STATUTORY INSTRUMENTS

2008 No. 548

MEDICINES

The Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008

Made - - - -	*28th February 2008*
Laid before Parliament	*6th March 2008*
Coming into force - -	*1st April 2008*

The Secretary of State for Health and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Order in the exercise of powers conferred upon them by sections 62(1)(a) and (2) and 129(4) of the Medicines Act 1968(**a**) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(**b**). It appears to them to be necessary to make the Order in the interests of safety.

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by this Order. In accordance with sections 62(3) and 129(7) of that Act they have consulted and taken into account the advice of the Herbal Medicines Advisory Committee(**c**). They have also taken into account the report of the Committee made under section 62(5) of that Act.

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 and shall come into force on 1st April 2008.

(2) In article 3 —

"the Act" means the Medicines Act 1968;

"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;

"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;

"third country" means any country other than an EEA State.

(**a**) 1968 c.67. The expression "the Ministers", which is relevant to the powers being exercised in the making of this Order, is defined in section 1 of the Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 2(1) of, and the Schedule to, S.I. 1999/3142, and by paragraph 2 of Part 1 of Schedule 8 to S.I. 2006/2407. Section 62 was amended by S.I. 2005/1094 and paragraph 35 of Part 1 of Schedule 8 to S.I. 2006/2407.

(**b**) By virtue of the powers vested in the Ministers 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).

(**c**) See section 4(6) of the Medicines Act 1968, as substituted by regulation 5(5) of S.I. 2005/1094, for the definition of "appropriate committee" in section 62(3) and (5).

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

2. Except as provided for in article 3, the sale, supply or importation of any medicinal product consisting of or containing—

(a) a plant(**a**) belonging to the species *Senecio*; 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 shall not apply where the medicinal product is—

(a) (i) for external use only; and

(ii) not a teething preparation, throat spray, throat pastille, throat lozenge, throat tablet, nasal spray or nasal inhalation or nasal drops;

(b) sold or supplied to, or 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(**b**) or Article 2(2) of the Food Safety (Northern Ireland) Order 1991(**c**),

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

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

(iv) a sampling officer within the meaning of paragraph 1(1) of Schedule 3 to the Act(**g**);

(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,

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

(d) the subject of—

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

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

(iii) a certificate of registration within the meaning of regulation 2(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**j**), or

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(**a**) "Plant" includes part of a plant; see the definition of "plant" in section 132(1) of the Act.
(**b**) 1990 c.16; section 5(6) was amended by paragraphs 7 and 8 of Schedule 5 to, the Food Standards Act 1999 (c.28).
(**c**) S.I. 1999/672 (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. 1996/6133 (N.I.12)), paragraphs 26 and 29 of Schedule 5 to, and Schedule 6 to, the Food Standards Act 1999 and article 3 of the Food Safety (Northern Ireland) Order 1991 (Amendment) Regulations (Northern Ireland) 2004 (S.R. (NI) 2004 No 482).
(**d**) Section 30 was amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999.
(**e**) Article 31 was amended by paragraphs 26 and 35 of Schedule 5 to the Food Standards Act 1999.
(**f**) Section 111 was amended by S.I. 2005/2789.
(**g**) Schedule 3 was amended by paragraph 12 of Schedule 3 to the Food Safety Act 1990.
(**h**) "Product licence" has the meaning assigned to it by section 7 of the Act.
(**i**) S.I. 1994/3144, as amended by S.I. 1998/3105, 2000/292, 2001/795, 2002/236 and 542, 2003/1618 and 2321, 2004/865, 1016, 1031, 2990 and 3224 and 2005/50, 768, 1094, 1520, 1710, 2754 and 2759.
(**j**) S.I. 1994/105; relevant amending instruments are 1996/482, 1998/574, 2001/795, 2002/236, 2003/625 and 2321, 2004/666 and 1031 and 2005/2753.

(iv) a traditional herbal registration within the meaning given in regulation 2(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**a**).

Amendment of the Medicines (Bal Jivan Chamcho Prohibition) (No.2) Order 1977

4.—(1) The Medicines (Bal Jivan Chamcho Prohibition) (No.2) Order 1977(**b**) is amended as follows.

(2) In article 2—

(a) for paragraph (4) substitute —

"(4) The prohibition imposed by paragraph (1) above shall not apply where the medicinal product is imported from an EEA State, if the product—

(a) originates in an EEA State, or

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

and is being, or is to be, exported to a third country or an EEA State other than the United Kingdom."; and

(b) after paragraph (4), insert —

"(5) For the purposes of paragraph (4)—

"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;

"third country" means any country other than an EEA State.".

Amendment of the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001

5.—(1) The Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001(**c**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2)—

(a) after the definition of "the Act", insert —

""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;";

(b) omit the definitions of "EEA Agreement" and "EEA State";

(c) after the definition of "medicinal product", insert —

"third country" means any country other than an EEA State.".

(3) In article 4, for paragraph (3), substitute —

"(3) The prohibition imposed by articles 2 and 3 above shall not apply where the medicinal product is imported from an EEA State, if the product—

(a) originates in an EEA State, or

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

and is being, or is to be, exported to a third country or an EEA State other than the United Kingdom.".

(**a**) S.I. 2005/2750, amended by S.I. 2006/395.
(**b**) S.I. 1977/670, as amended by S.I. 1997/856.
(**c**) S.I. 2001/1841.

Amendment of the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002

6.—(1) The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002(**a**) is amended as follows.

(2) In article 1(2)—

(a) omit the definitions of "EEA Agreement" and "EEA State";

(b) after the definition of "medicinal product", insert —

"third country" means any country other than an EEA State.".

(3) In article 3, for paragraph (c), substitute the following—

"(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,

and is being, or is to be, exported to a third country or an EEA State other than the United Kingdom.".

Signed by authority of the Secretary of State for Health.

Dawn Primarolo
Minister of State,
28th February 2008 Department of Health

Michael McGimpsey
27th February 2008 Minister for Health, Social Services and Public Safety

(**a**) S.I. 2002/3170.

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 *Senecio* or an extract from such a plant.

This prohibition is subject to exceptions.

This Order also makes minor amendments to three existing Orders made under section 62 of the Medicines Act 1968: the Medicines (Bal Jivan Chamcho Prohibition) (No.2) Order 1997 (S.I.1977/670); the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001 (S.I.2001/1841); and the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 (S.I.2002/3170). The amendments ensure that the exception for goods in transit in the three Orders applies to goods imported from an EEA State which are to be exported to a third country or an EEA State other than the United Kingdom.

This Order was notified to the European Commission in accordance with Article 8 of the European Parliament and Council Directive 98/34/EC (OJ No. 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 full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies have been placed in the libraries of both Houses of Parliament.

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