
STATUTORY INSTRUMENTS

1977 No. 2130

MEDICINES

The Medicines (Retail Sale or Supply of Herbal Remedies)
Order 1977

Made - - - - 20th December 1977

Laid before Parliament 5th January 1978

Coming into Operation 1st February 1978

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 56(3) and 57(1) of the Medicines Act 1968(a) and now vested in them(b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following order, and after taking into account the advice of the Medicines Commission, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 and shall come into operation on 1st February 1978.

(2) In this order, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

“external use” means—

(a) in relation to medicinal products for use by being administered to human beings, application to the skin, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal,

(b) in relation to veterinary drugs, application to the skin, hair, fur, feathers, scales, hoof, horn, ear, eye, mouth or mucosa of the throat or prepuce,

in either case when a local action only is necessary and extensive systemic absorption is unlikely to occur and references to “medicinal products for external use” shall be read accordingly except that in paragraph (a) above the references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

(a) 1968 c. 67.

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments 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).

“maximum daily dose” or “MDD” means the maximum quantity of the substance contained in the amount of the medicinal product for internal use which it is recommended should be taken or administered in any period of 24 hours;

“maximum dose” or “MD” means the maximum quantity of the substance contained in the amount of the medicinal product for internal use which it is recommended should be taken or administered at any one time; and other expressions have the same meanings as in the Act.

(3) For the purposes of this order, any reference to a substance listed in any Part of the Schedule to this order shall be construed as a reference to the substance having the common name listed therein being a substance obtained from the botanical source listed in relation to that substance.

(4) Except in so far as the context otherwise requires, any reference in this order to any enactment, order or regulations shall be construed as a reference to that enactment or order or to those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(5) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

Cessation of exemptions for certain herbal remedies

2. There are hereby specified the following classes of herbal remedies in respect of which section 56(1) and (2) of the Act (exemptions in respect of herbal remedies) shall not have effect, namely—

- (1) herbal remedies that are not medicinal products on a general sale list;
- (2) herbal remedies to which section 12(2) of the Act (exemptions from licensing in respect of herbal remedies) does not apply;
- (3) herbal remedies to which section 12(2) of the Act does apply but which contain one or more of the substances listed in Part I or Part II of the Schedule to this order.

Exemption for certain herbal remedies

3.—(1) The restrictions imposed by sections 52 and 53 of the Act shall not apply to the sale by retail, offer or exposure for sale by retail or supply in circumstances corresponding to retail sale of any herbal remedy falling within a class specified in Article 2 of this order where the processes to which the plant or plants are subjected consist of drying, crushing or comminuting with or without any subsequent process of tableting, pill-making, compressing or diluting with water but not any other process, if and so long as the conditions specified in paragraph (2) of this Article are satisfied.

(2) The conditions referred to in paragraph (1) above are that—

- (a) the herbal remedy referred to in paragraph (1) above does not contain a substance listed in Part I or Part II of the Schedule to this order,
- (b) the person selling or supplying the said herbal remedy is the occupier of the premises from which the said remedy is sold or supplied and is able to close those premises so as to exclude the public, and
- (c) the person selling or supplying the said herbal remedy either—
 - (i) has notified the enforcement authority in writing that he is

(a) 1889 c. 63.

selling or supplying or intends to sell or supply herbal remedies to which the exemption conferred by paragraph (1) of this Article applies from the premises specified in the notice, or

(ii) is the holder of a manufacturer's licence granted under Part II of the Act in respect of that remedy.

(3) Notwithstanding paragraph (1) above and subject to paragraph (5) below, the said restrictions also do not apply to the sale by retail, offer or exposure for sale by retail or supply in circumstances corresponding to retail sale of any herbal remedy falling within a class specified in Article 2 of this order if and so long as the conditions specified in paragraph (4) of this Article are satisfied.

(4) The conditions referred to in paragraph (3) above are that—

(a) the herbal remedy referred to in paragraph (3) above does not contain a substance listed in Part I of the Schedule to this order,

(b) the said herbal remedy does not contain a substance listed in column 1 of Part III of the said Schedule except when sold or supplied—

(i) in or from containers or packages labelled to show a dose not exceeding the maximum dose or the maximum daily dose specified in column 2 of the said Part III, and

(ii) where the herbal remedy is for external use only, with the percentage of the substance not exceeding that specified in column 3 of the said Part III,

(c) the person selling or supplying the said herbal remedy—

(i) has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required, and

(ii) has notified the enforcement authority in writing that he is selling or supplying or intends to sell or supply herbal remedies to which the exemption conferred by paragraph (3) of this Article applies from the premises specified in the notice.

(5) Where the enforcement authority serves on a person selling or supplying herbal remedies to which the exemption conferred by paragraph (3) of this Article applies a notice requiring him, within such time as may be specified in the notice, to furnish to the enforcement authority a list specifying the substances contained in the herbal remedies which he sells or supplies by virtue of the said exemption, that exemption shall not apply after the time so specified in the notice has elapsed and so long as that person fails to comply with the requirement.

David Ennals,

Secretary of State for Social Services.

15th December 1977.

John Morris,

Secretary of State for Wales.

15th December 1977.

Bruce Millan,

Secretary of State for Scotland.

15th December 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 15th December 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 19th day of December 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 30th day of December 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

SCHEDULE

PART I

Articles 2(3), 3(2)(a)
and 3(4)(a)

SUBSTANCES IN RESPECT OF WHICH THE EXEMPTIONS CONFERRED BY
SECTION 56(1) AND (2) DO NOT HAVE EFFECT

<i>Common Name</i>	<i>Botanical Source</i>
Areca	Areca catechu
Canadian Hemp	Apocynum cannabinum
Catha	Catha edulis
Chenopodium	Chenopodium ambrosioides var anthelminticum
Crotalaria fulva	Crotalaria berberoana
Crotalaria spect.	Crotalaria spectabilis
Cucurbita	Cucurbita maxima
Duboisia	Duboisia myoporoides Duboisia leichardtii
Elaterium	Ecballium elaterium
Embelia	Embelia ribes Embelia robusta
Erysimum	Erysimum canescens
Holarrhena	Holarrhena antidysenterica
Kamala	Mallotus philippinensis
Kousso	Brayera anthelmintica
Male Fern	Dryopteris filix—mas
Mistletoe berry	Viscum album
Poison Ivy	Rhus radicans
Pomegranate Bark	Punica granatum
Santonica	Artemisia cina
Savin	Juniperus sabina
Scopolia	Scopolia carniolica Scopolia japonica
Stavesacre Seeds	Delphinium staphisagria
Strophanthus	Strophanthus kombe Strophanthus courmonti Strophanthus nicholsoni Strophanthus gratus Strophanthus emini Strophanthus sarmentosus Strophanthus hispidus
Slippery Elm Bark (whole or unpowdered)	Ulmus fulva Ulmus rubra
Yohimbe Bark	Pausinystalia yohimbe

PART II

Articles 2(3) and 3(2)(a)

SUBSTANCES IN RESPECT OF WHICH THE EXEMPTIONS CONFERRED BY
SECTION 56(1) DO NOT HAVE EFFECT

<i>Common Name</i>	<i>Botanical Source</i>
Aconite	Aconitum napellus Aconitum stoerkianum Aconitum uncinatum var japonicum Aconitum deinorrhizum Aconitum balfourii Aconitum chasmanthum Aconitum spicatum Aconitum lycoctonum
Adonis vernalis	Adonis vernalis
Belladonna Herb	Atropa belladonna
Belladonna Root	Atropa acuminata Atropa belladonna Atropa acuminata
Celandine	Chelidonium majus
Cinchona bark	Cinchona calisaya Cinchona ledgerana Cinchona officinalis Cinchona succirubra Cinchona micrantha
Colchicum corm	Colchicum autumnale
Conium leaf	Conium maculatum
Conium fruits	Conium maculatum
Convallaria	Convallaria majalis
Ephedra	Ephedra sinica Ephedra equisetina Ephedra distachya Ephedra intermedia Ephedra gerardiana
Gelsemium	Gelsemium sempervirens
Hyoscyamus	Hyoscyamus niger Hyoscyamus albus Hyoscyamus muticus
Jaborandi	Pilocarpus jaborandi Pilocarpus microphyllus
Lobelia	Lobelia inflata
Poison Oak	Rhus toxicodendron
Quebracho	Aspidosperma quebracho-blanco
Ragwort	Senecio jacobaea
Stramonium	Datura stramonium Datura innoxia

PART III

Article 3(4)(b)

SUBSTANCES IN RESPECT OF WHICH THE EXEMPTIONS CONFERRED BY
SECTION 56(2) DO NOT HAVE EFFECT

Column 1		Column 2	Column 3
Common Name	Substance Botanical Source	Maximum dose and maximum daily dose	Percentage
Aconite	Aconitum napellus Aconitum stoerkianum Aconitum uncinatum var japonicum Aconitum deinorrhizum Aconitum balfourii Aconitum chasmanthum Aconitum spicatum Aconitum lycoctonum		1.3 per cent
Adonis vernalis	Adonis vernalis	100 mg (MD) 300 mg (MDD)	
Belladonna Herb	Atropa belladonna Atropa acuminata	50 mg (MD) 150 mg (MDD)	
Belladonna Root	Atropa belladonna Atropa acuminata	30 mg (MD) 90 mg (MDD)	
Celandine	Chelidonium majus	2 g (MD) 6 g (MDD)	
Cinchona bark	Cinchona calisaya Cinchona ledgerana Cinchona officinalis Cinchona succirubra Cinchona micrantha	250 mg (MD) 750 mg (MDD)	
Colchicum corm	Colchicum autumnale	100 mg (MD) 300 mg (MDD)	
Conium leaf	Conium maculatum		7.0 per cent
Conium fruits	Conium maculatum		7.0 per cent
Convallaria	Convallaria majalis	150 mg (MD) 450 mg (MDD)	
Ephedra	Ephedra sinica Ephedra equisetina Ephedra distachya Ephedra intermedia Ephedra gerardiana	600 mg (MD) 1800 mg (MDD)	
Gelsemium	Gelsemium sempervirens	25 mg (MD) 75 mg (MDD)	
Hyoscyamus	Hyoscyamus niger Hyoscyamus albus Hyoscyamus muticus	100 mg (MD) 300 mg (MDD)	
Jaborandi	Pilocarpus jaborandi Pilocarpus microphyllus		5.0 per cent
Lobelia	Lobelia inflata	200 mg (MD) 600 mg (MDD)	

Column 1		Column 2	Column 3
Common Name	Substance Botanical Source	Maximum dose and maximum daily dose	Percentage
Poison Oak	Rhus toxicodendron	50 mg (MD) 150 mg (MDD)	10.0 per cent
Quebracho	Aspidosperma quebracho- blanco		
Ragwort	Senecio jacobaea	50 mg (MD) 150 mg (MDD)	10.0 per cent
Stramonium	Datura stramonium Datura innoxia		

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order specifies, in Article 2, the classes of herbal remedies in respect of which the exemptions from the restrictions imposed by sections 52 and 53 of the Medicines Act 1968 conferred by section 56(1) and (2) of that Act do not have effect. Section 52 provides that medicinal products not on a general sale list shall only be sold or supplied on premises which are a registered pharmacy and by or under the supervision of a pharmacist. Section 53 provides that medicinal products on a general sale list may only be sold or supplied elsewhere than at a registered pharmacy if the conditions specified in that section are fulfilled.

The order also provides exemptions from the sections 52 and 53 restrictions for the classes of herbal remedies referred to above but subject to specified conditions, in particular that the person selling or supplying these herbal remedies has notified the enforcement authority that he is selling or supplying or intends to sell or supply them.