

MEDICINES (HERBAL REMEDIES EXEMPTIONS) (JERSEY) ORDER 1997

Official Consolidated Version

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MEDICINES (HERBAL REMEDIES EXEMPTIONS) (JERSEY) ORDER 1997

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MEDICINES (HERBAL REMEDIES EXEMPTIONS) (JERSEY) ORDER 1997¹

THE HEALTH AND SOCIAL SERVICES COMMITTEE in pursuance of Articles 55, 56 and 110 of the <u>Medicines (Jersey) Law 1995</u>, after consultation with the Medicines Advisory Council and having otherwise complied with Article 110 of the Law, orders as follows –

Commencement [see endnotes]

1 Interpretation

(1) In this Order, unless the context otherwise requires –

"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; but does not mean application by means of a throat spray, throat pastille, throat lozenge, throat tablet, nasal drop, nasal spray, nasal inhalation or teething preparation;

"g" means gram;

"herbal remedies" do not include veterinary drugs;

the "Law" means the Medicines (Jersey) Law 1995;

"maximum daily dose" or "MDD" means, in relation to a substance contained in the amount of a medicinal product for internal use, the recommended maximum quantity to be taken or administered in a period of 24 hours;

"maximum dose" or "MD" means, in relation to a substance contained in the amount of a medicinal product for internal use, the recommended maximum quantity to be taken or administered at any one time;

"mg" means milligram.

(2) For the purposes of this Order, any reference to a substance specified in any Part of the Schedule is a reference to the substance having the common name specified there (being a substance obtained from the botanical source specified in relation to that substance).

(3) Without prejudice to Article 10 of the <u>Interpretation (Jersey) Law 1954</u>, every provision in the <u>Medicines (Jersey) Law 1995</u> that relates in any other way to its interpretation shall also apply in the same way to this Order, unless the context otherwise requires.

2 Exemption in Law not to apply to specified herbal remedies

Article 55(1) and (2) of the Law shall not have effect in relation to herbal remedies of any of the following classes –

- (a) herbal remedies that are not medicinal products on a general sale list;
- (b) herbal remedies to which Article 13(2) of the Law does not apply; and
- (c) herbal remedies to which Article 13(2) of the Law does apply, but which contain any of the substances specified in Part 1 or 2 of the Schedule to this Order.

3 Exemption that applies instead in certain cases

- (1) The restrictions in Articles 51 and 52 of the Law shall not apply to the sale by retail, the offer or exposure for sale by retail or the supply in circumstances corresponding to retail sale of any herbal remedy of a class specified in Article 2 of this Order, where the conditions in paragraph (2) of this Article are fulfilled.
- (2) The conditions to which paragraph (1) refers are
 - (a) the herbal remedy does not contain a substance specified in Part 1 of the Schedule;
 - (b) if the herbal remedy contains a substance specified in column 1 of Part 3 of the Schedule
 - (i) the herbal remedy is sold or supplied in or from a container or package that is labelled to show a dose not exceeding the maximum dose and not exceeding the maximum daily dose, where specified, in column 2 of that Part in respect of the substance, and
 - (ii) if the herbal remedy is for external use only, the percentage of the substance in the herbal remedy does not exceed the percentage, where specified, in column 3 of that Part in respect of the substance;
 - (c) the person selling or supplying the herbal remedy has been requested by or on behalf of a particular person, and in that person's presence, to use his or her own judgment as to the treatment required; and
 - (d) the person selling or supplying the herbal remedy has informed the Minister in writing that he or she is selling or supplying or intends to sell or supply herbal remedies to which this Article applies from premises specified in the notice.

4 Further exemption in certain cases

(1) The restrictions in Articles 51 and 52 of the Law shall not apply to the sale by retail, the offer or exposure for sale by retail or the supply in circumstances corresponding to retail sale of any herbal remedy described in paragraph (2) of this Article, where the conditions in paragraph (3) of this Article are fulfilled.

- (2) Paragraph (1) refers to any herbal remedy of a class specified in Article 2, where the processes to which the plant or plants are subjected
 - (a) consist of drying, crushing or comminution, with or without any subsequent process of tabletting, pill-making, compression or dilution; and
 - (b) do not consist of any other process.
- (3) The conditions to which paragraph (1) refers are -
 - (a) the herbal remedy does not contain a substance specified in Part 1 or 2 of the Schedule;
 - (b) the person selling or supplying the herbal remedy is the occupier of the premises from which it is sold or supplied, and is able to close those premises so as to exclude the public; and
 - (c) either
 - the person has informed the Minister in writing that he or she is selling or supplying or intends to sell or supply herbal remedies to which this Article applies from the premises, or
 - (ii) the person is the holder of a manufacturer's licence in respect of the herbal remedy.

5 Power to require further information

- (1) The Minister may serve, on a person selling or supplying or intending to sell or supply any herbal remedy in respect of which an exemption under Article 3 is conferred, a notice in writing requiring the person to furnish to the Minister within a time specified in the notice a list of the substances contained in the herbal remedy.
- (2) Notwithstanding Article 3, where the Minister serves a notice under paragraph (1) and the notice is not complied with, within the time specified in it, the exemption shall cease to have effect until the notice is complied with.

6 Citation

This Order may be cited as the Medicines (Herbal Remedies Exemptions) (Jersey) Order 1997.

SCHEDULE

(Articles 1(2), 2(c), 3(2)(a) and 4(3)(a))

PART 1

SUBSTANCES IN RESPECT OF WHICH EXEMPTIONS FOR HERBAL REMEDIES DO NOT APPLY

Common Name	Botanical Source			
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	Ulmus fulva			
(whole or unpowdered)	Ulmus rubra			
Yohimbe bark	Pausinystalia yohimbe			

PART 2

(Articles 1(2), 2(c) and 4(3)(a))

SUBSTANCES IN RESPECT OF WHICH EXEMPTIONS FOR HERBAL REMEDIES ARE RESTRICTED

Common Name	Botanical Source
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
	Atropa acuminata
Belladonna root	Atropa belladonna
	Atropa acuminata
Celandine	Chelidonium majus
Cinchona bark	Cinchona calisaya
	Cinchona ledgerana
	Cinchona officinalis
	Cinchona succirubra
	Cinchona micrantha
Colchium corm	Colchium 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 3

(Articles 1(2) and 3(2)(b))

SUBSTANCES IN RESPECT OF WHICH EXEMPTION FOR HERBAL REMEDIES IS CONDITIONAL ON LABELLING AND STRENGTH

	Column 1		Column 2	Column 3
	Substance		Maximum dose and maximum daily dose	Percentage
(Common Name)	(Botanical Source)			
Aconite	Aconitum napellus	}		
	Aconitum stoerkianum	}		
	Aconitum uncinatum var	}		
	japonicum			
	Aconitum deinorrhizum	}		1.3%
	Aconitum balfourii	}		
	Aconitum chasmanthum	}		
	Aconitum spicatum	}		
	Aconitum lycoctonum	}		
Adonis vernalis	Adonis vernalis		100 mg (MD) 300 mg (MDD)	
Belladonna Herb	Atropa belladonna	}	50 mg (MD)	
	Atropa acuminata	}	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)	
Colchium corm	Colchium autumnale		100 mg (MD) 300 mg (MDD)	
Conium leaf	Conium maculatum			7.0%
Conium fruits	Conium maculatum			7.0%
Convallaria	Convallaria majalis		150 mg (MD) 450 mg (MDD)	

	Column 1		Column 2	Column 3
	Substance		Maximum dose and maximum daily dose	Percentage
· /				
Ephedra	Ephedra sinica	}		
	Ephedra equisetina	}		
	Ephedra distachya	}	600 mg (MD)	
	Ephedra intermedia	}	1800 mg (MDD)	
	Ephedra gerardiana	}		
Gelsemium	Gelsemium sempervirens		25 mg (MD) 75 mg (MDD)	
Hyoscyamus	Hyoscyamus niger	}	<u> </u>	
	Hyoscyamus albus	}	100 mg (MD)	
	Hyoscyamus muticus	}	300 mg (MDD)	
Jaborandi	Pilocarpus jaborandi Pilocarpus microphyllus	} }		5.0%
Lobelia	Lobelia inflata		200 mg (MD) 600 mg (MDD)	
Poison oak	Rhus toxicodendron			10.0%
Quebracho	Aspidosperma quebracho- blanco		50 mg (MD) 150 mg (MDD)	
Ragwort	Senecio jacobaea		<u> </u>	10.0%
Stramonium	Datura stramonium	}	50 mg (MD) 150 mg (MDD)	

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement
Medicines (Herbal Remedies	<u>R&O.9134</u>	1 January 1998
Exemptions) (Jersey) Order 1997		
States of Jersey (Amendments and	R&O.45/2005	9 December 2005
Construction Provisions No. 5)		
(Jersey) Regulations 2005		

Table of Renumbered Provisions

Original	Current
SCHEDULE	SCHEDULE
PART I	PART 1
PART II	PART 2
PART III	PART 3

Table of Endnote References

1

This Order has been amended by the States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005. The amendments replace all references to a Committee of the States of Jersey with a reference to a Minister of the States of Jersey, and remove and add defined terms appropriately, consequentially upon the move from a committee system of government to a ministerial system of government