



Notification Number: 1999/369/UK

The Medicines (Aristolochia) (Emergency Prohibition) Order 1999.

Date received : 28/07/1999

End of Standstill : 30/07/1999

Invocation of the Emergency Procedure : Yes

Message

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Message 001

Communication from the Commission - SG(1999) D/51757
Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notificación - Notifikation - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 1999/369/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: 199901757.EN)

1. Structured Information Line

MSG 001 IND 1999 0369 UK EN 28-07-1999 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 . 99/0369/UK

5. Title

The Medicines (Aristolochia) (Emergency Prohibition) Order 1999.

6. Products Concerned

Medicinal products consisting of or containing a plant belonging to a species of the genus *Aristolochia*, or any extracts 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

Temporary prohibition of the sale, supply and importation of medicinal products as referred to in 6 above, subject to 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 authorisation or a homoeopathic certificate of registration.

There is no provision for recognition of equivalent standards – unnecessary as there are already special rules in place under Directive 75/319 for the grant of a marketing authorisation in the UK, where a marketing authorisation has been granted in another member State.

9. Brief Statement of Grounds

There is strong evidence that *Aristolochia* can cause severe health problems, including renal failure and cancers. A number of measures have previously been taken to protect the public from the risk to health posed by the presence of *Aristolochia* in medicinal products (in particular, a requirement for a doctor's prescription before products containing it could be sold or supplied) . However, new evidence (see 12 below) about the continuing presence of *Aristolochia* in products on the UK market indicated a need for the additional protection of this Order.

10. Reference Documents - Basic Texts



i 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. 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 matter is urgent because public health may suffer in the absence of an immediate prohibition on sale, supply and importation.

13. Confidentiality

No.

14. Fiscal measures

No.

Carlo Trojan
General Secretary
European Commission