



Notification Number: 2011/243/E

## Draft Royal Decree laying down a procedure for determining whether a substance may be considered as a narcotic at national level

Date received : 20/05/2011

End of Standstill : 02/06/2011

Invocation of the Emergency Procedure : Yes

### Message

Message 002

Communication from the Commission - SG(2011) D/51212

Directive 98/34/EC

Translation of the message 001

Notification: 2011/0243/E

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201101212.EN)

#### 1. Structured Information Line

MSG 002 IND 2011 0243 E EN 20-05-2011 E NOTIF

#### 2. Member State

E

#### 3. Department Responsible

Subdirección General de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y Medio Ambiente.

Dirección General de Asuntos Generales y de Coordinación de Políticas del Tratado de Funcionamiento de la Unión Europea.

Secretaría de Estado para la Unión Europea.

Ministerio de Asuntos Exteriores y de Cooperación.

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### 3. Originating Department

Subdirección General de Inspección y Control de Medicamentos de la Agencia Española de Medicamentos y Productos Sanitarios. Área de Estupefacientes y Psicotropos.  
Ministerio de Sanidad, Política Social e Igualdad

### 4. Notification Number

2011/0243/E - C00P

### 5. Title

Draft Royal Decree laying down a procedure for determining whether a substance may be considered as a narcotic at national level

### 6. Products Concerned

SUBSTANCE TAPENTADOL, WITH THE FOLLOWING FORMULA:  
3-[(1R,2R)-3-(DIMETHYLAMINO)-1ETHYL-2-METHYLPROPYL] PHENOL

### 7. Notification Under Another Act

-

### 8. Main Content

The purpose of this draft royal decree is to lay down a procedure for determining whether a natural or synthetic substance, not included in lists I and II in the attachments to the United Nations Single Convention of 1961 or which has not received such consideration at international level, is to be considered as a narcotic at national level, as well as to regulate national oversight of the substance Tapentadol.

### 9. Brief Statement of Grounds

So that a substance not included on international oversight lists can be classified as a narcotic at national level, it is necessary to develop Law 17/67 of 8 April on narcotics, in order to define the legislative framework to be applied.

Since the entry into force of the aforementioned Law, it has not be deemed necessary to classify a substance as a narcotic at national level. However, the need has since arisen to lay down supplementary provisions to this Law, in order to develop a regulatory procedure for the national oversight of narcotic substances determined by the Ministry of Health, Social Policy and Equality, given that the oversight of the substance Tapentadol at national level is considered necessary before it is sold in Spain and subject to the control measures pursuant to Law 17/67 of 8 April for the substances included in List I of the S.C.1961. These control measures are essential for adequately managing the risk of improper use, abuse or illegal trafficking of Tapentadol.

Tapentadol is to be included as a narcotic following a process of evaluation, carried out by the Spanish agency of medicines and health products according to the provisions of this draft royal decree, which saw positive results.



In turn, and in support of this theory, it should be noted that various countries both within and outside of the European Union have classified Tapentadol as a narcotic through national procedures on their respective lists of controlled medicines. These countries include: the United States, Germany, Ireland, Italy, France, Sweden, Switzerland, Greece, Denmark, Lithuania, Mexico and Chile.

#### **10. Reference Documents - Basic Texts**

No basic texts exist

#### **11. Invocation of the Emergency Procedure**

Yes

#### **12. Grounds for the Emergency**

The sale of the substance Tapentadol, to be subject to oversight by virtue of this draft royal decree, is forecast for summer of this year.

In this respect, preclinical and clinical data obtained during the development of Tapentadol show that this substance has a similar efficacy to that of traditional high-strength opiates such as morphine, oxycodone and hydromorphone. For this reason, it is considered necessary to implement a national-level oversight of Tapentadol before it is sold in Spain and subject to the control measures pursuant to Law 17/67 of 8 April for the substances included in List I of the S.C.1961, since such control measures are essential for adequately managing the risk of improper use, abuse or illegal trafficking of Tapentadol and, consequently, for protecting human health, in accordance with Article 9.7 of Directive 98/34/EC.

Likewise, it should be noted that various countries in the European Union have classified Tapentadol as a narcotic through national procedures on their respective lists of controlled medicines, including Germany, Ireland, Italy, France, Sweden, Greece, Denmark and Lithuania. In all of these countries, Tapentadol has been included on the same list as the aforementioned traditional high-strength opiates.

#### **13. Confidentiality**

No

#### **14. Fiscal measures**

No

#### **15. Impact assessment**

Yes

#### **16. TBT and SPS aspects**

TBT aspect

No - the draft will have no noticeable effect on international trade.

SPS aspect:

No - the draft will have no noticeable effect on international trade.



**EUROPEAN COMMISSION**  
GROWTH DIRECTORATE-GENERAL

**Single Market for goods**  
Prevention of Technical Barriers

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