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Health and Ageing Legislation Amendment (Application of Criminal Code) Regulations 2002 (No. 1)¹

Statutory Rules 2002 No. ²

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I, PETER JOHN HOLLINGWORTH, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Industrial Chemicals (Notification and Assessment) Act 1989*, the *National Health Act 1953* and the *Therapeutic Goods Act 1989*.

Dated 14 FEB 2002 2002

PETER HOLLINGWORTH
Governor-General

By His Excellency's Command

KAY PATTERSON
Minister for Health and Ageing

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1 Name of Regulations

These Regulations are the *Health and Ageing Legislation Amendment (Application of Criminal Code) Regulations 2002* (No. 1).

2 Commencement

These Regulations commence on gazettal.

3 Amendment of *Industrial Chemicals (Notification and Assessment) Regulations 1990*

Schedule 1 amends the *Industrial Chemicals (Notification and Assessment) Regulations 1990*.

2	<i>Health and Ageing Legislation Amendment (Application of Criminal Code) Regulations 2002</i> (No. 1)	2002, 1	9 1
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4 Amendment of *National Health (Pharmaceutical Benefits) Regulations 1960*

Schedule 2 amends the *National Health (Pharmaceutical Benefits) Regulations 1960*.

5 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 3 amends the *Therapeutic Goods Regulations 1990*.

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Schedule 1 **Amendment of *Industrial
Chemicals (Notification and
Assessment) Regulations
1990***
(regulation 3)

- [1] **Subregulation 16 (4)**
omit
knowingly or recklessly

Schedule 2 Amendments of *National Health (Pharmaceutical Benefits) Regulations 1960*
(regulation 4)

[1] Regulation 9

substitute

**9 Certain requirements to be met after
 cancellation etc of approval**

- (1) If the approval of an approved pharmacist is suspended, revoked or cancelled, the pharmacist must not, in any way, indicate that he or she has been, or is, approved to supply pharmaceutical benefits.

Penalty: 1 penalty unit.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[2] Regulation 17

substitute

**17 Supply of pharmaceutical benefits by
 chemists for the purposes of section 93**

- (1) An approved pharmacist commits an offence if:
- (a) he or she supplies a pharmaceutical benefit on an order given under regulation 16; and
 - (b) neither of the following circumstances applies:
 - (i) the pharmacist knows the medical practitioner whose signature appears on the order;

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- (ii) if he or she does not know the medical practitioner, the pharmacist:
- (A) obtains the full name, address and medical registration number of the medical practitioner from the person who presented the order; and
 - (B) endorses on the order form the particulars of the medical practitioner mentioned in sub-subparagraph (A).

Penalty: 0.4 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[3] Regulation 18A

substitute

18A Benefits obtained by approved medical practitioners for the purposes of section 93

- (1) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act by lodging with an approved pharmacist an order under regulation 16.

Penalty: 0.2 penalty units.

- (2) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act more than once in each month.

Penalty: 0.2 penalty units.

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- (3) An approved medical practitioner who obtains a pharmaceutical benefit for the purpose of section 93 of the Act must give a notice to the Secretary that he or she has obtained the benefit.

Penalty: 0.2 penalty units.

- (4) For subregulation (3), the notice must be:
- (a) in a form authorised by the Secretary; and
 - (b) signed and dated by the practitioner.
- (5) An approved medical practitioner who gives a notice to the Secretary under subregulation (3) must retain a copy of the notice for at least 1 year from the date on which he or she gives the notice to the Secretary.

Penalty: 0.2 penalty units.

- (6) An offence against subregulation (1), (2), (3) or (5) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

- (7) An approved medical practitioner who:
- (a) obtains a pharmaceutical benefit for the purpose of section 93 of the Act in accordance with these Regulations; and
 - (b) gives a notice to the Secretary under subregulation (3) about the benefit; and
 - (c) gives the Secretary a claim in accordance with a form made available by the Secretary to approved medical practitioners for that purpose; and
 - (d) completes the claim form in accordance with directions on that form;

is entitled to payment from the Commonwealth in respect of the pharmaceutical benefit at the rate applicable for the supply of the same benefit on an order under regulation 16.

[4] Regulation 19B*substitute***19B Restriction on using PBS and NHS forms**

- (1) A person commits an offence if:
 - (a) he or she writes a prescription on a form bearing the letters 'PBS', 'NHS' or 'N. H. S'; and
 - (b) the prescription is not written in accordance with, or for a purpose authorised by, these Regulations; and
 - (c) the letters 'PBS', 'NHS' or 'N. H. S' (as the case may be) are not clearly struck out, or obliterated.

Penalty: 0.4 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[5] Subregulation 22 (3), penalty*substitute*

Penalty: 0.2 penalty units.

[6] After subregulation 22 (3), including the penalty*insert*

- (3A) An offence against subregulation (3) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[7] Subregulation 22 (4), penalty*substitute*

Penalty: 0.2 penalty units.

[8] After subregulation 22 (4), including the penalty

insert

- (4A) An offence against subregulation (4) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[9] Subregulation 26 (1)

substitute

- (1) Subregulation (1A) applies if:
- (a) an approved pharmacist, or an approved medical practitioner, or an approved hospital authority supplies a pharmaceutical benefit under:
 - (i) an HIC/DVA copy of a prescription that contains a direction to supply the benefit more than once; or
 - (ii) a pharmacist/patient copy to which is attached a deferred supply authorisation that contains a direction to supply the benefit more than once; or
 - (iii) a pharmacist/patient copy to which is attached a repeat authorisation that contains a direction to supply the benefit more than once; and
 - (b) subsequent supplies of the pharmaceutical benefit can be made under the prescription at the time of supply under paragraph (a).

[10] Subregulation 26 (1A), penalty

substitute

Penalty: 0.2 penalty units.

[11] After subregulation 26 (1A), including the penalty

insert

- (1B) An offence against subregulation (1A) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[12] Subregulation 28 (2)

substitute

- (2) An approved pharmacist must supply a pharmaceutical benefit as soon as practicable if:
- (a) a prescription is presented to the pharmacist under subregulation (1); and
 - (b) any charge lawfully demanded for the prescription is paid.

Penalty: 0.2 penalty units.

- (3) An offence against subregulation (2) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

- (4) It is a defence to a prosecution for an offence against subregulation (2) if the pharmacist had a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in subregulation (4) (see section 13.3 of the *Criminal Code*).

[13] Subregulation 31 (1), at the foot

insert

Penalty: 0.2 penalty units.

[14] Subregulation 31 (2), at the foot

insert

Penalty: 0.2 penalty units.

[15] After subregulation 31 (3), including the penalty

insert

- (4) An offence against subregulation (1), (2) or (3) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[16] Regulation 32

substitute

32 Retention of prescriptions etc

- (1) If:

- (a) an approved pharmacist, approved medical practitioner, or approved hospital authority supplies a pharmaceutical benefit; and
(b) the benefit supplied is not a dangerous drug within the meaning of regulation 19;

he or she must retain the forms mentioned in subregulation (2) in his or her possession for at least 1 year from the date of supply.

Penalty: 0.2 penalty units.

- (2) For subregulation (1), the following forms are specified:

- (a) in the case of supply upon a prescription not bearing instructions to supply the pharmaceutical benefit more than once — the pharmacist/patient copy;
(b) in the case of supply upon a prescription bearing instructions to supply the pharmaceutical benefit more than once, if it is supplied on the last

occasion on which supply is authorised — the pharmacist/patient copy in respect of which repeat authorisations were issued;

- (c) in the case of supply under section 93 of the Act — the duplicate of the order lodged under regulation 16, or the notification form mentioned in regulation 18A, as the case requires.

- (3) An offence against subregulation (1) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[17] Regulation 33

substitute

33 Proper stocks to be kept

- (1) An approved pharmacist must, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits.

Penalty: 0.2 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[18] Subregulation 37 (2), penalty

substitute

Penalty: 0.2 penalty units.

[19] After subregulation 37 (2), including the penalty

insert

- (3) An offence against subregulation (2) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

Schedule 3 **Amendments of *Therapeutic Goods Regulations 1990***

(regulation 5)

[1] **Paragraphs (6) (1) (e) and (f)**

substitute

- (e) that refers to goods, or substances or preparations containing goods, mentioned in Schedule 3, 4 or 8 to the Poisons Standard; or
- (f) that are not registered or listed; or

[2] **Subregulation 6 (1), penalty**

substitute

Penalty: 10 penalty units.

[3] **After subregulation 6 (1A)**

insert

- (1B) For the purposes of an offence under subregulation (1), strict liability applies to the following physical elements:
 - (a) that the use of a restricted representation has not been approved under subregulation 7C (1) or permitted under subregulation 9 (1);
 - (b) that the goods, substances or preparations are mentioned in Schedule 3, 4 or 8 to the Poisons Standard;
 - (c) the elements mentioned in subparagraphs (1) (g) (i), (ii) and (iii).

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

(1C) It is a defence to a prosecution under subregulation (1) if:

- (a) in relation to an advertisement mentioned in paragraph (1) (e) — the goods, substances or preparations are mentioned in Appendix H of the Standard; and
- (b) in relation to goods mentioned in paragraph (1) (f) — the goods are exempt goods, other than goods of a kind mentioned in paragraph (1) (g).

Note A defendant bears an evidential burden in relation to the matters mentioned in subregulation (1C) (see section 13.3 of the *Criminal Code*).

[4] Subregulation 6 (2), at the foot

insert

Note A defendant bears a legal burden in relation to the matters mentioned in subregulation (2) (see section 13.4 of the *Criminal Code*).

[5] Subregulation 6 (5), at the foot

insert

Note A defendant bears a legal burden in relation to the matters mentioned in subregulation (5) (see section 13.4 of the *Criminal Code*).

[6] Paragraph 9A (1) (a)

substitute

- (a) specified in Part 1 of Schedule 10; and

[7] Subregulation 9A (1)

omit

unless the sponsor supplies

insert

if the sponsor does not supply

[8] Subregulation 9A (1), penalty*substitute*

Penalty: 10 penalty units.

[9] After subregulation 9A (1), including the penalty*insert*

(1AAA) For the purposes of an offence under subregulation (1), strict liability applies to the physical element mentioned in paragraph (1) (a).

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

(1AA) It is a defence to a prosecution under subregulation (1) if the goods are specified in Schedule 3 to the Poisons Standard.

Note A defendant bears an evidential burden in relation to the matters mentioned in subregulation (1AA) (see section 13.3 of the *Criminal Code*).

[10] Subregulation 9A (1A)*omit*

unless the sponsor supplies

insert

if the sponsor does not supply

[11] After subregulation 9A (1A), including the penalty*insert*

(1B) For the purposes of an offence under subregulation (1A), strict liability applies to the physical element mentioned in paragraph (1A) (a).

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[12] After subregulation 9R (2), including the penalty

insert

- (2A) For the purposes of an offence under subregulation (1) or (2) in relation to information of a kind mentioned in paragraph (1) (f) or (2) (f), strict liability applies to the physical element that the goods mentioned in that paragraph are not listed in Appendix 5 to the Therapeutic Goods Advertising Code.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[13] Subregulation 12A (3), penalty

substitute

Penalty: 10 penalty units.

[14] After subregulation 12A (3), including the penalty

insert

- (3A) An offence under subregulation (3) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[15] Subregulation 13 (9), penalty

substitute

Penalty: 5 penalty units.

[16] After subregulation 13 (9), including the penalty

insert

- (10) An offence under subregulation (9) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[17] Subregulation 14 (2), penalty*substitute*

Penalty: 5 penalty units.

[18] After subregulation 14 (2), including the penalty*insert*

(2A) An offence under subregulation (2) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.**[19] Paragraph 32 (1) (b)***omit*

by an authorised officer, refuse or fail, without reasonable excuse:

insert

by an authorised officer, fail:

[20] Paragraph 32 (1) (c)*omit*

by an official analyst, refuse or fail, without reasonable excuse, to give any information

insert

by an official analyst, fail to give any information

[21] Subregulation 32 (1), penalty*substitute*

Penalty: 10 penalty units.

[22] After subregulation 32 (1), including the penalty

insert

- (1A) For the purposes of an offence under paragraph (1) (a), strict liability applies to the physical element that the duties mentioned in that paragraph are duties under these Regulations.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

- (1B) An offence under paragraph (1) (b) or (c) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

- (1C) It is a defence to a prosecution under paragraph (1) (b) or (c) if the person has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in subregulation (1C) (see section 13.3 of the *Criminal Code*).

[23] Subregulation 32 (2)

omit

to refuse or fail to comply

insert

to fail to comply

[24] Subregulation 33 (3), penalty

substitute

Penalty: 1 penalty unit.

[25] After subregulation 33 (3), including the penalty

insert

- (4) An offence under subregulation (3) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

Notes

1. These Regulations amend (in Schedule 1) Statutory Rules 1990 No. 231, as amended by 1990 No. 440; 1991 No. 165; 1992 Nos. 29, 245 and 282; 1993 No. 35; 1994 Nos. 21, 320, 368 and 454; 1995 Nos. 81 and 358; 1997 Nos. 181, 193, 203 and 419; 1999 No. 224.

These Regulations also amend (in Schedule 2) Statutory Rules 1960 No. 17, as amended by 1960 Nos. 90 and 102; 1961 Nos. 59 and 137; 1962 Nos. 34, 101 and 114; 1963 Nos. 34, 69 and 107; 1964 Nos. 12, 57 and 135; 1965 Nos. 51, 151 and 152; 1966 Nos. 80 and 144; 1967 Nos. 67, 116 and 158; 1968 Nos. 44, 76, 88 and 146; 1969 Nos. 44, 107 and 185; 1970 Nos. 39, 94, 119 and 186; 1971 Nos. 44, 101, 136 and 154; 1972 Nos. 32, 121 and 205; 1973 Nos. 15, 57, 139 and 229; 1974 Nos. 37, 126 and 222; 1975 Nos. 50, 148 and 209; 1976 Nos. 84, 150, 195 and 255; 1977 Nos. 39, 125 and 221; 1978 Nos. 47, 142, 153 and 245; 1979 Nos. 51, 55, 144 and 250; 1980 Nos. 69, 213 and 338; 1981 Nos. 52, 212, 218 and 345; 1982 Nos. 69, 76, 179, 334 and 372; 1983 Nos. 28, 102, 116 and 292; 1984 Nos. 50, 148, 169 and 342; 1985 Nos. 32, 184 and 320; 1986 Nos. 38, 194, 319, 320 and 391; 1987 Nos. 47, 262 and 279; 1988 No. 56; 1990 Nos. 226, 267, 337, 338 and 437; 1991 Nos. 1 and 474; 1992 No. 226; 1994 No. 348, 1996 No. 70; 1998 No. 374; 2000 No. 369; 2001 No. 68.

These Regulations also amend (in Schedule 3) Statutory Rules 1990 No. 394, as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111, 192, 208, 253, 320 and 328; 1996 Nos. 9, 25 (disallowed by the House of Representatives on 10 September 1996), 131, 200 and 208; 1997 Nos. 162, 398, 399, 400 and 401 (disallowed by the Senate on 31 March 1998); 1998 Nos. 227, 247 and 369; 1999 Nos. 62, 209 and 324; 2000 Nos. 29, 48, 70, 123, 124, 267 and 358; 2001 Nos. 159, 160^{and 252}

2. Notified in the *Commonwealth of Australia Gazette* on 2002.

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21 February