Notification Number: 2002/299/UK

The Medicines for Human Use (Kava – kava) (Prohibition) Order 2002

Date received : 24/07/2002

End of Standstill : 25/10/2002

Message

Message 001

Communication from the Commission - SG(2002) D/51495
Directive 98/34/EC
Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notification - Notifica - Kennisgeving - Notificacão - Ilmoitus - Anmälan : 2002/299/UK.

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: 200201495.EN)

1. Structured Information Line
MSG 001 IND 2002 0299 UK EN 25-10-2002 24-07-2002 UK NOTIF 25-10-2002

2. Member State
United Kingdom.

3. Department Responsible
Department of Trade and Industry: Standards and Technical Regulations Directorate

3. Originating Department
Department of Health, Medicines Control Agency

4. Notification Number
2002/299/UK - COOP

5. Title
The Medicines for Human Use (Kava – kava) (Prohibition) Order 2002

6. Products Concerned
Prohibition of sale, supply and importation of any medicinal product consisting of or containing a plant belonging to the species Piper methysticum (known as Kava-kava), or an extract from such a plant.

7. Notification Under Another Act
Article 123 (1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use

8. Main Content
Prohibition of the sale, supply or importation of medicinal products as referred to in 6 above, subject to the following exemptions

(a) where the product is for external use only;

(b) where the sale or supply is to, or the importation is made by or on behalf of, a person exercising functions in relation to the enforcement of food or medicines legislation;

(c) where the product is imported from an EEA State, if it originates from such a State or originates from outside the EEA but is in free circulation in Member States (within the meaning of Article 23.2, when read with Article 24 of the EC Treaty) and is being, or is to be exported to an EEA State other than the United Kingdom;

(d) where the product is the subject of a product licence, marketing authorization or homeopathic certificate of registration.

The UK will fulfil its obligation under Article 12 of Directive 98/34/EC (as amended) when these Regulations are officially published.

9. Brief Statement of Grounds
There is evidence that Kava - kava is associated with the risk of liver toxicity. A voluntary withdrawal of Kava - kava products was effected in December 2001 following the emergence of safety concerns. Since then, the Medicines Control Agency (MCA) has been involved in identifying and gathering further data from the herbal sector and other regulatory authorities worldwide. The MCA is currently aware of 68 cases worldwide of liver problems suspected to be associated with Kava – kava. These include cases of liver failure resulting in 6 liver transplants and 3 deaths. There have been 3 reports of liver toxicity in the UK suspected to be associated with the consumption of Kava – kava. On 10 July 2002, the Committee on the Safety of Medicines (CSM), which is responsible for providing advice on the safety of medicines in the UK, advised the MCA that the risk benefit profile for Kava-kava was negative. In the light of the new evidence and that advice, it is proposed that it is necessary in the interests of safety to prohibit the sale, supply and importation of Kava-kava.

10. Reference Documents - Basic Texts
i The Medicines for Human Use (Kava – kava) (Prohibition) Order 2002

ii N/A

iii Partial Regulatory Impact Assessment (RIA)

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
General Secretary
European Commission

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sent to :

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SPERATI Marie
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