



Notification Number: 2000/744/UK

The Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001.

Date received : 22/12/2000

End of Standstill : 23/03/2001

Message

Bundesministerium für Wirtschaft Referat VD2
Frau Christina Jäckel

Bundesministerium für Wirtschaft und Arbeit - Abt. II/1
Frau M. Haslinger-Fenzl

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

Délégation Interministérielle aux Normes
Mme Piau

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

Erhvervsfremme Styrelsen
Hr. Keld Dybkjaer

European Free Trade Association
Ms Anne-Lise Bakke-D'Aloya

Institut Belge de Normalisation
Mme F. Hombert

Instituto Português da Qualidade
Sra. Candida Pires

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

Min. of Industry, Energy & Technology



Mr K. Polychronidis

Min. para Relaciones con la Comunida
Maria Angeles Martinez Alvarez

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

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

Ministère des Affaires Economiques
Mme Descamps

NSAI
Mr Tony Losty

Représentation Permanente du Luxembourg
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Message 001

Communication from the Commission - SG(2001) D/50011
Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notificación - Notification - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 2000/744/UK.

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ala tästä - Inleder ingen frist.

(MSG: 200100011.EN)

1. Structured Information Line

MSG 001 IND 2000 0744 UK EN 23-03-2001 11-12-2000 UK NOTIF 23-03-2001

2. Member State

United Kingdom

3. Department Responsible

Department of Trade and Industry
Standards and Technical Regulations Directorate.

3. Originating Department

Department of Health

4. Notification Number

2000/744/UK - COOP



5. Title

The Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001.

6. Products Concerned

Medicinal products:

- (a) consisting of or containing a plant belonging to a species of the genus *Aristolochia*, or an extract from such a plant;
- (b) consisting of or containing a plant belonging to any of the species *Akebia quinata*, *Akebia trifoliata*, *Clematis armandii*, *Clematis montana*, *Cocculus laurifolius*, *Cocculus orbiculatus*, *Cocculus trilobus*, *Stephania tetrandra*, or an extract from such a plant; or
- (b) presented as consisting of or containing Mu Tong or Fangji, a plant as referred to in (b), or an extract from such a plant.

7. Notification Under Another Act

Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, Article 33.1.

8. Main Content

Prohibits the sale, supply and importation of medicinal products as referred to in 6 above, subject to the following exceptions-

- (a) where the sale or supply is to, or the importation is made by or on behalf of, persons exercising functions in relation to the enforcement of food or medicines legislation;
- (b) in the case of the prohibition on importation, the product is imported from a member State or, where the product originates in an EEA State, from an EEA State other than a member State;
- (c) where the product is the subject of a product licence granted under the Medicines Act 1968, a marketing authorization or a homoeopathic of registration.

There is no provision for recognition of equivalent standards.

9. Brief Statement of Grounds

There is strong evidence that *Aristolochia* can cause severe health problems, including renal failure and cancers. In particular, there have been two recently reported cases in the United Kingdom in which serious kidney damage appears to have been caused by the presence of *Aristolochia*.

Evidence suggests that a large proportion of products presented as containing Mu Tong and Fangji contain *Aristolochia* species. Mu Tong is a name applied, in particular, to plants of the species *Akebia quinata*, *Akebia trifoliata*, *Aristolochia manshuriensis*, *Clematis armandii*, and *Clematis montana*. Fangji is a name applied, in particular, to plants of the species *Aristolochia Fangchi*, *Cocculus laurifolius*, *Cocculus orbiculatus*, *Cocculus trilobus* and *Stephania tetrandra*.



A recent sampling exercise by the Medicines Control Agency of Mu Tong and Fangji products revealed that 44% of the samples taken up contained aristolochic acids. There are, at present, no effective quality and safety controls having effect in relation to the marketing of Mu Tong and Fangji products.

Due to the high degree of contamination of Mu Tong and Fangji products with Aristolochia and the lack of effective quality and safety controls in relation to their marketing, it is currently considered necessary to prohibit the sale, supply and importation of those products, in order to protect public health.

However, the necessity of prohibiting the sale, supply and importation of Mu Tong and Fangji products is being kept under review and consideration will be given to relaxing the prohibition if and when the Medicines Control Agency are satisfied that the quality and safety of these products can be guaranteed.

It is proposed that the Order the subject of this notification will revoke and replace the Medicines (Aristolochia and Mu Tong etc.) (Temporary Prohibition) Order 1999 (S.I. 1999/2889) (the temporary Order), which will expire on 30th June 2001. The temporary Order was the subject of a previous UK notification under the urgent procedure in Article 9.7 of Directive 98/34.

10. Reference Documents - Basic Texts

The Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001
Previous notifications: 99/369/UK and 99/480/UK

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