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

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);
“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—

(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);
(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,  

Department of Health  

8th May 2001  

Bairbre de Brún  

Minister of Health, Social Services and Public Safety  

9th May 2001  


(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.  


(11) “Product licence” has the meaning assigned to it by section 7 of the Act.  


(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 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.