STATUTORY INSTRUMENTS

1994 No. 2410

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment Order 1994

Made	-	-	-	-		7th September 1994
Coming	into	force	?	-	-	12th October 1994

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly in exercise of powers conferred upon them by sections 51 and 129(4) of the Medicines Act 1968(1) or, as the case may be, those conferred by those provisions and now vested in them(2), 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 this Order(3) and after consulting and taking into account the advice of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Order:

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment Order 1994 and shall come into force on 12th October 1994.

(2) In this Order, "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(4).

(3) In this Order, a reference to inserting an entry in a column in a Table of a Schedule to the principal Order shall be construed, in the case of an entry to be inserted in column 1, as a reference to inserting that entry at the appropriate point in the alphabetical order of the entries in column 1 of that Table and (except where the context otherwise requires), in the case of an entry to be inserted (as the case may be) in column 2, 3 or 4 of that Table, as a reference to inserting that entry so as to appear against the column 1 entry against which it is listed in Schedule 1, or, as the case may be, Schedule 2 to this Order.

^{(1) 1968} c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by S.I.1969/388, Schedule 1.

⁽²⁾ 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); in the case of the Department of Health and Social Services for Northern Ireland 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).

⁽³⁾ See section 129(6) of the Medicines Act 1968.

⁽⁴⁾ S.I. 1984/769, amended by S.I. 1985/1540, 1987/910, 1989/969, 1990/1129 and 1992/1535.

Amendment of article 1(2) of the principal Order

2. In article 1(2) of the principal Order (interpretation), after the definition of "dosage unit" there is inserted the following definition—

""effervescent", in relation to a tablet, means containing not less than 75 per cent., by weight of the tablet, of ingredients included wholly or mainly for the purpose of releasing carbon dioxide when the tablet is dissolved or dispersed in water;".

Amendment of Schedule 1 to the principal Order

3.—(1) Schedule 1 to the principal Order (which specifies the class of medicinal products, other than products the subject of a product licence of right, on general sale by virtue of article 2(a) of that Order) is amended in accordance with the following provisions of this article.

- (2) In Table A (internal or external use)-
 - (a) there are inserted in column 1 and, as the case may be, columns 2, 3 and 4, those entries set out in columns 1, 2, 3 and 4 respectively of Schedule 1 to this Order;
 - (b) in relation to the substance "Aspirin"-
 - (i) there is inserted in column 2 the entry "(3) 500 mg",
 - (ii) there is substituted, for the entry "(1) Tablet or capsule" in column 3, the entry "(1) Tablet (except effervescent tablet) or capsule" and
 - (iii) there is inserted in column 3 the entry "(3) Effervescent tablets";
 - (c) there are omitted the entry "Capsicum Oleoresin" in column 1 and the entries in relation to it in columns 2, 3 and 4;
 - (d) in relation to the substance "Chlorbutol"—
 - (i) there is inserted in column 2 the entry "(4) 7.0 per cent.",
 - (ii) there is substituted, for the entry "(3) External" in column 3, the entry "(3) External (except toothache gel)", and
 - (iii) there is inserted in column 3 the entry "(4) External: toothache gel";
 - (e) for the entry "Cranesbill Root" in column 1, there is substituted the entry "Cranesbill (Geranium)";
 - (f) for the entry "Dandelion Root" in column 1, there is substituted the entry "Dandelion";
 - (g) in relation to the substance "Ferrous Sulphate", there is inserted in column 2 the entry
 - "(2) 15.8 per cent. (Fe SO4 7H2O)", and in column 3 the entries
 - "(1) Internal: except for use as cyanide antidote
 - (2) Internal: for use as cyanide antidote only",

and for the entry in column 4 there is substituted the entry

"(1) Equivalent to 24 mg elemental Iron (MD)";

- (h) in relation to the substance "Nicotinamide", there is inserted in column 4 the entry "300 mg (MDD)";
- (i) in relation to the substance "Nicotinic Acid", there is inserted in column 4 the entry "100 mg (MDD)";
- (j) in relation to the substance "Salicylic Acid", there is inserted in column 2 at the end the entry "(h) 3.0 per cent." and there are inserted in column 3 at the end the entries "(h) soap" and "(i) wart plasters";

- (k) in relation to the substance "Zinc Oxide", for the entry in column 4 there is substituted the entry "Equivalent to 5 mg elemental Zinc (MDD)"; and
- (l) in relation to the substance "Zinc Sulphate", for the entry in column 4 there is substituted the entry "(1) Equivalent to 5 mg elemental Zinc (MDD)".
- (3) In Table B (external use only)—
 - (a) there are inserted in column 1 and, as the case may be, columns 2 and 3, those entries set out in columns 1, 2 and 3 respectively of Schedule 2 to this Order;
 - (b) there are omitted the entries "Hamamelis" and "Siberian Fir Oil" in column 1;
 - (c) there are omitted the entry "Lignocaine" in column 1 and the entry "0.6 per cent" in relation to it in column 2;
 - (d) there are omitted the entry "Lignocaine Hydrochloride" in column 1 and the entry "0.7 per cent" in relation to it in column 2;
 - (e) in relation to the substance "Povidone-Iodine", for the entry in column 3 there is substituted the entry "All preparations except those for use in surgical operations and those for vaginal use".

Signed by authority of the Secretary of State for Health

Tom Sackville Parliamentary Under Secretary of State, Department of Health

16th September 1994

6th September 1994

John Redwood Secretary of State for Wales

Allan Stewart Parliamentary Under Secretary of State, The Scottish Office

6th September 1994

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

7th September 1994.

F. A. Elliott Permanent Secretary

SCHEDULE 1

Article 3(2)(a)

ENTRIES INSERTED IN TABLE A OF SCHEDULE 1 TO THE PRINCIPAL ORDER (INTERNAL OR EXTERNAL USE)

Agnus castus (Chaste Tree) Air Alexitol Sodium Alpha Tocopheryl Acid Succinate Aluminium Carbonate (Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (I) Internal (I) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate Black Catechu Black Catechu Black Haw Black Currant	Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 4 Maximum dose and maximum daily dose
Tree) Air Alexitol Sodium Alpha Tocopheryl Acid Succinate Aluminium Carbonate (Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate Black Catechu Black Catechu Black Haw Black Currant	Acerola			
Alexitol Sodium Alexitol Sodium Alpha Tocopheryl Acid Succinate Aluminium Carbonate (Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (I) Internal (I) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 9 mg (MDD) Arrowroot Black Catechu Black Catechu Black Catrant	Agnus castus (Chaste Tree)			
Alpha Tocopheryl Acid Succinate Aluminium Carbonate (Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 9 mg (MDD)	Air			
Acid Succinate Aluminium Carbonate (Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 Bismuth Oxide	Alexitol Sodium			
(Basic) Aluminium Oxide Aminoacetic Acid (Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Anseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 9 mg (MDD) Arrowroot Black Catechu Black Haw Black Haw	Alpha Tocopheryl Acid Succinate			
Aminoacetic Acid (Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 Black Catechu Black Haw Black Durrant	Aluminium Carbonate (Basic)			
(Glycine) Aminobenzoic Acid (1) Internal (1) 30mg (MDD) (2) External Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 8 mg (MDD) Bismuth Aluminate 9 mg (MDD) Bismuth A	Aluminium Oxide			
(2) External (2) External (2) External (2) External (2) External (2) External (2) External (3) (2) External (4) (5) (4) (5) (5) (5) (5) (5) (5) (5) (5) (5) (5	Aminoacetic Acid (Glycine)			
Ammonium Acetate Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD), calculate as Bismuth Oxide Black Catechu Black Catechu Black Haw Blackberry Black Currant	Aminobenzoic Acid		(1) Internal	(1) 30mg (MDD)
Solution Strong Amyloglycosidase Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD) Bismuth Aluminate 6 mg (MDD), calculate as Bismuth Oxide Black Catechu Black Haw Black Haw			(2) External	
Concentrate Anethole Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MDD), calculate as Bismuth Oxide Black Catechu Black Haw Black Haw	Ammonium Acetate Solution Strong			
Aniseed (Anise) Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MD), calculate as Bismuth Oxide Black Catechu Black Haw Black Haw	Amyloglycosidase Concentrate			
Arrowroot Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MD), calculate as Bismuth Oxide Black Catechu Black Haw Blackberry Black Currant	Anethole			
Balm of Gilead Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MD), calculate as Bismuth Oxide Black Catechu Black Haw Black Currant	Aniseed (Anise)			
Bayberry Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MD), calculate as Bismuth Oxide Black Catechu Black Haw Blackberry Black Currant	Arrowroot			
Betacarotene 6 mg (MDD) Bismuth Aluminate 6 mg (MD), calculate Black Catechu 8 Bismuth Oxide Black Haw 9 Black Black Currant	Balm of Gilead			
Bismuth Aluminate 6 mg (MD), calculate as Bismuth Oxide Black Catechu Black Haw Blackberry Black Currant	Bayberry			
as Bismuth Oxide Black Catechu Black Haw Blackberry Black Currant	Betacarotene			6 mg (MDD)
Black Haw Blackberry Black Currant	Bismuth Aluminate			6 mg (MD), calculated as Bismuth Oxide
Blackberry Black Currant	Black Catechu			
Black Currant	Black Haw			
	Blackberry			
Bladderwrack (Fucus)	Black Currant			
	Bladderwrack (Fucus)			

Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 4 Maximum dose and maximum daily dose
Blue Cohosh (Caulophyllum)			265 mg (MD)
Boneset (Eupatorium perfoliatum)			
Buckthorn			
Butternut (White Walnut)			
Calamus (Sweet Flag)			
Calcium Chloride			
Calcium Heptagluconate			
Calcium Phosphate			
Calumba			
Capsicum Oleoresin BPC 1923			
Capsicum Oleoresin BPC 1973		(1) Internal	(1) 1.2mg (MD)
			(1) 1.8mg (MDD)
	(2) 2.5 per cent.	(2) External	
Caraway Oil			
Centaury			
Chickweed			
Chlorophenols	(1) 1 mg	(1) Internal	
	(2) 0.6 per cent.	(2) External	
Cinnamic Acid	(1) 500 mcg	 (1) Internal: pastilles, lozenges, throat tablets (2) External 	
Clove		(2) External	
Clover (Red Clover)			
Cobalt Sulphate			Equivalent to 0.25 mg elemental Cobalt (MDD)
Coriander			

Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 4 Maximum dose and maximum daily dose
Dexpanthenol (Panthenol, Pantothenol)			
Docosahexaenoic Acid (DHA)			
Domiphen Bromide			
Eicosapentaenoic Acid (EPA)			
Euphorbia hirta (Euphorbia pilulifera, Pill-Bearing Spurge)			
Fast Green FCF			
Fennel Oil			
Fenugreek			
Ferric Chloride			Equivalent to 24 mg elemental iron (MD)
Fibre, Vegetable			
Fig			
Fir Oil, Siberian			
Frangulin			
Fringe Tree			
Fumitory			160 mg (MD)
Ginseng			
Glutamic Acid Hydrochloride			
Glycerophosphoric Acid			
Gravel Root (Eupatorium purpureum)			
Hamamelis			
Heartsease			
Hemlock Spruce (Pine Canadian)			400 mg (MD)
Horseradish			
Hydrangea			

Column 1	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Iceland Moss			
Inositol			
Iodophenol	(1) 0.2 mg(2) 0.08 per cent.	(1) Internal: pastilles, lozenges, throat tablets	
		(2) External	
Kaolin Heavy			
Kava			625 mg (MD)
Kelp			
Lady's Mantle			
Lemon			
Lignocaine	(1) 0.6 per cent.(2) 0.6 per cent.	(1) Internal: teething gel	
	(2) 0.0 per cent.	(2) External, except local ophthalmic use	
Lignocaine Hydrochloride	 (1) 0.7 per cent. (2) 0.7 per cent. 	(1) Internal: teething gel	
		(2) External, except local ophthalmic use	
Liquorice Extract Deglycyrrhizinised			
Lucerne (Alfalfa)			
Lungwort			
Magnesium Stearate			
Maize			
Malted Milk			
Maltose			
Manganese			Equivalent to 1 mg
Glycerophosphate			elemental Manganese (MDD)
Marshmallow Root			
Methionine, DL			
Motherwort			
Myrrh			
Nutmeg			
Oak Bark			

Column 1 Substance	Column 2 Maximum strength	Column 3 Use, pharmaceutical form or route of administration	Column 4 Maximum dose and maximum daily dose
Orange			
Pantothenic Acid			
Papain			
Parsley			
Pellitory			
Pilewort			
Pleurisy Root			
Poke Root (Phytolacca)		 (1) Internal (2) External 	(1) 120 mg (MD)
Poplar (Aspen)			
Potassium Acid Tartrate			
Potassium Bicarbonate			
Potassium Carbonate			
Potassium Citrate			
Potassium Molybdate			Equivalent to 200 mcg elemental molybdenum (MDD)
Psyllium			
Queen's Delight			320 mg (MD)
Raspberry			
Rosemary			
Rubellin			
Rutin			
Saw Palmetto			
Shepherd's Purse			
Skunk Cabbage (Symplocarpus)			
Sodium Sulphate			
Sodium Acid Phosphate			
Sodium Glycerophosphate			
Sodium Phosphate			

Column 1	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical	Maximum dose and
Substance	Maximum strength	form or route of	maximum daily dose
		administration	5
Squaw Vine			
Squill, Indian			
Stone Root			
Tilia (Lime Flowers)			
Unicorn Root False			
Uva Ursi (Bearberry)			
Wahoo (Euonymus			
atropurpureus)			
Watercress			
Wheat			
Wild Indigo			
Wood Betony			
Xanthan Gum			
Yellow Dock			
Zinc Gluconate			Equivalent to 5 mg elemental zinc (MDD)

SCHEDULE 2

Article 3(3)(a)

ENTRIES INSERTED IN TABLE B OF SCHEDULE 1 TO THE PRINCIPAL ORDER (EXTERNAL USE ONLY)

Column 1	Column 2	Column 3
Substance	Maximum Strength	Use, Pharmaceutical Form or Route of Administration
Aldioxa (Aluminium Dihydroxyallantoinate)		
Allantoin		
Aminacrine Hydrochloride		
Arnica		
Bay Oil		
Borax (Sodium Borate)	(1) 5.0 per cent.(2) 0.7 per cent.	(1) All preparations except ophthalmic lotions(2) Ophthalmic lotions
Boric Acid	2.5 per cent.	

Column 1 Substance	Column 2 Maximum Strength	Column 3 Use, Pharmaceutical Form or Route of Administration
Bryony, Black		
Burgundy Pitch		
Calcium Undecylenate		
Calendula (Marigold)		
Cedar Wood Oil		
Colophony		
Comfrey Root		
Crotamiton		
Dichlorotetrafluroethane		
Emulsifying Wax		
European Birch		
Geranium Oil		
Guaiacol		
Halquinol	0.6 per cent.	
Heparin		
Hexetidine	0.1 per cent.	
Hexyl Nicotinate	2.0 per cent.	
Horse-chestnut (Aesculus)		
Hypericum (St. John's Wort)		
Hypophosphorous Acid		
Isopentane		
Labrador Tea		
Lactic Acid		
Light Liquid Paraffin		
Linseed Oil		
Mastic		
Melaleuca Oil		
Methoxymethane		
Mexenone		
Microcrystalline Wax		
Oleyl Alcohol		
Paeony (Peony)		
Polyethoxyethanol		

Column 1	Column 2	Column 3
Substance	Maximum Strength	Use, Pharmaceutical Form or
		Route of Administration
Potassium Chloride		
Potassium Hydroxide		
Potassium Thiocyanate		
Propylene Glycol		
Pyrethrum (Chrysanthemum	ı)	
Rue	0.1 per cent.	
Shark Liver Oil	(1) 3.0 g	(1) Suppositories
		(2) All preparations for external use except
		suppositories
Sodium Acid Pyrophosphate		
Sodium Pyrophosphate		
Southern Wood		
Talc		
Tar		
Terebene (Terepene)		
Thurfyl Salicylate		
Titanium Peroxide		
Titanium Salicylate		
Wool Alcohols, Acetylated		
Zinc Oleate		

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 ("the principal Order") which specifies classes of medicinal products which can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist (the general sale list).

Article 2 inserts a definition of "effervescent" in the principal Order.

Article 3 amends Schedule 1 to the principal Order (medicinal products, other than products the subject of a product licence of right, on general sale). Article 3(2) inserts in Table A (internal or

external use) of that Schedule the entries specified in Schedule 1 to this Order and amends other entries in Table A as described in paragraph (2)(d) to (1).

Article 3(3) inserts in Table B (external use only) of Schedule 1 to the principal Order the entries specified in Schedule 2 to this Order, omits from Table B the entries in respect of Hamamelis, Siberian Fir Oil, Lignocaine and Lignocaine Hydrochloride (which now appear, amended, in Table A of that Schedule) and amends the entry in respect of Povidone-Iodine.