Notification Number: 2004/24/UK

The Medicines for Human Use (Senecio) (Prohibition) Order 2004

Date received : 28/01/2004

End of Standstill : 29/04/2004

Message

Message 001

Communication from the Commission - SG(2004) D/50197
Directive 98/34/EC
Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notification - Notifica - Kennisgeving - Notificacão - Ilmoitus - Anmälan : 2004/0024/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: 200400197.EN)

1. Structured Information Line
MSG 001 IND 2004 0024 UK EN 29-04-2004 28-01-2004 UK NOTIF 29-04-2004

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 and Healthcare products Regulatory Agency

4. Notification Number
2004/0024/UK – C10P

5. Title
The Medicines for Human Use (Senecio) (Prohibition) Order 2004

6. Products Concerned
Prohibition of sale, supply and importation of any unlicensed medicinal product consisting of, or containing any plant belonging to the genus Senecio, or an extract from such plants.

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 authorisation or homeopathic certificate of registration.

9. Brief Statement of Grounds
In March 2002 it came to the attention of the Medicines and Healthcare products Regulatory Agency (MHRA) that a Chinese medicinal product, Qian Bai Biyan Pian, which traditionally contains the toxic plant Senecio scandens, had been placed on the UK market. Senecio scandens is a member of the plant genus Senecio. All species of plants within this genus contain unsaturated pyrrolizidine alkaloids (PAs) which are known to cause serious liver damage, known as veno-occlusive disease in man. Unsaturated pyrrolizidine alkaloids have also been shown to be carcinogenic, mutagenic and genotoxic in animals.

In response to the risk to public health posed, the MHRA wrote to all herbal interest groups on 26 March 2002 highlighting the toxicity of the genus and requesting a voluntary withdrawal of all unlicensed medicines that may contain Senecio species. The Agency specifically asked to be made aware of any herbal interest groups that disagreed with its initial safety assessment or proposed not to advise its members to remove any relevant products from supply. No such representations were received. However, the Agency has recently received a number of reports indicating that unlicensed herbal remedies that may contain Senecio continue to be supplied to the public.

On the basis of the available evidence, the MHRA considers any continued supply of Senecio in unlicensed medicines for internal use poses a serious risk to public health. Therefore, in the interest of public safety, Ministers and the MHRA are now proposing to make an order prohibiting the sale, supply or importation of unlicensed medicinal products containing Senecio species.

10. Reference Documents - Basic Texts
Draft measure is contained in Annex B of the Consultation Package.
e) No basic texts.

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
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13. Confidentiality
NO

14. Fiscal measures
NO

15. Impact assessment
Information on the impact assessment can be found in the Consultation Package.

16. TBT and SPS aspects
TBT Aspect: Yes

SPS Aspect: The draft is not a sanitary or phytosanitary measure in the sense of Annex A of the SPS Agreement.

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European Commission

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