STATUTORY INSTRUMENTS

2002 No. 3170

MEDICINES

The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002

Made - - - -	*18th December 2002*
Laid before Parliament	*23rd December 2002*
Coming into force - -	*13th January 2003*

As respects England, Wales and Scotland, the Secretary of State concerned with health in England and as respects Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by section 62(1)(a) and (2) of the Medicines Act 1968(**1**) or, as the case may be, the powers conferred by those provisions 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 for Human Use (Kava-kava) (Prohibition) Order 2002 and shall come into force on 13th January 2003.

(2) In this Order—

"the Act" means the Medicines Act 1968;

(**1**) 1968 c. 67; the expression "the appropriate Ministers" and the expression "the Health Ministers", which are 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 Department of Health, Social Services and Public Safety, the powers vested in the Minister in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to the Northern Ireland Act 1998 (c. 47) may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Department was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).

(**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.

"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;

"external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur, and references to medicinal products being "for external use" shall be read accordingly—except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

"free circulation in member States" has the same meaning as in Article 23.2, as read with Article 24, of the Treaty establishing the European Community; and

"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 PIPER METHYSTICUM (known as Kava-kava)

2. Subject to article 3 below, the sale, supply or importation of any medicinal product consisting of or containing—

(a) a plant(**6**) belonging to the species *Piper methysticum* (known as Kava-kava); or

(b) an extract from such a plant,

is prohibited.

Exceptions to the prohibition imposed by article 2

3. The prohibition imposed by article 2 above shall not apply where the medicinal product is—

(a) for external use only;

(b) sold or supplied to, or is imported by or on behalf of, any of the following persons—

(i) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990(**7**) or Article 2(2) of the Food Safety (Northern Ireland) Order 1991(**8**),

(ii) a food analyst or food examiner within the meaning of section 30 of the Food Safety Act 1990(**9**) or Article 30 or 31 of the Food Safety (Northern Ireland) Order 1991(**10**),

(iii) a person duly authorised by an enforcement authority under sections 111 and 112 of the Act, or

(iv) a sampling officer within the meaning of Schedule 3 to the Act(**11**);

(c) imported from an EEA State, if the product—

(i) originates in an EEA State, or

(ii) originates outside the European Economic Area, but is in free circulation in member States,

(**4**) OJ No. L1, 3.1.1994, p.3.
(**5**) OJ No. L1, 3.1.1994, p.572.
(**6**) "Plant" includes part of a plant; *see* the definition of "plant" in section 132(1) of the Act.
(**7**) 1990 c. 16; section 5(6) was amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c. 28).
(**8**) S.I. 1991/672 (N.I. 7); article 2(2) was amended by articles 3(1) and 7(1) of the Food Safety (Amendment) (Northern Ireland) Order 1996 (S.I. 1996/1633 (N.I. 12)) and paragraphs 26 and 29 of Schedule 5 to, and Schedule 6 to, the Food Standards Act 1999.
(**9**) Section 30 was amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999.
(**10**) Article 31 was amended by paragraphs 26 and 35 of Schedule 5 to the Food Standards Act 1999.
(**11**) Schedule 3 was amended by paragraph 12 of Schedule 3 to the Food Safety Act 1990.

and is being, or is to be, exported to an EEA State other than the United Kingdom; or

(d) the subject of—

(i) a product licence(**12**),

(ii) a marketing authorization within the meaning given in regulation 1(4)(a) of the Medicines for Human Use (Marketing Authorisation Etc.) Regulations 1994(**13**), or

(iii) a certificate of registration within the meaning given in regulation 1(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**14**).

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

18th December 2002

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D. C. Gowdy
Permanent Secretary,
Department of Health, Social Services and
Public Safety

18th December 2002

(**12**) "Product licence" has the meaning assigned to it by section 7 of the Act.
(**13**) S.I. 1994/3144; as amended by S.I. 1998/3105, 2000/292, 2001/795 and 2002/236 and 542.
(**14**) S.I. 1994/105; as amended by S.I. 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795 and 2002/236 and 542.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order prohibits the sale, supply or importation of any medicinal product for human use which consists of or contains a plant (or part of a plant) belonging to the species *Piper methysticum* (known as Kava-kava) or an extract from such a plant.

This prohibition is subject to the following exceptions—

(a) where the product is for external use only;

(b) 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;

(c) where the product is imported from an EEA State, if it originates from such a State or originates outside the EEA but is in free circulation in Member States (within the meaning of Article 23.2, when read with Article 24, of the EC Treaty), and is being, or is to be, exported to an EEA State other than the United Kingdom;

(d) 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 Article 8 of the European Parliament and Council Directive 98/34/EC (OJNo. L204, 21.7.1998, p.37), as amended by Article 1(4) of the European Parliament and Council Directive 98/48/EC (OJ No. L217, 5.8.1998, p.18).

A Regulatory Impact Assessment in relation to this Order has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.