



Notification Number: 2000/263/UK

The Medicines (Aristolochia and Mu Tong etc.) (Temporary Prohibition) Order 2000.

Date received : 15/05/2000

End of Standstill : 16/05/2000

Invocation of the Emergency Procedure : Yes

Message

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Message 001

Communication from the Commission - SG(2000) D/51100
Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notificación - Notification - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 2000/263/UK.

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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: 200001100.EN)

1. Structured Information Line

MSG 001 IND 2000 0263 UK EN 15-05-2000 UK NOTIF

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



2000/263/UK

5. Title

The Medicines (Aristolochia and Mu Tong etc.) (Temporary Prohibition) Order 2000.

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 certificate 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*. The Medicines (Aristolochia) (Temporary Prohibition) Order 1999 (S.I. 1999/2889), which was the subject of a previous UK notification under Directive 98/34, prohibited, on a temporary basis, the sale, supply and importation of products consisting of or containing *Aristolochia* species.



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 considered necessary to prohibit the sale, supply and importation of those products, in order to protect public health.

The Order referred to at paragraph 5 above also subsumes the provisions of the Medicines (Aristolochia) (Temporary Prohibition) Order 1999.

10. Reference Documents - Basic Texts

Sections 62 and 129 of the Medicines Act 1968;

11. Invocation of the Emergency Procedure

Yes

12. Grounds for the Emergency

The grounds are the existence of urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health. Those circumstances are as detailed in paragraph 9 above. The matter is urgent because public health may suffer in the absence of an immediate prohibition on sale, supply and importation. It is proposed to replace the Order referred to in paragraph 5 above with a permanent Order. That Order will, pursuant to sections 62 and 129 of the Medicines Act 1968, need to be the subject of a consultation of interested organisations, the Committee on Safety of Medicines and also, possibly, the Medicines Commission. Notification of the draft permanent Order will be made as soon as possible.

13. Confidentiality

No

14. Fiscal measures

No

Carlo Trojan
General Secretary
European Commission