Table 1 Part 2

Volume 6

## Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

## Part 2 – Table 1

Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5019	UBIDECARENONE	A, E	<ul> <li>When used as an excipient, the route of administration must be topical and the concentration in the medicine must not be more than 0.05%.</li> <li>Not to be included in medicines intended for use in the eye.</li> <li>When for internal use, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone.</li> <li>When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone.</li> <li>When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubiquinol-10 and ubidecarenone combined.</li> <li>When for internal use, the following warning statement is required on the medicine label:</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			- (WARF) 'Do not take while on warfarin therapy without medical advice'.
5020	UBIQUINOL-10	A, E	<ul> <li>When used as an excipient, the route of administration must be topical and the concentration in the medicine must be no more than 0.05%.</li> <li>Not to be included in medicines intended for use in the eye.</li> <li>When for internal use, the maximum recommended daily dose must provide no more than 300 milligrams of ubiquinol-10.</li> <li>When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined.</li> <li>The medicine requires the following warning statement on the medicine label:</li> <li>- (WARF) 'Do not take while on warfarin therapy without medical advice.'</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5021	ULEX EUROPAEUS	А, Н	
5022	ULMUS AMERICANA	А, Н	
5023	ULMUS CAMPESTRIS	A, H	
5024	ULMUS GLABRA	A, H	
5025	ULMUS PARVIFOLIA	A, H	
5026	ULMUS PROCERA	A, H	
5027	ULMUS PUMILA	A, H	
5028	ULMUS RUBRA	A, H	
5029	ULTRALIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5030	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5031	ULVA LACTUCA	A, H	Iodine is a mandatory component of Ulva lactuca. Only for use in topical medicines for dermal application and not to be included in medicines intended

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye. The concentration in the medicine must be no more than 0.1%.
5032	UMBELLULARIA CALIFORNICA	A, H	
5033	UNCARIA GAMBIR	A, H	
5034	UNCARIA RHYNCOPHYLLA	A, H	
5035	UNCARIA SINENSIS	А, Н	
5036	UNCARIA TOMENTOSA	А, Н	
5037	UNDARIA PINNATIFIDA	А, Н	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5038	UNDECANAL	E	<ul> <li>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</li> <li>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</li> <li>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5039	UNDECANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a
5040	UNDECENOIC ACID	E	medicine must be no more than 5%.
5041	UNDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5042	UNDECYLCRYLENE DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			10%.
5043	UNDECYLENAMIDE DEA	Е	
5044	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5045	URANIUM NITRATE	Н	Only for use as an active homoeopathic ingredient.
5046	UREA	A, E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10% (w/w).
5047	URTICA DIOICA	А, Е, Н	
5048	URTICA URENS	A, H	
5049	USNEA BARBATA	A, H	
5050	UVA URSI LEAF DRY	A, H	
5051	UVA URSI LEAF POWDER	А, Е, Н	
5052	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	E	Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>copolymer.</li> <li>The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 ppm.</li> <li>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</li> <li>The concentration in the medicine must be no more than 5%.</li> </ul>
5053	VACCARIA SEGATALIS	A, H	
5054	VACCINIUM BRACTEATUM	A, H	
5055	VACCINIUM CORYMBOSUM	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5056	VACCINIUM MACROCARPON	А, Е, Н	
5057	VACCINIUM MYRTILLOIDES	A, H	

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5058	VACCINIUM MYRTILLUS	А, Е, Н	
5059	VACCINIUM OXYCOCCUS	А, Н	
5060	VACCINIUM VITIS-IDAEA	A, H	Arbutin is a mandatory component of Vaccinium vitis- idaea. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
5061	VALENCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5062	VALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%.
5063	VALERIAN DRY	A, H	
5064	VALERIAN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5065	VALERIAN POWDER	A, H	
5066	VALERIANA EDULIS	A, H	
5067	VALERIANA OFFICINALIS	A, H	
5068	VALERIANA SORBIFOLIA	A, H	
5069	VALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5070	VALINE	A, E	
5071	VANADIUM	Н	
5072	VANILLA	E	<ul> <li>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</li> <li>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</li> <li>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</li> </ul>
5073	VANILLA DRY	А, Е, Н	
5074	VANILLA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5075	VANILLA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5076	VANILLA PLANIFOLIA	A, E, H	
5077	VANILLA POWDER	А, Е, Н	
5078	VANILLA TAHITENSIS	A, H	
5079	VANILLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5080	VANILLIN	E	
5081	VANILLIN ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
5082	VANILLYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5083	VAT RED 1	E	Permitted for use only as a colour for topical use.
5084	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5085	VAT RED 5	E	Permitted for use only as a colour for topical use.
5086	VEGETABLE OIL	E	
5087	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label:

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
5088	VEIN	Н	Only for use as an active homoeopathic ingredient.
5089	VERATRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5090	VERATROL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5091	VERATRUM ALBUM	А, Н	Solanidine is a mandatory component of Veratrum album. The concentration of equivalent dry Veratrum album in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
5092	VERBASCUM DENSIFLORUM	А, Н	
5093	VERBASCUM THAPSUS	A, H	
5094	VERBENA OFFICINALIS	A, H	
5095	VERBENA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5096	VERONICA CHAMAEDRYS	A, H	
5097	VERONICA OFFICINALIS	А, Н	
5098	VERONICASTRUM VIRGINICUM	А, Е, Н	
5099	VERTONAL	E	Permitted for use only in combination with other permitted ingredients as part of

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>a fragrance proprietary excipient formulation.</li> <li>When included in a medicine for use on the lips the concentration of vertonal must be no more than 0.2%.</li> <li>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</li> </ul>
5100	VETIVER OIL	E	<ul> <li>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</li> <li>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</li> <li>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</li> </ul>
5101	VETIVERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			1%.
5102	VIBURNUM OPULUS	A, E, H	
5103	VIBURNUM PRUNIFOLIUM	A, E, H	
5104	VICIA FABA	A, H	Levodopa (of Vicia faba) is a mandatory component of Vicia faba. The concentration of Levodopa (of Vicia faba) from all ingredients in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
5105	VIGNA ANGULARIS VAR. ANGULARIS	А, Н	
5106	VIGNA RADIATA	А, Н	
5107	VIGNA UMBELLATA	A, H	
5108	VINCA MAJOR	A, H	Vincamine is a mandatory component of Vinca major. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
5109	VINCA MINOR	А, Н	Vincamine and vincristine are mandatory components of

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			Vinca minor. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5110	VINCETOXICUM OFFICINALE	A, H	
5111	VINEGAR	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5112	VIOLA ODORATA	А, Е, Н	
5113	VIOLA TRICOLOR	A, H	
5114	VIOLA YEDOENSIS	A, H	
5115	VIOLET LEAF ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5116	VIOLET LEAVES	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5117	VIPER	Н	Only for use as an active homoeopathic ingredient.
5118	VISCUM ALBUM	А, Е, Н	
5119	VISCUM COLORATUM	A, H	
5120	VISCUM FLAVESCENS	A, H	
5121	VITELLARIA PARADOXA	А, Е, Н	
5122	VITEX AGNUS-CASTUS	А, Е, Н	
5123	VITEX NEGUNDO	A, H	

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5124	VITEX ROTUNDIFOLIA	A, H	
5125	VITEX TRIFOLIA	A, H	
5126	VITIS VINIFERA	А, Е, Н	
5127	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5128	WAHLENBERGIA GRACILIS	А, Н	
5129	WALNUT	Е	
5130	WALNUT OIL	Е	
5131	WATER MELON	Е	
5132	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5133	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5134	WHEAT DEXTRIN	A, E	Only for use when the dosage form is capsule, tablet or pill. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5135	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>when the route of administration is other than topical and mucosal.</li> <li>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</li> <li>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</li> </ul>
5136	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of Wheat germ glycerides when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5137	WHEAT LEAF	E	
5138	WHEAT SPROUT	E	Gluten is a mandatory

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>component of Wheat sprout when the route of administration is other than topical and mucosal.</li> <li>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</li> <li>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</li> </ul>
5139	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
5140	WHEATGERM OIL	А, Е, Н	

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5141	WHEY POWDER	Е	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5142	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5143	WHEY PROTEIN CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5144	WHITE BEESWAX	E	
5145	WHITE HOREHOUND HERB DRY	А, Н	
5146	WHITE HOREHOUND HERB POWDER	А, Н	
5147	WHITE SOFT PARAFFIN	Α, Ε	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5148	WHOLE DRY MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
5149	WIKSTROEMIA VIRIDIFLORA	А, Н	
5150	WILD CARROT HERB DRY	A, E, H	
5151	WILD CARROT HERB POWDER	A, H	
5152	WILD CHERRY BARK DRY	A, H	
5153	WILD CHERRY BARK POWDER	A, H	
5154	WILD LETTUCE LEAF DRY	А, Н	
5155	WILD LETTUCE LEAF POWDER	А, Н	
5156	WINTERGREEN OIL	А, Е, Н	Methyl salicylate is a mandatory component of wintergreen oil. Not to be included in medicines for use in the eye or on damaged skin.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.
			When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.
			When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging if:
			- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
			- direct suction through the delivery device results in delivery of no more than one dosage unit; and
			- actuation of the spray device is ergonomically difficult for young children to accomplish.
			In addition, when the ingredient is included in a medicine that is listed in the Register:

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	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);
			- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or
			- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).
			a) The following warning statement is required on the medicine label:
			- (METSAL) 'Contains methyl salicylate' (or words to that effect).
			b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
			- (CHILD4) 'Do not use [this

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>product/insert name of product]</li> <li>in children 6 years of age or</li> <li>less';</li> <li>- (SENS) 'Application to skin</li> <li>may increase sensitivity to</li> <li>sunlight'. (or words to that</li> <li>effect);</li> </ul>
			<ul> <li>- (IRRIT) 'If irritation develops, discontinue use.'; and</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</li> </ul>
5157	WITHANIA SOMNIFERA	А, Е, Н	
5158	WOLFIPORIA COCOS	A, E, H	When the ingredient is included in a medicine that is listed in the Register before 1 July 2018 and supplied before 1 January 2020, the medicine label may refer to the ingredient name as 'Poria cocos' instead of 'Wolfiporia cocos'.
5159	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5160	WOOL FAT	A, E	When used as an active ingredient, can only be

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5161	XANTHAN GUM	E	
5162	XANTHIUM SIBIRICUM	А, Н	
5163	XANTHIUM STRUMARIUM	A, H	
5164	XANTHOMONA CAMPESTRIS	A, H	
5165	XEROPHYLLUM ASPHODELOIDES	A, H	
5166	XYLENE	E	The residual solvent limit for xylene is 21.7 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.217%.
5167	XYLITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the

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	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>medicine requires the following warning statement on the medicine label:</li> <li>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.</li> </ul>
5168	XYLOSE	E	
5169	YAM	Е	
5170	YARROW HERB DRY	A, H	
5171	YARROW HERB POWDER	A, H	
5172	YEAST AUTOLYSATE	E	
5173	YEAST DRIED	А, Е, Н	
5174	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5175	YELLOW BEESWAX	E	
5176	YELLOW MERCURIC OXIDE	Н	Only for use as an active homoeopathic ingredient.
5177	YELLOW SOFT PARAFFIN	A, E	Only for use in topical medicines for dermal

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			application. When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5178	YLANG YLANG OIL	А, Е, Н	
5179	YUCCA BACCATA	А, Н	
5180	YUCCA ELATA	А, Н	
5181	YUCCA FILAMENTOSA	А, Н	
5182	YUCCA GLORIOSA	А, Н	
5183	YUCCA WHIPPLEI	А, Н	
5184	ZANTHOXYLUM AMERICANUM	А, Н	
5185	ZANTHOXYLUM BUNGEANUM	А, Е, Н	
5186	ZANTHOXYLUM CLAVA- HERCULIS	А, Н	
5187	ZANTHOXYLUM NITIDUM	А, Н	
5188	ZANTHOXYLUM PIPERITUM	А, Н	
5189	ZANTHOXYLUM SIMULANS	А, Н	

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5190	ZEA MAYS	А, Е, Н	
5191	ZEAXANTHIN	Α, Ε	
5192	ZEIN	Е	
5193	ZINC	Н	Only for use as an active homoeopathic ingredient. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily
			<ul> <li>dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</li> <li>- (ZINC) 'WARNING: May be</li> </ul>
			dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.
5194	ZINC AMINO ACID CHELATE	A, E, H	When used internally, zinc is a mandatory component of zinc amino acid chelate.
			The concentration of zinc in zinc amino acid chelate must

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>be no more than 30%.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</li> <li>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</li> </ul>
5195	ZINC ASCORBATE	A, E, H	<ul> <li>When used internally, zinc is a mandatory component of zinc ascorbate.</li> <li>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5196	ZINC ASCORBATE MONOHYDRATE	A, E, H	<ul> <li>When used internally, zinc is a mandatory component of zinc ascorbate monohydrate.</li> <li>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: <ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.</li> </ul> </li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5197	ZINC CHLORIDE	A, E, H	The concentration of zinc chloride in the medicine must be no more than 5%. When used internally, zinc is a mandatory component of zinc chloride. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5198	ZINC CITRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate. When for internal use, the

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5199	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5200	ZINC CITRATE TRIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate trihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5201	ZINC DIASPARTATE	A	When used internally, zinc is a mandatory component of zinc diaspartate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5202	ZINC GLUCONATE	A, E, H	When used internally, zinc is a mandatory component of zinc gluconate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5203	ZINC GLYCINATE	A	When used internally, zinc is a mandatory component of Zinc glycinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			taken in large amounts or for a long period (or words to that effect).'
5204	ZINC GLYCINATE MONOHYDRATE	A	<ul> <li>When used internally, zinc is a mandatory component of Zinc glycinate monohydrate.</li> <li>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: <ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.</li> </ul> </li> </ul>
5205	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			The concentration of zinc lactate in a medicine intended for topical use should be no more than 2%.
			The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.
			Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.
			Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:
			- (CHILD3) 'Use in children under 12 years is not recommended'.
5206	ZINC LACTATE DIHYDRATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.
			The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%.
			The concentration of Zinc

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Column 2	Column 3	Column 4
Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
		lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.
		Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.
		Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:
		- (CHILD3) 'Use in children under 12 years is not recommended'.
ZINC LYSINATE	A	When used internally, zinc is a mandatory component of Zinc lysinate.
		When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
		When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement
	Ingredient Name	Ingredient Name       Purpose of the ingredient in the medicine         Image: Contract of the ingredient in the medicine       Image: Contract of the ingredient in the medicine         Image: Contract of the ingredient in the medicine       Image: Contract of the ingredient in the medicine         Image: Contract of the ingredient ing

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5208	ZINC METHIONINE SULFATE	A	<ul> <li>For topical use, the concentration of zinc methionine sulfate must be no more than 5%.</li> <li>When used internally, zinc is a mandatory component of zinc methionine sulfate.</li> <li>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</li> <li>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5209	ZINC MYRISTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5210	ZINC OXIDE	A, E, H	<ul> <li>When used internally, zinc is a mandatory component of zinc oxide.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</li> <li>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR</li> <li>-'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a</li> </ul>

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			long period (or words to that effect).'
			When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
			When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5211	ZINC PARA- PHENOLSULFONATE	E	The concentration of zinc para- phenolsulfonate in the medicine must not exceed 5%. When used internally, zinc is a mandatory component of zinc para-phenolsulfate. The percentage of zinc from zinc para-phenolsulfonate should be calculated based on the molecular weight of zinc para-phenolsulfonate. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
5212	ZINC STEARATE	E	When used internally, zinc is a mandatory component of zinc stearate.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate.
5213	ZINC SUCCINATE	A, E, H	<ul> <li>When used internally, zinc is a mandatory component of zinc succinate.</li> <li>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: <ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' or</li> <li>'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</li> </ul> </li> </ul>
5214	ZINC SULFATE	Α, Ε	For topical use, the

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			concentration of zinc sulfate must be no more than 5%.
			For internal use, zinc is a mandatory component of zinc sulfate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5215	ZINC SULFATE HEPTAHYDRATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%.
			For internal use, zinc is a

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			mandatory component of zinc sulfate heptahydrate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5216	ZINC SULFATE HEXAHYDRATE	А, Е, Н	For topical use, the concentration of zinc sulfate must be no more than 5%.
			For internal use, zinc is a mandatory component of zinc sulfate hexahydrate.
			When for internal use, the

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5217	ZINC SULFATE MONOHYDRATE	A, E, H	When the route of administration is topical the concentration of zinc sulfate in the medicine must be no more than 5%.
			When the medicine is for internal use, zinc is a mandatory component of zinc sulfate monohydrate.
			When for internal use, the maximum recommended daily dose must be no more than

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
			<ul> <li>50mg of zinc.</li> <li>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</li> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR</li> <li>'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</li> </ul>
5218	ZINC VALERATE	H	Only for use as an active homoeopathic ingredient. For internal use, zinc is a mandatory component of zinc valerate. The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5219	ZINGERONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5220	ZINGIBER OFFICINALE	A, E, H	When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine'.
5221	ZIZIPHUS JUJUBA	А, Н	
5222	ZIZIPHUS JUJUBA VAR. SPINOSA	А, Н	

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Column 1	Column 2	Column 3	Column 4
	Ingredient Name	Purpose of the ingredient in the medicine	Specific requirements(s) applying to the ingredient in Column 2
5223	ZIZYPHUS SATIVA	А, Н	
5224	ZOSTERA MARINA	А, Н	
5225	ZUCCHINI	Е	