STATUTORY INSTRUMENTS

2001 No. 1841

MEDICINES

The Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001

Made - - - -	*9th May 2001*
Laid before Parliament	*10th May 2001*
Coming into force - -	*1st July 2001*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, 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 report of the Medicines Commission made under section 62(5) of that Act, hereby make the following Order:—

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001, and shall come into force on 1st July 2001.

(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 expression "the appropriate Ministers", and the expression "the Health Ministers" which is relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2), of, and Schedule 1 to, S.I. 1969/388, and by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142.

(**2**) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**3**) Section 62(3) refers to "the appropriate committee", which is defined in section 4(6) of the Act. 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.

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

(**5**) OJ No. L1, 3.1.94, p. 572.

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

"medicinal product" does not include a medicinal product which is a veterinary drug.

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

2. Subject to article 4 below, the sale, supply and importation of any medicinal product consisting of or containing a plant(**6**)—

(a) belonging to a species of the genus Aristolochia; or

(b) belonging to any of the species—

Akebia quinata,

Akebia trifoliata,

Clematis armandii,

Clematis montana,

Cocculus laurifolius,

Cocculus orbiculatus,

Cocculus trilobus,

Stephania tetrandra,

or consisting of or containing an extract from such a plant, is prohibited.

Prohibition of sale, supply and importation of medicinal products presented as consisting of or containing Mu Tong etc.

3. Subject to article 4 below, the sale, supply and importation of any medicinal product is prohibited where, at the time of the sale, supply or importation—

(a) the label on the product's container or package; or

(b) any document accompanying the product,

indicates in any language—

(i) that the product consists of or contains Mu Tong or Fangji, or any term derived from either of those terms; or

(ii) that the product consists of or contains a plant specified in article 2(b) above or an extract from such a plant.

Exceptions to the prohibitions imposed by articles 2 and 3 above

4.—(1) The prohibitions imposed by articles 2 and 3 above are subject to the exceptions specified in the following paragraphs of this article.

(2) The prohibitions imposed by articles 2 and 3 above shall not apply where a medicinal product as referred to in those articles 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**);

(**6**) "Plant" includes part of a plant; see section 132(1) of the Act.

(**7**) 1990 c. 16; section 30 was amended by section 40 of, and paragraph 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28).

(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(**9**);

(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 prohibitions on importation imposed by articles 2 and 3 above shall not apply where a medicinal product as referred to in those articles is imported—

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

(b) where the product originates(**10**) in the European Economic Area, from an EEA State which is not also a member State of the European Community.

(4) The prohibitions imposed by articles 2 and 3 above shall not apply where a medicinal product as referred to in those articles is the subject of a product licence(**11**), a marketing authorisation within the meaning of regulation 1(4)(a) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**12**) or a certificate of registration within the meaning of regulation 1(2) of the Medicines (Homoeopathic Products for Human Use) Regulations 1994(**13**).

Revocation

5. The Medicines (Aristolochia and Mu Tong etc.) (Temporary Prohibition) Order 2000(**14**) is revoked.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
8th May 2001 Department of Health

Bairbre de Brún
Minister of Health, Social Services and Public
9th May 2001 Safety

(**8**) S.I. 1991/762 (N.I. 7); as amended by S.I. 1996/1633 (N.I. 12).
(**9**) Section 5(6) was amended by section 40 of, and paragraph 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28), and article 2(2) was amended by paragraph 29 of Schedule 5 to, and Schedule 6 to, that Act.
(**10**) *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).
(**11**) "Product licence" has the meaning assigned to it by section 7 of the Act.
(**12**) S.I. 1994/3144; as amended by S.I. 1998/3105 and 2000/292.
(**13**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/3105, 1999/566 and 2000/592.
(**14**) S.I. 2000/1368.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order prohibits the sale, supply, and importation, of any medicinal product for human use which—

(a) consists of or contains a plant belonging to a species of the genus Aristolochia or 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) is presented as consisting of or containing Mu Tong or Fangji, 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.

These prohibitions are subject to the following exceptions—

(i) 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;

(ii) in the case of the prohibitions 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;

(iii) where the product is the subject of a product licence, marketing authorisation 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 and Mu Tong etc.) (Temporary Prohibition) Order 2000 (S.I.2000/1368) which expires on 30th June 2001. The provisions of that Order are re-enacted in this Order.