays down common provisions. Article 7 on packaging and labelling and Article 8 on Standards for correct manufacture must also be highlighted.
Article 9 (Supply, delivery or dispensing) is of particular interest, given that this point, in which the difference between the dispensing or administration of a medicine and that of a medicinal gas are made patently clear, is an important factor for consideration. This alone would justify the need to establish an unequivocal standard for medicinal gases.

8.2 For the purposes of mutual recognition with regard to the authorisation of medicinal gases by Royal Decree No 767/93, they must also comply with the provisions of Chapter VII(50) thereto.

9. Brief Statement of Grounds
The draft Royal Decree regulating medicinal gases will provide a remedy to the current legislative void and the uncertainty which has existed until this point in Spain with regard to which type of gases should be regarded as medicines by means of specific legislation.

The Standard clearly defines which products are medical devices and which, in their action by pharmacological, immunogenic or metabolic means, must be included in the category of medicines, as laid down in Article 8 of Law No 25 of 20 December 1990 on Medicines.

Medicinal gases must, therefore, comply with current legislation on medicines. However, given their particular use and distribution, it has been necessary to supplement their conditions for authorisation with a specific

regulation.

10. Reference Documents - Basic Texts
Law No 25 of 20 December 1990 on Medicines.
Royal Decree No 1564 of 18 December 1992 implementing and regulating the system for the authorisation of pharmaceutical laboratories and the guarantee of quality in their industrial manufacture
Royal Decree No 767 of 21 May 1993 regulating the evaluation, authorisation, registration and conditions for the dispensing of industrially-manufactured medicines for human use.
Royal Decree No 109 of 27 January 1995 on veterinary medicines.

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
No

16. TBT and SPS aspects
TBT Aspects: No
The draft shall have no noticeable effect on international trade

SPS Aspects: No
The draft is not a sanitary or phytosanitary measure pursuant to Annex A of the SPS agreement

David O'Sullivan
Secretary-General
European Commission

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sent to :

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