

Part 3 Offences under the Health (Needles and Syringes) Regulations 1998 and the Medicines Act 1981

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Overview

Introduction

The <u>Health (Needles and Syringes) Regulations 1998</u> sets out the 'Needle and Syringe Exchange Programme' by regulating:

- the sale of new (and therefore clean) needles and syringes by:
 - pharmacists
 - pharmacy employees
 - medical practitioners
 - authorised representatives
- notification of prohibition or revocation of approval, etc.
- return (safe disposal) of used needles and syringes
- offences relating to sale and importation of needles and syringes.

The <u>Medicines Act 1981</u> consolidates and amends the law relating to the manufacture, sale, and supply of medicines, medical devices and related products.

Exemptions under the Medicines Act

The following exemptions in sections 25 to 34 in the <u>Medicines Act 1981</u> apply to offences under that Act in relation to:

- medical practitioners and dentists (s25)
- pharmacists (s 26)
- veterinarian (s27)
- herbal remedies (s28)
- medicine required by medical practitioner (s29)
- clinical trial (s30)
- agents and employees of licensee (s31)
- natural therapists and others (s32)
- importation by the Crown (s32A)
- procuring and exporting medicines (s33)
- sale by wholesale of medicines that are not prescription, restricted or pharmacy-only medicines (s34).

Offering or accepting for use any used needle or syringe, or disposing of any needle or syringe in a public place

Regulation/Jurisdiction

- Regulation 11(1) Health (Needles and Syringes) Regulations 1998.
- Category 1 offence.

What you must prove

You must prove the identity of the suspect and they:

- offered for use by any person

or

- accepted for use any used needle or syringe

or

- disposed of any needle or syringe in a public place.

Note: That the portions of these provisions do not apply to the offering or accepting of a needle or syringe for the treatment of animals (Reg.11(2)).

Penalty

Liable on conviction to a fine not exceeding \$500.

Selling or supplying, or attempting to sell or supply, any needle or syringe

Regulation/Jurisdiction

- Regulation 12 Health (Needles and Syringes) Regulations 1998.
- Category 1 offence.

What you must prove

You must prove the identity of the suspect and:

- they sold or supplied, or
- they attempted to sell or supply,
- any needle or syringe.

Note: Pharmacies, medical practitioners and authorised representatives of the Department of Health are exempt from this regulation, unless they have been prohibited under regulation $\underline{3}(2)$ or sells/supplies otherwise than in accordance to regulation $\underline{3}$, $\underline{4}$ or $\underline{5}$ and these provisions do not apply to the sale and supply of needles and syringes for the treatment of animals or for therapeutic purposes under section $\underline{4}$ of the Medicines Act or for dentists in the course of their practice.

Penalty

Liable on conviction to a fine not exceeding \$500.

Importing used or new needle/syringe not approved by Director-General

Regulation/Jurisdiction

- Regulation 13(1) Health (Needles and Syringes) Regulations 1998.
- Category 1 offence.

What you must prove

You must prove the identity of the suspect and they imported:

- a **used** needle or syringe, **or**
- a **new** needle or syringe other than a kind approved by the Director-General.

Note: These provisions do not apply to the sale and supply of needles and syringes for the treatment of animals or for therapeutic purposes under section $\underline{4}$ of the Medicines Act or for dentists in the course of their practice (s $\underline{13}$ (2) & (3)).

Penalty

Liable on conviction to a fine not exceeding \$500.

Offences involving manufacture, retail, administering of medicines and breaches of Minister's notice

Manufactures, wholesales, packs, labels any medicine or operates any pharmacy without a licence

Section/Act/Jurisdiction

- Section 17(1) Medicines Act 1981.
- Category 1 offence.

What you must prove

You must prove the identity of the suspect and:

- that in the course of any business carried on by them:
 - manufactures any medicine, or
 - sell any medicine by wholesale, or
 - pack or label any medicine, or
 - operate any pharmacy
- otherwise than in accordance with a licence issued under Part 3 of the Act.

Penalty

Liable on conviction to a fine not exceeding \$40,000.

Possessing prescription medicines

Section/Act/Jurisdiction

- Section 43(1)&(5) Medicines Act 1981.
- Category 2 offence.

What you must prove

You must prove the identity of the suspect and that without reasonable excuse:

- they imported, procured, received, stored, used, or otherwise had in their possession
- any prescription medicine.

Things to note

Professional people, caregivers and others who are exempt from this section are listed in subsection section $\frac{43}{2}$.

The burden of proof lies with the defendant - section 43(3) of the Medicines Act 1981 refers.

The fact that the defendant did not know the medicine was a prescription medicine is not in itself a sufficient excuse - section $\underline{43}(4)$ of the Medicines Act 1981 refers.

Penalty

Liable to imprisonment for a term not exceeding 3 months or a fine not exceeding \$500, and, if the offence is a continuing one, to a further fine not exceeding \$50 for every day or part of a day during which the offence has continued.

Packaging prescription medicines

Section/Act/Jurisdiction

- Section 44(1)&(3) Medicines Act 1981.
- Category 2 offence.

What you must prove

You must prove the identity of the suspect and they:

- in the course of any business,
- packed, stored, sold, supplied or caused to be transported any medicine unless:
- the medicine was in a container that was:
 - impervious to the medicine, and
 - constructed so that it could be readily and effectively resealed after any of the contents had been used, and
 - of the prescribed character or type, and
 - labelled in the prescribed manner; and
- the container was enclosed in a package that was required to be of a prescribed character or type, or labelled in a prescribed manner, and the package met the requirements.

Note: If the container has a label saying that the whole of the contents must be used immediately on opening, and the contents are such that it is unlikely they would not all be used on one occasion, the container need not be able to be readily and effectively resealed.

Penalty

Liable to imprisonment for a term not exceeding 3 months or a fine not exceeding \$500, and, if the offence is a continuing one, to a further fine not exceeding \$50 for every day or part of a day during which the offence has continued.

Custody of prescription medicines

Section/Act/Jurisdiction

- Section 46 Medicines Act 1981.
- Category 2 offence.

What you must prove

You must prove the identity of the suspect and they:

- had any medicine in their charge or possession
- that was not in a container conforming to any relevant requirements of the Act
- except in the course of manufacturing or packing that medicine.

Defence

It is a defence to prove that:

- the medicine was in the container in which the defendant had acquired it, and the container bore the label it had when they acquired it; or
- the medicine had been necessarily removed from the container for its effective and lawful use.

Penalty

Liable to imprisonment for a term not exceeding 3 months or a fine not exceeding \$500, and, if the offence is a continuing one, to a further fine not exceeding \$50 for every day or part of a day during which the offence has continued.

Other offences under the Medicines Act 1981

Offences involving retail, administering, restrictions on sale or supply of medicines, breaching Minister's notice or other provisions include:

Offence and section	Penalty
Sale of medicines by retail (s <u>18</u>)	6 months imprisonment or a fine not exceeding \$40,000
Administering prescription medicines (s 19)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
Sell, distribute or advertise any medicine before the Minister's consent	Individual - 6 months imprisonment or a fine not exceeding \$20,000;
(s <u>20</u>)	Body corporate - a fine not exceeding \$100,000
Sell or supply any medicine in contravention of Minister's notice	6 months imprisonment or a fine not exceeding \$5,000
(s <u>36</u>)	
Contravenes Minister's prohibition notice (\$37)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
Having received notice, fails to comply and sells medical device (\$38)	6 months imprisonment or a fine not exceeding \$5,000
Adulteration of medicine (s39)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)

Sells or supplies substance or article under a name that fails to comply with standard (\$40)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
duty to report untoward effects of medicines $(s41)$	Fine not exceeding \$1,000
Importer or manufacturer fails to produce specifications of medicines	Individual - 3 months imprisonment or a fine not exceeding \$10,000;
(s <u>42</u>)	Body corporate - a fine not exceeding \$100,000
Fails to keep records Obstructs or hinders inspection of records	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day
(s <u>45</u>)	(s <u>78</u>)
Without reasonable excuse contravenes storage	3 months imprisonment or a fine not exceeding \$500
and delivery of medicines provisions (s47)	and if offence is a continuing one a further fine of \$50 for every day and part of a day
	(s <u>78</u>)
Prescribes or supplies prescription or restricted	3 months imprisonment or a fine not exceeding \$500
medicine in contravention of notice	and if offence is a continuing one a further fine of \$50 for every day and part of a day
(s <u>49</u> (6)(a))	(s <u>78</u>)
Being a restricted person procures or attempts	3 months imprisonment or a fine not exceeding \$500
to procure prescription or restricted medicine	and if offence is a continuing one a further fine of \$50
(s <u>49</u> (6)(b)	for every day and part of a day (s <u>78</u>)
Publishing information regarding persons dependent on prescription or restricted medicines	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day
(s <u>49A</u>)	(s <u>78</u>)

Failing to display or produce licence (s <u>54</u>)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
Publishing or cause or permit to be published any medical advertisement against restrictions under the Act (\$58)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s <u>78</u>)
Publishing or cause or permit to be published any medical advertisement untrue name or address of advertiser (\$59\$)	Fine not exceeding \$1,000.
Sell medicine or medical device with misleading branding (s61)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
Obstruction of officer of the Ministry of Health or person appointed by Director-General (s <u>75</u>)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)
Knowingly making, uttering producing false declaration or statement, or using any document knowing it is not genuine (s76)	6 months imprisonment or a fine not exceeding \$1,000.
Unauthorised specified biotechnical procedure (s96B)	6 months imprisonment or a fine not exceeding \$200,000.
Publishing name of medicine that Court has restricted its publication (s 100)	3 months imprisonment or a fine not exceeding \$500 and if offence is a continuing one a further fine of \$50 for every day and part of a day (s78)

Failing to provide information for purposes of regulations	Fine not exceeding \$1,000.
(s <u>107</u>)	

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