STATUTORY INSTRUMENTS

1999 No. 2889

MEDICINES

The Medicines (Aristolochia) (Temporary Prohibition) Order 1999

Made - - - -	*20th October 1999*
Laid before Parliament	*21st October 1999*
Coming into force - -	*28th October 1999*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of the powers conferred upon them by sections 62(1)(a) and (2) and 129(4) of the Medicines Act 1968(**1**) and now vested in them(**2**), and of all other powers enabling them in that behalf, it appearing to them to be necessary in the interests of safety to make the following Order, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the Order pursuant to section 129(6) of that Act, after consulting and taking into account the advice of the Committee on Safety of Medicines pursuant to sections 62(3) and 129(7) of that Act(**3**), and after taking into account the advice of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Order:–

Citation, commencement, expiry and interpretation

1.—(1) This Order may be cited as the Medicines (Aristolochia) (Temporary Prohibition) Order 1999, shall come into force on 28th October 1999 and shall continue in force until the end of 30th June 2001, when it shall expire.

(2) In this Order–

"the Act" means the Medicines Act 1968;

"EEA Agreement" means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**4**) as adjusted by the Protocol signed at Brussels on 17th March 1993(**5**);

(**1**) 1968 c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388.

(**2**) In the case of the Secretaries of State concerned with health in England and Wales, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388; and in the case of the Department of Health and Social Services for Northern Ireland, by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) Section 62(3) refers to "the appropriate committee", which is defined in section 4(6) of that Act. The Committee on Safety of Medicines was established under section 4 of that Act, by S.I. 1970/1257, for the purposes set out in that instrument.

(**4**) OJ No. L1, 3.1.94, p. 3.

"EEA State" means a State which is a Contracting Party to the EEA Agreement.

Prohibition of sale, supply and importation of any medicinal product consisting of or containing Aristolochia

2.—(1) Subject to paragraphs (2), (3) and (4) below, the sale, supply and importation of any medicinal product consisting of or containing a plant(**6**) belonging to a species of the genus *Aristolochia*, or any extract from such a plant, is prohibited.

(2) The prohibition imposed by paragraph (1) above shall not apply where a medicinal product as referred to in that paragraph is sold or supplied to, or, in the case of importation, is imported by or on behalf of, any of the following persons–

(a) a food analyst or food examiner within the meaning of section 30 of the Food Safety Act 1990(**7**);

(b) a food analyst or food examiner within the meaning of Article 30 or 31 of the Food Safety (Northern Ireland) Order 1991(**8**);

(c) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990, or Article 2(2) of the Food Safety (Northern Ireland) Order 1991;

(d) a person duly authorised by an enforcement authority under sections 111 and 112 of the Act;

(e) a sampling officer within the meaning of Schedule 3 to the Act.

(3) The prohibition on importation imposed by paragraph (1) above shall not apply where a medicinal product as referred to in that paragraph is imported–

(a) from a member State of the European Community; or

(b) where the product originates(**9**) in the European Economic Area, from an EEA State which is not also a member State of the European Community.

(4) The prohibition imposed by paragraph (1) above shall not apply where a medicinal product as referred to in that paragraph is the subject of a product licence(**10**), a marketing authorization within the meaning of regulation 1(4)(a) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**11**) or a certificate of registration within the meaning of regulation 1(2) of the Medicines (Homoeopathic Products for Human Use) Regulations 1994(**12**).

Revocation

3. The Medicines (Aristolochia) (Emergency Prohibition) Order 1999(**13**) is revoked.

(**5**) OJ No. L1, 3.1.94, p. 572.
(**6**) "Plant" includes any part of a plant; *see* section 132(1) of the Act.
(**7**) 1990 c. 16.
(**8**) S.I. 1991/762 (N.I. 7); as amended by S.I. 1996/1633 (N.I. 12).
(**9**) *See* Protocol 4 (on rules of origin) annexed to the EEA Agreement, as amended by the Decision of the EEA Joint Committee No. 6/94 amending Protocol 4 to the EEA Agreement (OJ No. L95, 14.4.94, p. 22).
(**10**) "Product licence" has the meaning assigned to it by section 7 of the Act.
(**11**) S.I. 1994/3144; as amended by S.I. 1998/3105.
(**12**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482 and 1999/566.
(**13**) S.I. 1999/2109.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
16th October 1999 Department of Health

Signed by authority of the Secretary of State for Wales

David Hanson
Parliamentary Under Secretary of State, Welsh
19th October 1999 Office

John Reid
19th October 1999 Secretary of State, Scotland Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 20th October 1999.

L.S.

D.C. Gowdy
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Order)

This Order prohibits the sale, supply and importation of any medicinal product consisting of or containing a plant belonging to a species of the genus *Aristolochia*, or any extract from such a plant.

This prohibition is subject to the following exceptions–

(a) 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;

(b) in the case of the prohibition on importation, where the product is imported from a member State of the European Community, or, where the product originates in the European Economic Area, from a State Party to the European Economic Area Agreement which is not also a member State;

(c) where the product is the subject of a product licence, marketing authorization or homoeopathic certificate of registration.

This Order was notified to the European Commission in accordance with European Parliament and Council Directive 98/34/EC, Article 8 (OJNo. L204, 21.7.1998, p. 37) as amended by European Parliament and Council Directive 98/48/EC, Article 1(4) (OJ No. L217, 5.8.1998, p. 18), and in accordance with Council Directive 75/319/EEC, Article 33 (OJ No. L147, 9.6.1975, p. 13).

This Order revokes the Medicines (Aristolochia) (Emergency Prohibition) Order 1999 (S.I.1999/2109), which provides for the same prohibition as in this Order and which expires at the end of 27th October 1999.

This Order shall come into force on 28th October 1999 and shall continue in force until the end of 30th June 2001, when it shall expire.