Health and Ageing Legislation Amendment (Application of Criminal Code) Regulations 2002 (No. 1) 2002 No. 9

EXPLANATORY STATEMENT

STATUTORY RULES 2002 No. 9

Issued by authority of the Minister for Health and Ageing

Industrial Chemicals (Notification and Assessment) Act 1989

Therapeutic Goods Act 1989

National Health Act 1953

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

The *Industrial Chemicals (Notification and Assessment) Act 1989* provides for a national system of notification and assessment of industrial chemicals for purposes that include assisting in the protection of Australians and the environment through finding out risks to occupational health and safety, to public health and the environment, that could be associated with the importation, manufacture or use of chemicals, and to provide information and make recommendations about chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals, as well as give effect to Australia's international obligations with respect to the regulation of chemicals.

Section 111 of the *Industrial Chemicals (Notification and Assessment) Act 1989* provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *National Health Act 1953* provides, among other things, for payments to approved suppliers by way of pharmaceutical benefits.

Section 140 of the *National Health Act 1953* provides that the Governor-General may make regulations for required or permitted to be prescribed by the Act, or that are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

The Governor-General may, under section 63 of the *Therapeutic Goods Act*, make regulations required or permitted to be prescribed by the Act, or that are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to ensure that offence creating provisions in the National Health (Pharmaceutical Benefits) Regulations 1960, the Therapeutic Goods Regulations 1990 and the Industrial Chemicals (Notification and Assessment) Regulations 1990 continue to operate in the same manner, following the application of the Criminal Code (the Code) to all Commonwealth legislation from 15 December 2001.

The Code was enacted in the *Criminal Code Act 1995.* It provides a consistent framework for the interpretation of all criminal offence provisions in all Commonwealth statutes. In particular, Chapter 2 of the Code codifies the general principles of criminal responsibility and may be summarised as follows:

(a) the common law notion of a criminal act and a guilty mind is replaced with physical and fault elements respectively;

(b) offences of strict liability, that is offences in respect of which a fault element need not previously be proven, will gain fault elements by force of Chapter 2 after 15 December 2001, unless the regulations specifically state otherwise so as to indicate the offences are offences of strict liability;

(c) defence will require proof at an `evidential' standard unless the law creating the offence expressly imposes proof at the higher, `legal' standard. An `evidential' burden means the burden of adducing or pointing to evidence that suggest a reasonable possibility that a matter exists or does not exist. By contrast a legal burden is more onerous than an evidential burden, and is defined in the Criminal Code to mean the burden of positively proving the existence of a matter.

The Code applies to existing offence provisions from 15 December 2001.

The Regulations will not only preserve the status quo of existing offences so that current offences of strict liability are not affected by the effect of the introduction of the Code, but also clarify the operation of current defences under the new Code, including the fault elements of the offences.

Details of the Regulations are set out in the Attachment.

The Regulations commenced on gazettal.

ATTACHMENT A

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

Regulation 1 provides for the Regulations to be referred to as the *Health and Ageing Legislation Amendment (Application of Criminal Code) Regulations 2002 (No. 1)*.

Regulation 2 provides for the Regulations to commence on gazettal.

Regulation 3 provides for Schedule 1 to the Regulations to amend the *Industrial Chemicals (Notification and Assessment) Regulations 1990*.

Regulation 4 provides for Schedule 2 to amend the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Regulation 5 provides for Schedule 2 to the Regulations to amend the *Therapeutic Goods Regulations 1990*.

SCHEDULE 1 - Amendments to the *Industrial Chemicals (Notification and Assessment) Regulations 1990*

Item 1

Item 1 removes the reference to "knowingly and recklessly" in the offence because "intention" is now the ordinary fault element for conduct and is applied to the correct elements of the offence by the Criminal Code.

SCHEDULE 2 - Amendments to the *National Health (Pharmaceutical Benefits) Regulations 1960*

Item 1

Item 1 substitutes the wording of Regulation 9 to ensure that it continues to be an offence of strict liability where a pharmacist indicates that he or she is an approved pharmacist if his or her approval has been revoked, suspended, or cancelled.

This item also substitutes a penalty in penalty unit form instead of the pecuniary penalty.

Item 2

Item 2 substitutes the wording of Regulation 17 to ensure that it continues to be an offence of strict liability for a pharmacist to supply a pharmaceutical benefit to a medical practitioner for that practitioner to supply to patients under section 93 of the *National Health Act 1953* (the Act) (from his or her "doctor's bag", for which a prescription is not required for pharmaceutical benefits purposes) unless the pharmacist knows the medical practitioner whose signature appears on the order, or obtains particulars of the medical practitioner and endorses them on the order form.

This item also substitutes a penalty in penalty unit form instead of the pecuniary penalty.

Item 3

Item 3 amends Regulation 18A to ensure that it continues to be an offence of strict liability for a medical practitioner approved under section 92 of the Act to supply pharmaceutical benefits to patients to:

- order pharmaceutical benefits for supply under section 93 of the Act (from his or her "doctor's bag") using the order form under Regulation 16, which is for use by medical practitioners not approved under section 92;

- obtain a pharmaceutical benefit (ie one item in the schedule of pharmaceutical benefits) for supply under section 93 more than once per month;

- having obtained pharmaceutical benefits for supply under section 93, not to notify the Secretary on the approved form; or

- not retain a copy of the approved form for at least twelve months.

This item also substitutes a penalty in penalty unit form instead of the pecuniary penalty.

Item 4

Item 4 amends Regulation 19B to ensure that it continues to be an offence of strict liability for a medical practitioner to write a prescription, which is not in accordance with, or for a purpose authorised by, the Regulations (for example, to treat a condition which is not in a list in the schedule of pharmaceutical benefits of conditions for which the drug can be prescribed), on a PBS prescription form, without crossing out letters "PBS", "NHS" or "N.H.S." as the case may be.

This item also substitutes a penalty in penalty unit form instead of the pecuniary penalty.

Item 5

Item 5 substitutes in Subregulation 22(3) a penalty in penalty unit form instead of the pecuniary penalty.

Item 6

Item 6 amends Subregulation 22(3) to ensure that it continues to be an offence of strict liability for a medical practitioner who has, in a case of urgency, communicated, or transmitted a facsimile of, a prescription to an approved pharmacist or an approved (dispensing) medical practitioner, not to ensure that the original and a duplicate of the prescription is received by the approved pharmacist or the approved (dispensing) practitioner within seven days.

Item 7

Item 7 substitutes in Subregulation 22(4) a penalty in penalty unit form instead of the pecuniary penalty.

Item 8

Item 8 amends Subregulation 22(4) to ensure that it continues to be an offence of strict liability if a medical practitioner who has, in a case of urgency, communicated, or transmitted a facsimile of, a prescription requiring prior authority from the Commonwealth to an approved pharmacist or an approved (dispensing) medical practitioner, does not ensure that the original and a duplicate of the prescription is received by the approved pharmacist or the approved (dispensing) practitioner within seven days.

Item 9

Item 9 amends Subregulation 26(1) to clarify when Subregulation 26(1A) applies.

Item 10

Item 10 inserts in Subregulation 26(1A) a penalty in penalty unit form instead of the pecuniary penalty formerly provided for following Subregulation 26(1A).

Item 11

Item 11 amends Subregulation 26(1A) to ensure that it continues to be an offence of strict liability if an approved pharmacist or approved medical practitioner does not observe requirements in relation to prescriptions for multiple supplies of pharmaceutical benefits (repeat prescriptions). These requirements are mainly that he or she must:

- prepare a repeat authorisation;
- mark the authorisation number on it if it is an authority prescription;
- attach the repeat authorisation to the pharmacist/patient copy of the prescription; and
- give it to the patient.

There are additional requirements depending on whether it is the first supply under the prescription or a later supply.

Item 12

Item 12 clarifies the conduct elements of the offence in Subregulation 28(2) which makes it an offence for an approved pharmacist to fail to supply as soon as practicable a pharmaceutical benefit having been presented with a prescription marked "urgent", this mark having been initialled by the prescriber, and ensures that it continues to be an offence of strict liability. The item also converts the pecuniary penalty to penalty unit form.

Item 13

Item 13 substitutes in Subregulation 31(1) a penalty in penalty unit form instead of the pecuniary penalty.

Item 14

Item 14 substitutes in Subregulation 31(2) a penalty in penalty unit form instead of the pecuniary penalty.

Item 15

Item 15 amends Subregulation 31 to ensure that it continues to be an offence of strict liability if:

- a person fails to acknowledge receipt of a pharmaceutical benefit by writing on the prescription or authorisation;
- the supplier demands such an acknowledgment without having first supplied the benefit;

- if it is not practicable to obtain such an acknowledgment, if the supplier does not certify on the prescription or authorisation the reason it was not practicable and the date of supply.

Item 16

Item 16 amends Regulation 32 to clarify the elements of the offence, to convert the penalty from a pecuniary form to a penalty unit form, and to ensure that it continues to be an offence of strict liability if an approved pharmacist, medical practitioner or hospital authority, having supplied a pharmaceutical benefit which is not a dangerous drug as defined in the Subregulation 19(3), fails to keep the appropriate copy of a prescription for at least one year.

Item 17

Item 17 amends Regulation 33 to convert the penalty from a pecuniary penalty to penalty unit form, and to ensure that it continues to be an offence of strict liability if an approved pharmacist fails to keep in stock an adequate supply of drugs and medicinal preparations which might be required for supply as pharmaceutical benefits or for use as ingredients of pharmaceutical benefits.

Item 18

Item 18 substitutes in Subregulation 37(2) a penalty in penalty unit form instead of the pecuniary penalty.

Item 19

Item 19 amends Subregulation 37(2) to ensure that it continues to be an offence of strict liability if a person fails to surrender any forms supplied by the Commonwealth under

Part VII of the *National Health Act 1953* (the part dealing with pharmaceutical benefits), when required to do so by a notice in writing from the Secretary.

SCHEDULE 3

Items 1 and 3

Items 1 and 3 preserve the existing qualifications in the current offences for publishing advertisements about therapeutic goods so that the qualifications are not construed as elements of the offences, as a result of the application of the new Code, but will retain their status as an exception or defence. Hence, the qualifications included in the offences in paragraphs 6(1)(e) and (f) of the Regulations have been removed from the main offence (Item 1) and incorporated in new subregulation 6(1C) by Item 3.

Items 2, 8, 13, 21

Items 2, 8, 13, 21 update the language used in describing the amount of the penalty by reference to "penalty units" rather than the actual amount. "Penalty units" are currently defined in the *Crimes Act 1900* as $110 for each penalty unit.

Item 3

Item 3 adds new subregulation 6(1B) that applies strict liability to the physical elements in paragraphs 6(ba), (e) and (g) about the use of a restricted representation that has not been approved under subregulations 7C(1) or permitted under subregulation 9(1); that goods,

substances or preparations are mentioned in certain Schedules of the Poisons Standard, or that certain therapeutic goods are not required to be included in the Australian Register of Therapeutic Goods. The application of strict liability to these paragraphs reflects subsection 9.3(1) of the *Criminal Code* (and the common law position) that ignorance of the law is no excuse. The insertion of new subregulation 6(1B) maintains the current operation of paragraphs 6(ba), (e) and (g) after Chapter 2 of the *Criminal Code* takes effect.

Items 4 and 5

Items 4 and 5 insert Notes to explain that the defendant bears the legal burden of proof in relation to the offences set out in subregulations 6(2) and (5) of the Regulations.

Items 6, 7 and 9

Items 6, 7 and 9 preserve the existing qualifications in the current offence for not supplying information to consumers about certain medicines, other than pharmacy only medicines, so that the qualifications are not construed as elements of the offence, as a result of the application of the new Code, but will retain its status as an exception or defence. Hence, the qualifications included in the description of the offence in regulation 9A(1) of the Regulations have been removed from the main offence (Items 6 and 9) and incorporated in new subregulation 9A(1AA) by Item 9.

Item 9

Item 9 adds new subregulation 9A(1AAA) that applies strict liability to the physical element in paragraph 9A(1)(a) of the regulations about medicines that are specified in Part 1 of Schedule 10 of the Regulations. The application of strict liability to this paragraph reflects subsection 9.3(1) of the *Criminal Code* (and the common law position) that ignorance of the law is no excuse. The insertion of new subregulation 9A(1AAA) maintains the current operation of paragraphs 9A(1)(a) after Chapter 2 of the *Criminal Code* takes effect. It is an offence under subregulation 9A(1) to supply what are in the main prescription medicines without also providing adequate information about the proper use of the goods and any risks associated with its use.

Item 10

Item 10 makes "failure to supply by a sponsor" an integral part of the offence rather than a defence, so that the prosecution rather than the defendant will be required to prove that the sponsor did not supply written information about pharmacy only medicines to consumers at the time the sponsor supplied the medicines. "Pharmacy only" medicines are medicines that are available only through pharmacies.

Item 11

Item 11 inserts new subregulation 9A(1B) that applies strict liability to the physical element in paragraph 9A(1A)(a) of the regulations about medicines that are specified in Schedule 3 of the Poisons Standard. These are in the main medicines available only through pharmacies. The application of strict liability to this paragraph reflects subsection 9.3(1) of the *Criminal Code* (and the common law position) that ignorance of the law is no excuse. The insertion of new subregulation 9A(1B) maintains the current operation of paragraphs 9A(1A)(a) after Chapter 2 of the *Criminal Code* takes effect.

Item 12

Item 12 adds new subregulation 9R(2A) that applies strict liability to the physical element in paragraphs 9R(1)(f) and (2)(f) of the regulations about the publication of generic information

about therapeutic goods directed to persons under 18 years where the information is about therapeutic goods not listed in Appendix 5 to the Therapeutic Goods Advertising Code. The application of strict liability to these paragraphs reflect subsection 9.3(1) of the *Criminal Code* (and the common law position) that ignorance of the law is no excuse. The insertion of new subregulation 9R(2A) maintains the current operation of paragraphs 9R(1)(f) and (2)(f) after Chapter 2 of the *Criminal Code* takes effect.

Items 14, 16 and 18

Items 14, 16 and 18 insert new subregulations 12A(3A), 13(10) and 14(2A) to preserve the status quo of the existing offences under regulations 12A(3), 13(9) and 14(2) as strict liability offences. An offence of strict liability is an offence where no fault elements apply to the physical elements of the offence. For an offence of strict liability the defence of reasonable mistake of fact under section 9.2 of the Criminal Code (the Code) is available. Strict liability is described in section 6.1 of the Code. The Code requires that provisions that create an offence of strict liability must expressly state that they are strict liability offences. If the provision does not specifically state this, the offence is not a strict liability offence.

Currently, the offence under subregulation 12A(3) relates to a failure by a medical practitioner to send a statement to the Secretary, within 4 weeks of signing the statement, that the person to whom unapproved therapeutic goods has been supplied is a patient who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment. The offence under subregulation 13(9) is for a failure by a person to return a certificate of registration or a certificate of listing where the registration or listing has been cancelled by the Secretary in the circumstances described under that regulation. Subregulation 14(2) creates an offence for a failure to lodge an application to transfer goods from one part of the Australian Register of Therapeutic Goods to another part, where this is required because of a change in status of the therapeutic goods from being "registered goods" to "listable goods", or vice versa.

Items 15 and 17

Items 15 and 17 update the language used in describing the amount of the penalty. The standard practice now is to describe the amount by reference to "penalty units" rather than the actual amount, and "penalty units" are currently described in the *Crimes Act 1900* to refer to $110 for each penalty unit.

Items 19 and 20

Items 19 and 20 remove the defence of "reasonable excuse" in paragraphs 32(1)(b) and (c) of the regulations, as offences of strict liability under the Code will attract the defence of reasonable mistake of fact under section 9.2 of the Code. The offences under these paragraphs are offences of strict liability.

Item 22

Subregulation 32(1) creates offences for molesting, obstructing, intimidating or influencing an authorised officer, or refusing to comply with an authorised officer's or an official analyst's requests under the regulations when that officer or analyst is performing duties to establish whether therapeutic goods conform to applicable standards.

Item 22 adds new subregulations that apply strict liability to the physical elements in paragraph 32(1)(a) of the regulations. That is, the duties mentioned in paragraph 32(1)(1)(a) are duties under the regulations. The item also clarifies that the offences in paragraphs 32(1)(b) and (c) are strict liability offences.

Item 23

Item 23 removes the reference to "refuse" in the offence under subregulation 32(2) of the Regulations. A "refusal" is considered to be already embodied in the word "fail".

Item 24

Item 24 updates the language used in describing the amount of the penalty. The standard practice now is to describe the amount by reference to "penalty units" rather than the actual amount, and "penalty units" are currently described in the *Crimes Act 1900* to refer to $110 for each penalty unit.

Item 25

Subregulation 33(3) creates an offence where an "authorised officer" issued with an identity card fails to return it after ceasing to be an authorised officer. The amendment clarifies that the offence will remain an offence of strict liability.