STATUTORY INSTRUMENTS

1999 No. 2109

MEDICINES

The Medicines (Aristolochia) (Emergency Prohibition) Order 1999

Made - - - -	*23rd July 1999*
Laid before Parliament	*27th July 1999*
Coming into force - -	*28th July 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), (2) and (3) and 129(6) 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, and their being of the opinion that it is essential to make the Order with immediate effect to avoid serious danger to the health of human beings, and after taking into account the advice of the Committee on Safety of Medicines and the Medicines Commission pursuant to section 129(7) of that Act(**3**), hereby make the following Order:—

Citation, commencement, expiry and interpretation

1.—(1) This Order may be cited as the Medicines (Aristolochia) (Emergency Prohibition) Order 1999, shall come into force on 28th July 1999 and shall continue in force until the end of 27th October 1999, when it shall expire.

(2) In this Order, "the Act" means the Medicines Act 1968.

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

(**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, the Transfer of Functions (Wales) Order 1969 (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**) The Committee on Safety of Medicines was established under section 4 of the Act, by S.I. 1970/1257, for the purposes set out in that instrument.

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

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

(2) The prohibition imposed by paragraph (1) above shall not apply to the sale, supply or importation of the medicinal products referred to where the sale or supply is to, or, in the case of importation, the importation is made 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(**5**);

(b) a food analyst or food examiner within the meaning of Article 30 or 31 of the Food Safety (Northern Ireland) Order 1991(**6**);

(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 to the importation of the medicinal products referred to—

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

(b) if the products originated in an EEA State within the meaning of Article 9 of, and Protocol 4 to, the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**7**), as adjusted by the Protocol signed at Brussels on 17th March 1993(**8**), from an EEA State other than a member State.

(4) The prohibition imposed by paragraph (1) above shall not apply to the sale, supply or importation of the medicinal products referred to where the products are the subject of a product licence(**9**), a marketing authorization within the meaning of regulation 1(4)(a) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**10**) or a certificate of registration within the meaning of regulation 1(2) of the Medicines (Homoeopathic Products for Human Use) Regulations 1994(**11**).

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State
Department of Health

22nd July 1999

(**4**) "Plant" includes any part of a plant; *see* section 132(1).
(**5**) 1990 c. 16.
(**6**) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12).
(**7**) OJ No. L1, 3.1.94, p.3
(**8**) OJ No. L1, 3.1.94, p.572.
(**9**) "Product licence" has the meaning assigned to it by section 7 of the Act; *see* section 132(1) of the Act.
(**10**) S.I. 1994/3144 as amended by S.I. 1998/3105.
(**11**) S.I. 1994/105 as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/3105 and 1999/566.

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State Welsh Office

23rd July 1999

Calum MacDonald
Parliamentary Under Secretary of State Scottish Office

23rd July 1999

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

D. C. Gowdy
Permanent Secretary

23rd July 1999

EXPLANATORY NOTE

(This note is not part of the Order)

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

Those prohibitions are 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 products are imported from a member State of the European Community, or, where the products originate in a State party to the European Economic Area Agreement (EEA State), from an EEA State other than a member State,

(c) where the products are 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 (OJNo. L204, 22.7.1998, p.37/48) as amended by European Parliament and Council Directive 98/48/EC (OJ No. L217, 5.8.1998, p.18/26).

The Order shall come into force on 28th July 1999, and shall expire at the end of 27th October 1999.