

Table of changes from SUSDP to SUSMP

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Refer to 'KEY CHANGES' summarised at Attachment 1.

SUSMP Reference	Corresponding SUSDP 21 Reference	Identification of and reasons for any change
PRELIMINARY - Introduction	PREFACE	Title changed (<i>see KEY CHANGE 9</i>) Editorial & improved usability Please note that 'poison' has been replaced by 'medicine and poison or veterinary chemical' throughout the document.
PRELIMINARY - Classification of Medicines and Poisons	INTRODUCTION - Classification	Editorial Improved usability
PRELIMINARY - Principles of Scheduling Medicines and Poisons	PRINCIPLES OF SCHEDULING	Editorial Improved usability
PART 1 – INTERPRETATION	PART 1 – INTERPRETATION	
1.01 Definitions	1(1) Definitions	Any changes to the current definitions are due to the need to be consistent (in as much as possible) with the definitions in the new therapeutic products legislation. Definitions will require further consideration, particularly following the development of the Aust-only legislation (chemicals scheduling).
1.02 References to substances <i>Paragraph no longer referenced</i>	1(2) References to substances [for current paragraph numbering refer to Amendment 21/2] 1(2)(i)	Amended references: Provision no longer required - Appendix G blank - requirements for dilute preparations to be transferred to each individual substance entry (see 'Appendices') Policy approval to be obtained. (<i>see KEY CHANGE 10</i>)
1.02(i)	1(2)(j)	Wording slightly amended
1.03 Specification of concentration, strength or quantity		

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1.03(a) & (b)	1(3)	Paragraph is unchanged
1.04 References to temperatures	1(4)	Paragraph is unchanged
PART 2 – LABELLING REQUIREMENTS FOR MEDICINES AND POISONS	PART 2 – LABELS AND CONTAINERS	
2.01 General 2.01(1)(a) - (e)	General requirements 3(1), (2), (3), (4) & (5)	Includes "...must be clearly visible and not obscured..." and "... and legible..."
2.01(2)(a) & (b)	4(1) & (2)	Paragraph is unchanged
2.01(3)(a) & (b)	5(1) & (2)	Paragraph is unchanged
2.01(4)(a) - (c)		New provision (see KEY CHANGE 5)
2.02 Signal headings for medicines	Primary Packs and Immediate Containers	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>)
2.02(1) (a) & (b)	7(1)(a), (b)(iii) & (c)(iii) as it applies to medicines	The 'purpose' ('for any purpose') has been removed as the amendments have made it redundant & cautionary statements have been included with the signal words.
2.02(2) (a) - (c)	7(2)(a), (b) & (c)	
2.03 Exemptions for signal headings for medicines 2.03(1)(a) –(g) 2.03(2)		New provision (see KEY CHANGE 5)
2.04 Signal headings for poisons 2.04(1)(a) & (b) 2.04(2)(a) - (c)	Primary Packs and Immediate Containers Duplicates 7(1)(a) & (c)(iii) for poisons Duplicates 7(2)(a), (b) & (c) for poisons	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>)
2.05 Applications and exemptions 2.05(1) 2.05(2)(a) - (c)	2 14(1), (2) & (3)	This section has been reformatted in SUSMP. Paragraph is unchanged. Changed to include 'authorised prescriber' and removed reference to labelling requirements.
2.05(3)(a) & (b)	13(1) & (2)	Removed reference to labelling requirements.

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2.05(4)	12	Removed reference to labelling requirements
2.06 Prohibitions 2.06 (1)(a) - (d)	18(1), (2), (3) & (4)(a)-(c)	Paragraph is unchanged
2.06 (2)(a) & (b)	19(1) & (2)	Paragraph is unchanged
2.07 Identification information – immediate wrapper 2.07(1)(a) & (b)	Immediate wrapper 6(1) & (2) – Applies to poisons other than agvet chemicals	Reworded to take account of the transfer of requirements for agricultural and veterinary chemicals from the Scheduling Standard (<i>see KEY CHANGE 1</i>)
2.08 Primary packs and immediate containers 2.08(1)(a) - (d) 2.08 (2)(a) 2.08(2)(b)	7(1)(q) & (k) 7(1)(d) 7(1)(e)	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>) Table included to improve usability
<i>Paragraph no longer referenced</i>	7(1)(f) if the poison is an aqueous solution of paraquat, with the cautionary statements - CAN KILL IF SWALLOWED DO NOT PUT IN DRINK BOTTLES KEEP LOCKED UP	Provision transferred. It is currently required under para 2.1.2 of the Ag Labelling Code. (<i>see KEY CHANGE 1</i>)
2.08(2)(c) 2.08(2)(d)	7(1)(g) 7(1)(h)	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>) Table for improved usability
<i>Paragraph no longer referenced</i>	7(1)(i) if the poison is for the treatment of animals, with the cautionary statement- FOR ANIMAL TREATMENT ONLY	Provision transferred. It is currently required under para 2.1(e) of the Vet Labelling Code. (<i>see KEY CHANGE 1</i>)
2.08(2)(e)	7(1)(j) reference to internal and pesticidal use has been removed	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>) Table for improved usability
<i>Paragraph no longer referenced</i>	7(1)(k)(i) relates to approved name &	Provision transferred (<i>see KEY CHANGE 4</i>).

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	statement of strength for medicines if the poison is for human therapeutic use, written in accordance with orders made under section 10(3) of the Commonwealth <i>Therapeutic Goods Act, 1989</i>	
<i>Paragraph no longer referenced</i>	7(1)(l) if the poison is an organophosphorus compound or carbamate for pesticidal use or for the treatment of animals, with the following expression written immediately below the approved name or the list of declared contents - AN ANTICHOLINESTERASE COMPOUND	Provision transferred. It is currently required under section 2.3 and para 2.34 of the Vet and Ag Labelling Codes respectively (<i>see KEY CHANGE 1</i>)
2.08(2)(f) 2.08(2)(g) 2.08(2)(h)	7(1)(n) 7(1)(o) 7(1)(p) 7(1)(m)	Reformatted to take account of the separation of requirements for medicines and poisons (<i>see KEY CHANGE 2</i>) Table for improved usability
<i>Paragraph no longer referenced</i>	7(1)(m)(i) relates to directions for use where the poison is included in Schedule 4 or Schedule 8;	Provision transferred (<i>see KEY CHANGE 4</i>).
2.09 Approved name 2.09(1)(a)- (c) 2.09 (2) 2.09 (3)	7(1)(k)(ii) 7(1)(k)(iii) 7(1)(k)(iv)	Reformatted – improved usability
2.10 Statements of quantity, proportion or strength	8 Statements of quantity, proportion or strength	
<i>Paragraph no longer referenced</i>	8(1) Relates to statements of quantity etc if the poison is for human therapeutic use, in the manner prescribed by orders made under section 10(3) of the Commonwealth <i>Therapeutic Goods</i>	Provision transferred (<i>see KEY CHANGE 4</i>)

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	<i>Act, 1989</i>	
2.10(a) - (g) 2.10(h) 2.10(i) 2.10(j) 2.10(k) 2.10(l) 2.10(m)	8(2)(a)-(g) 8(3) 8(4) 8(5) 8(6) 8(7) 8(8)	Unchanged
2.11 Exemptions from additional labelling requirements for certain medicines 2.11(1)	15 Gas cylinders	Unchanged
2.11(2)	16(1) & (2) Paints	Reformatted (including table) for improved usability. Paint and tinter requirements have been combined where possible.
2.11(3)	17 Camphor and naphthalene	Unchanged
2.12 Exemptions from additional labelling requirements for certain medicines 2.12(1) 2.12(2)(a)-(c)	Exemptions 9 Selected containers and measure packs 9(1) 9(2)(a)-(c)	Unchanged
<i>Paragraph no longer referenced</i>	9(2)(d) relates to exemptions for certain packs if the poison is for the treatment of animals, with the cautionary statement- FOR ANIMAL TREATMENT ONLY	Provision transferred (<i>see KEY CHANGE 1</i>)
<i>Paragraph no longer referenced</i>	10 relates to ampoules, pre-filled syringes and injection vials	Provision transferred (<i>see KEY CHANGE 4</i>)
<i>Paragraph no longer referenced</i>	11 relates to the labelling of plastic ampoules.	Provision transferred (<i>see KEY CHANGE 4</i>)
PART 3 – CONTAINER REQUIREMENTS FOR POISONS OTHER THAN AGRICULTURAL AND VETERINARY CHEMICALS	Containers	Reformatted to take account of KEY CHANGES 1 and 2

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3.01 Applications and exemptions 3.01(1) 3.01(2)	20 26(1)(f) & 26(2)	Provision removes reference to agvet chemicals These two paragraphs have been combined
3.02 Child-resistant closures 3.02(1) & (2)	Child-resistant closures 25(1) & (2)	Unchanged
<i>Paragraph no longer referenced</i>	25A(1) & (2) relates to the supply of Schedule 8 poisons	Provision transferred (see KEY CHANGE 4)
3.03 Containers for poisons other than Schedule 5 poisons 3.03(1) 3.03(2)(a) & (b)	Containers for poisons other than Schedule 5 poisons 21 22	Unchanged Slightly reformatted
3.04 Containers for Schedule 5 poisons 3.04(1) & (2)	Containers for Schedule 5 poisons 23(1) & (2)	Unchanged
3.05 Approved containers for poisons 3.05(1) 3.05(2)	Approved container 24 21A	Unchanged Unchanged
<i>Paragraph(s) no longer referenced</i>	Exemptions 26 (1)(a)-(b) – relate to containers of poisons for human or animal use	Provision transferred – this may need further consideration following agreement of mechanism to facilitate transfer of labelling and packaging requirements from S5 and S6
3.06 Exemptions from container requirements for certain poisons 3.06(1) 3.06(2) 3.06(3)	26(1)(c)-(e) 27 28 Camphor and naphthalene	Unchanged other than removing reference to 'therapeutic' in paragraph (c) Unchanged Unchanged
3.07 Prohibitions 3.06(a) 3.06(b) 3.06(c)	Prohibitions 29 30 31	Unchanged

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<i>Paragraph no longer referenced</i>	PART 3 – MISCELLANEOUS REGULATIONS Advertising 32 relates to S3, 4 and 8 medicines	Provision transferred (see KEY CHANGE 3).
PART 4 – ADVERTISING, SALE, SUPPLY, POSSESSION, STORAGE AND DISPENSING OF MEDICINES AND POISONS Advertising 4.01	33	Unchanged
4.02 Sale or supply of Schedule 2 medicines 4.02(1) 4.02(2)(a)-(c) 4.02(2)(d)	Sale or supply – Schedule 2 poisons 34 35 No corresponding reference – relates to the sale of S2 medicines by licensed poisons sellers	Slightly changed Unchanged other than paragraph (c) New provision required as a result of new Appendix L (<i>see KEY CHANGE 7</i>)
4.03 Sale or supply of Schedule 3 medicines 4.03(1) 4.03(2)	Sale or supply – Schedule 3 poisons 36 37(1) & (2)	Slightly changed Slightly changed
4.04 Supply of certain Schedule 3 medicines to be recorded 4.04(1) & (2)	37(3) relates to recording S3 medicines	Transfer of provision and revised wording, required as a result of new Appendix H (<i>see KEY CHANGE 6</i>)
4.05 Sale or supply of Schedule 4 medicines or veterinary chemicals 4.05(1) 4.05(2)(a) – (c) 4.05(3)	Sale or supply - Schedule 4 poisons 38 39(1)-(3) 40	Unchanged other than use of the terms 'authorised prescriber', 'medicine' and 'veterinary chemical'
4.06 Possession, use, sale and supply of Schedule 7 poisons	Sale or supply – Schedule 7 poisons	

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4.06(1) 4.06(2)(a) – (c) 4.06(3)(a) – (g) 4.06(4) 4.06(5)	41(1) 41(2)(a) - (c) 41(3) 41(4) No corresponding reference	Paragraphs unchanged other than clarification of use of the term 'notice' in 4.06(5).
4.07 Prohibitions on sale, prescribing and possession of certain medicines and poisons 4.07(a) – (c)	Prohibitions on sale, prescribing and possession 42(1) – (3)	Unchanged apart from paragraph 1 which now includes 'obtain' and 'administer'
4.08 Storage of certain medicines and poisons 4.08(1) 4.08(2)	Storage 43 44	Slightly changed Slightly changed
4.09 Dispensed medicines and dispensed veterinary chemicals 4.09(1) 4.09(2)(a) 4.09(2)(b)	Dispensed medicines No corresponding reference No corresponding reference 45(1) 45(2) – (5)	Provisions transferred to new Appendix M - Requirements for dispensing labels for medicines and veterinary chemicals Part 2 (1) (<i>see KEY CHANGE 8</i>)
PART 5 – LIST OF SCHEDULES Schedule 1 (Intentionally blank) Schedule 2 (Pharmacy medicine) Schedule 3 (Pharmacist-only medicine) Schedule 4 (Prescription-only medicine or Prescription animal remedy) Schedule 5 (Caution) Schedule 6 (Poison) Schedule 7 (Dangerous poison) Schedule 8 (Controlled drug)	PART 4 – THE SCHEDULES Schedule 1 (intentionally blank) Schedule 2 (Pharmacy medicine) Schedule 3 (Pharmacist-only medicine) Schedule 4 (Prescription-only medicine or Prescription animal remedy) Schedule 5 (Caution) Schedule 6 (Poison) Schedule 7 (Dangerous poison) Schedule 8 (Controlled drug)	Intent unchanged for all Schedules.

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Schedule 9 (Prohibited substance)	Schedule 9 (Prohibited substance)	
PART 6 – APPENDICES <i>Appendix A</i> General exemptions from this Scheduling Standard for medicines and poisons or poisons in certain kinds of products	PART 5 – APPENDICES <i>Appendix A</i> General exemptions from the Standard for medicines and poisons	Intent unchanged
<i>Appendix B</i> Medicines and poisons considered not to require scheduling	<i>Appendix B</i> Medicines and poisons not considered to require scheduling	Unchanged
<i>Appendix C</i> Medicines and poisons – the sale, supply or use of which should be prohibited because of their known potential harm to human and/or animal health	<i>Appendix C</i> Medicines and poisons – the sale, supply or use of which should be prohibited because of their known potential harm to human and/or animal health	Unchanged
<i>Appendix D</i> Additional controls on possession or supply of poisons included in Schedule 4 or Schedule 8	<i>Appendix D</i> Additional controls on possession or supply of poisons included in Schedule 4 or Schedule 8	Intent of Appendix will be retained. <i>However, the new Appendix has been reformatted into a legal style which will allow States and Territories to adopt by reference. Flexibility has also been built in to enable States and Territories to further define those substances which can only be prescribed by a specialist physician.</i>
<i>Appendix E</i> First aid instructions for poisons (other than agricultural or veterinary chemicals or industrial chemicals packed and sold solely for industrial use)	<i>Appendix E</i> First aid instructions for poisons (other than agricultural or veterinary chemicals or industrial chemicals packed and sold solely for industrial use)	Intent of Appendix will be retained for poisons only. <i>The requirements for medicines will be removed from the list accordingly and transferred to the ANZTPA document 'Required Advisory Statements for Medicine Labels' (RASML). The requirements for agricultural and veterinary chemicals are outlined in the FAISD Handbook (Handbook of First Aid Instructions, Safety Directions and Warning Statements for Agricultural and Veterinary Chemicals). (see KEY CHANGE 4)</i>
<i>Appendix F</i> Warning statements and general	<i>Appendix F</i> Warning statements and general	Intent of Appendix will be retained for poisons only

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safety directions for poisons (other than agricultural or veterinary chemicals or industrial chemicals packed and sold solely for industrial use)	safety directions for poisons (other than agricultural or veterinary chemicals or industrial chemicals packed and sold solely for industrial use)	(other than agricultural or veterinary chemicals or industrial chemicals packed and sold solely for industrial use). <i>The requirements for medicines are to be removed from the list accordingly and transferred to the ANZTPA document 'Required Advisory Statements for Medicine Labels' (RASML). (see KEY CHANGE 4)</i>
<i>Appendix G</i> Blank	<i>Appendix G</i> Dilute preparations	<i>The requirements for dilute preparations will be transferred to each individual substance entry. This Appendix will therefore become blank.</i>
<i>Appendix H</i> Schedule 3 substances subject to mandatory recording requirements	<i>Appendix H</i> Schedule 3 poisons permitted to be advertised	<i>The advertising requirements currently included in Appendix H of the SUSDP will be transferred to the relevant ANZTPA Rule, Order or Australian-only parts of the new therapeutic products legislation. (see KEY CHANGE 3)</i> Appendix H will become a new appendix that will contain those Schedule 3 substances that should be subject to national mandatory recording. (see KEY CHANGE 6)
<i>Appendix I</i> Uniform paint standard	<i>Appendix I</i> Uniform paint standard	Intent of Appendix to be retained. <i>However, the new Appendix has been reformatted into a legal style which will allow States and Territories to adopt by reference.</i>
<i>Appendix J</i> Conditions for availability and use of Schedule 7 poisons	<i>Appendix J</i> Conditions for availability and use of Schedule 7 poisons	Substances included in Appendix J to be reviewed by NDPSC prior to transfer to SUSMP
<i>Appendix K</i> Medicines required to be labelled with a sedation warning	<i>Appendix K</i> Drugs required to be labelled with a sedation warning	Draft criteria for inclusion of substances in Appendix K to be developed.
<i>Appendix L</i> Schedule 2 medicines that cannot	No corresponding reference	New appendix that will list substances that may not

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be sold by licensed poisons sellers		be sold by licensed poisons sellers. (<i>see KEY CHANGE 7</i>)
<i>Appendix M</i> Requirements for dispensing labels for medicines and veterinary chemicals	No corresponding reference	New appendix that will list requirements for dispensing labels.

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KEY CHANGES:

1	As part of the implementation of Recommendation 22 of the Galbally Review, controls on advertising, labelling and packaging of agricultural and veterinary chemicals will be transferred from the SUSDP to relevant Agricultural and Veterinary Chemicals Legislation. It is anticipated that this will be achieved through: amendment of the <i>Agricultural and Veterinary Chemicals Code Act 1994</i> to include restrictions on advertising of Schedule 4 and Schedule 8 veterinary chemicals; and amendment to the <i>Agricultural and Veterinary Chemicals Code Regulations 1995</i> to include Ministerial Orders on labelling and packaging of agricultural and veterinary chemicals.
2	As decisions relating to the scheduling of poisons will not apply in New Zealand, requirements for medicines and poisons have been separated to assist New Zealand to adopt only the relevant aspects of the SUSMP
3	As part of the implementation of Recommendation 22 of the Galbally Review, controls on advertising of therapeutic products will be transferred from the SUSDP to the new therapeutic products legislation.
4	As part of the implementation of Recommendation 22 of the Galbally Review, controls on packaging and labelling of therapeutic products (except signal headings) will be transferred from the SUSDP to the new therapeutic products legislation. Draft Managing Director Orders are currently being developed which will reflect this transfer of controls. Building on this recommendation, the NCCTG has also recommended that all packaging and labelling controls on therapeutic products in Schedule 5 and 6 are transferred into Managing Director Orders in the Australia New Zealand Therapeutic Products Authority. Substances in Schedules 5 and 6 in the new scheduling standard will therefore not include substances which are specifically used for human therapeutic use.
5	As part of the implementation of Recommendation 20 of the Galbally Review, criteria have been developed by the National Coordinating Committee on Therapeutic Goods (NCCTG) to allow mutual recognition of labelling exemptions granted by other jurisdictions.
6	As part of the implementation of Recommendation 16 of the Galbally Review, jurisdictions will adopt the new Appendix H of the SUSMP that will list substances which have been shown to pose a significant risk of diversion to the illicit market and the public health benefits of recording the supply of these substances has been established.
7	Recommendation 15 of the Galbally Review recommended that persons holding Poisons Licences which permit the retail sale of Schedule 2 products in remote areas where there is no pharmacy be allowed to sell the full range of products in Schedule 2 unless risk of diversion, poisoning or medical misadventure is such that the sale of that product should only be from a pharmacy. As part of the implementation of this Recommendation, the new Appendix L will list substances which licensed poison sellers are not allowed to sell.
8	New Appendix M will list all of the requirements for dispensing labels previously included in the body of the SUSDP.
9	Recommendation 7 of the Galbally Review proposed that the title of the <i>Standard for the Uniform Scheduling of Drugs and Poisons</i> be changed to the <i>Standard for the Uniform Scheduling of Medicines and Poisons</i> .
10	As part of the proposed new joint regulatory arrangements for therapeutic products, SUSDP provisions pertaining to homoeopathic and anthroposophic medicines will be transferred to a Managing Director's Order.