



Notification Number: 1999/480/UK

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

Date received : 19/10/1999
End of Standstill : 27/10/1999
Invocation of the Emergency Procedure : Yes

Message

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Message 001

Communication from the Commission - SG(1999) D/52348
Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notificação - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 1999/480/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: 199902348.EN)

1. Structured Information Line

MSG 001 IND 1999 0480 UK EN 19-10-1999 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. Notification Number



1999/0480/UK

5. Title

The Medicines (Aristolochia) (Temporary 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 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 the EEA, 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 and testing. It should be noted that there are already special rules in place under Directive 75/319 for the grant of a marketing authorisation in the UK, where a marketing authorization 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. By virtue of limitations in section 62(3) of the Medicines Act 1968, the current Emergency Order (notification 99/0369/UK) expires on 27th October. This Order continues the prohibition imposed by that Order, to allow time for consideration by the Commission and other Member States on the text of a permanent Order. The draft permanent Order is likely to also cover various products which may be substituted, or contaminated, with Aristolochia. Notification of the text 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