**1998/254**

# HEALTH (NEEDLES AND SYRINGES) REGULATIONS 1998

MICHAEL HARDIE BOYS, Governor-General

ORDER IN COUNCIL

At Wellington this 31st day of August 1998

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT,—

(a) In the case of regulation 10, to section 37 of the Misuse of Drugs Act 1975; and

(b) In the case of the other provisions of these regulations, to section 117 of the Health Act 1956,—

His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, makes the following regulations.

ANALYSIS

REGULATIONS

**1. Title and commencement**—(1) These regulations may be cited as the Health (Needles and Syringes) Regulations 1998.

(2) These regulations come into force on 1 October 1998.

**2. Interpretation**—In these regulations, unless the context otherwise requires,—

"Agricultural compound" has the same meaning as in section 2 (1) of the Agricultural Compounds and Veterinary Medicines Act 1997:

"Animal" has the same meaning as in section 2 of the Animals Protection Act 1960:

"Animal research work" means any research, experimental, diagnostic, toxicity, or potency testing work involving the manipulation of a live animal, or teaching involving the manipulation of a live animal:

"Approved by the Director-General" means approved by the Director-General under and for the purposes of these regulations:

"Approved medical practitioner" means a medical practitioner for the time being approved by the Director-General:

"Authorised representative", in relation to an agency, an association, or a body approved by the Director-General, means a person for the time being approved by the Director-General as a representative of that agency, association, or body:

"Code of ethical conduct" means a code of ethical conduct under the Animals Protection (Codes of Ethical Conduct) Regulations 1987*:

"Director-General" means the Director-General of Health:

"Manipulation" has the same meaning as in section 2 of the Animals Protection Act 1960:

"Needle" means a needle forming part of, or attached to, or designed for attachment to and use with, a syringe:

"New", in relation to a needle or syringe, means unused:

"Pharmacist" means a pharmacist registered under the Pharmacy Act 1970:

"Pharmacy employee" means a person employed in a registered pharmacy:

"Public place" has the same meaning as in section 2 (1) of the Summary Offences Act 1981:

"Registered pharmacy" means a pharmacy within the meaning of, and registered under, the Pharmacy Act 1970; and includes a pharmacy operated by a hospital and health service:

*S.R. 1987/12

"Veterinarian" means a person for the time being registered as a veterinarian under the Veterinarians Act 1994.

*Sale of Needles and Syringes by Pharmacists and Pharmacy Employees*

**3. Sale of needles and syringes by pharmacists and pharmacy employees**—(1) Subject to subclauses (2) and (3), a pharmacist or pharmacy employee may sell a new needle or new syringe, as long as the sale is made—

(a) In accordance with regulation 7; and

(b) From a registered pharmacy; and

(c) To—

(i) A person who is aged 16 years or older; or

(ii) A person under 16 years of age in accordance with a prescription from a medical practitioner authorising the dispensing of a new needle or new syringe to that person.

(2) The Director-General may from time to time prohibit a pharmacist or pharmacy employee from selling new needles and new syringes if—

(a) The pharmacist or pharmacy employee is convicted of an offence against these regulations; or

(b) In the opinion of the Director-General, the pharmacist or pharmacy employee is unsuitable to sell needles and syringes on the grounds that the pharmacist or pharmacy employee has failed to comply with any provision of these regulations.

(3) A pharmacy employee may sell new needles or new syringes from a registered pharmacy only if there is a registered pharmacist practising in that pharmacy who is entitled to sell new needles and new syringes.

(4) The Director-General may from time to time, in the manner specified in regulation 6 for imposing a prohibition, revoke a prohibition imposed under subclause (2).

*Sale of Needles and Syringes by Approved Medical Practitioners*

**4. Sale of needles and syringes by approved medical practitioners**—(1) An approved medical practitioner may sell a new needle or new syringe, in accordance with regulation 7, from any place to any person.

(2) The Director-General may from time to time revoke the approval of a medical practitioner to sell new needles and new syringes if—

(a) The medical practitioner is convicted of an offence against these regulations; or

(b) In the opinion of the Director-General, the medical practitioner is unsuitable to sell needles and syringes on the grounds that the medical practitioner has failed to comply with any provision of these regulations.

*Sale of Needles and Syringes by Authorised Representatives*

**5. Sale of needles and syringes by authorised representatives**—(1) An authorised representative may sell a new needle or new syringe, as long as the sale is made—

(a) In accordance with regulation 7; and

(b) From any of the places specified in subclause (2); and

(c) To—

(i) A person who is aged 16 years or older; or

(ii) A person under 16 years of age in accordance with a prescription from a medical practitioner authorising the dispensing of a new needle or new syringe to that person.

(2) The places referred to in subclause (1) (b) are as follows:

(a) The usual place of business of the authorised representative:

(b) The usual place of business of the agency, association, or body for whom the authorised representative acts:

(c) Any other place or vehicle approved by a Medical Officer of Health for the purpose of this regulation.

(3) The Director-General may from time to time revoke the approval of an authorised representative to sell new needles and new syringes if—

(a) The authorised representative is convicted of an offence against these regulations; or

(b) In the opinion of the Director-General, the authorised representative is unsuitable to sell needles and syringes on the grounds that the authorised representative has failed to comply with any provision of these regulations.

*Notification of Prohibition or Revocation of Approval, Etc*

**6. Notification of prohibition or revocation of approval, etc**—(1) If, under regulation 3 (2), the Director-General prohibits a pharmacist or pharmacy employee from selling new needles and new syringes, the Director-General must, in accordance with subclause (2), send written notice of that prohibition to—

(a) That pharmacist or pharmacy employee; and

(b) If a pharmacy employee is prohibited, the proprietor of the registered pharmacy where the pharmacy employee is employed.

(2) A notice sent under subclause (1) must be sent by registered post addressed to the pharmacist, pharmacy employee, or proprietor, at the registered pharmacy where the person practises or is employed or of which the person is the proprietor, as the case may be.

(3) If, under regulation 4 (2), the Director-General revokes the approval of a medical practitioner to sell new needles and new syringes, the Director-General must send written notice to that medical practitioner, by registered post addressed to him or her at his or her usual place of business, that he or she is no longer an approved medical practitioner.

(4) If, under regulation 5 (3), the Director-General revokes the approval of an authorised representative to sell new needles and new syringes, the Director-General must send written notice to that person, by registered post addressed to him or her at his or her usual place of business, that he or she is no longer an authorised representative.

(5) A notice sent in accordance with subclause (1) or subclause (3) or subclause (4) is to be treated as having been received on, and takes effect from, the close of the third working day after the day on which the notice is sent.

(6) If a notice is sent in accordance with subclause (1) or subclause (3) or subclause (4), in proving the delivery of that notice,—

(a) It is sufficient to prove that the notice was properly addressed; and

(b) It is presumed, in the absence of proof to the contrary, that the notice was sent on the day on which it was dated.

*Further Provisions Relating to Sale of Needles and Syringes*

**7. Further provisions relating to sale of needles and syringes**—(1) No new needle or new syringe may be sold under regulation 3 or regulation 4 or regulation 5 unless it is—

(a) Of a kind approved by the Director-General; and

(b) Contained in a container of a kind, and labelled in a manner, approved by the Director-General.

(2) The Director-General may from time to time approve for the purposes of these regulations—

(a) Any kind of needle or syringe:

(b) Any kind of container, and the labelling of any container, intended to contain a needle or syringe for the purposes of the sale.

(3) The price that may be charged to the purchaser of a new needle or new syringe sold under regulation 3 or regulation 4 or regulation 5 is the sum of the following amounts:

(a) A service fee fixed by the Director-General in accordance with regulation 8:

(b) The cost of the needle or syringe (whether or not including the cost of packaging) fixed by the Director-General in accordance with that regulation.

**8. Director-General to fix fees and costs**—(1) The Director-General must from time to time, in accordance with this regulation, fix—

(a) The amount of the service fee to be paid to a pharmacist, pharmacy employee, an approved medical practitioner, or an authorised representative for the sale of a new needle or new syringe under regulation 3 or regulation 4 or regulation 5:

(b) The amount of the cost of any such needle or syringe (whether or not including the cost of packaging) sold under any of those regulations to be borne by the purchaser.

(2) Different costs may be so fixed according to whether the purchaser is or is not returning a used needle or used syringe at the time of purchase.

(3) Before fixing a fee or cost under subclause (1), the Director-General must consult with such interested persons as the Director-General thinks fit.

(4) The fees and costs fixed by the Director-General under this regulation must be published in the *Gazette*, and those fees and costs have effect from a date (not being earlier than the date of publication) specified for that purpose in the notice.

(5) A fee or cost charged in accordance with regulation 7 (3) and this regulation is for the purposes of section 43 of the Commerce Act 1986 specifically authorised by these regulations.

*Return of Used Needles and Syringes*

**9. Return of used needles and syringes**—(1) A pharmacist, pharmacy employee, an approved medical practitioner, or an authorised representative who sells a new needle or new syringe under regulation 3 or regulation 4 or regulation 5 must accept for disposal a needle or syringe of a kind approved by the Director-General if it is returned to him or her—

(a) In a container of a kind approved by the Director-General; and

(b) In accordance with any directions printed on the container.

(2) The Medical Officer of Health must arrange for the collection and disposal of all needles and syringes so returned to a pharmacist, pharmacy

employee, an approved medical practitioner, or an authorised representative.

*Exemptions from Liability under Misuse of Drugs Act 1975*

**10. Exemptions from liability under Misuse of Drugs Act 1975**—(1) No person is guilty of an offence against section 13 (1) (aa) of the Misuse of Drugs Act 1975 in respect of the possession of a needle or syringe if that person shows that the needle or syringe was purchased by or on behalf of that person—

(a) From any other person whom the person making the purchase reasonably believed, at the time of the purchase, was a registered pharmacist, pharmacy employee, an approved medical practitioner, or an authorised representative; and

(b) In accordance with regulation 3 or regulation 4 or regulation 5, as the case may be.

(2) No pharmacist, pharmacy employee, approved medical practitioner, or authorised representative is liable in proceedings under the Misuse of Drugs Act 1975 in respect of the sale or supply of a needle or syringe to any person in accordance with regulation 3 or regulation 4 or regulation 5, as the case may be.

*Offences*

**11. Offences relating to use or disposal**—(1) Every person commits an offence who—

(a) Offers to any other person, for use by that other person, a used needle or used syringe; or

(b) Accepts for use a used needle or used syringe; or

(c) Disposes of a needle or syringe in a public place.

(2) Subclauses (1) (a) and (1) (b) do not apply to the offer or acceptance of a used needle or used syringe—

(a) For the purpose of administering an agricultural compound to an animal; or

(b) For the purpose of taking any substance from an animal; or

(c) For the purpose of conducting any animal research work in accordance with a code of ethical conduct; or

(d) To or by a veterinarian in the course of practice.

**12. Offences relating to sale**—(1) Every person commits an offence who, not being a pharmacist, a pharmacy employee, an approved medical practitioner, or an authorised representative, sells or supplies or attempts to sell or supply a needle or syringe to any other person who—

(a) Is not a pharmacist, a pharmacy employee, an approved medical practitioner, or an authorised representative; or

(b) Is a pharmacist or pharmacy employee who is prohibited under regulation 3 (2) from selling new needles and new syringes.

(2) Every person commits an offence who, being a pharmacist or pharmacy employee, sells or supplies or attempts to sell or supply a needle or syringe to any other person otherwise than in accordance with regulation 3.

(3) Every person commits an offence who, being a pharmacist or pharmacy employee who is prohibited under regulation 3 (2) from selling new needles and new syringes, sells or supplies or attempts to sell or supply a needle or syringe to any other person.

(4) Every person commits an offence who, being an approved medical practitioner, sells or supplies or attempts to sell or supply a needle or syringe to any other person otherwise than in accordance with regulation 4.

(5) Every person commits an offence who, being an authorised representative, sells or supplies or attempts to sell or supply a needle or syringe to any other person otherwise than in accordance with regulation 5.

(6) Subclause (1) does not apply to the sale or supply of a needle or syringe—

(a) For the purpose of administering an agricultural compound to an animal; or

(b) For the purpose of taking any substance from an animal; or

(c) For the purpose of conducting any animal research work in accordance with a code of ethical conduct; or

(d) To or by a veterinarian in the course of practice.

(7) Subclauses (1), (2), (4), and (5) do not apply to the sale or supply of a needle or syringe—

(a) For a therapeutic purpose specified in section 4 of the Medicines Act 1981; or

(b) To or by a dentist in the course of practice.

**13. Offence relating to importation**—(1) Every person commits an offence who imports into New Zealand—

(a) A used needle or used syringe; or

(b) A new needle or new syringe other than of a kind approved by the Director-General.

(2) Subclauses (1) (a) and (1) (b) do not apply to the importation of a needle or syringe—

(a) For the purpose of administering an agricultural compound to an animal; or

(b) For the purpose of taking any substance from an animal; or

(c) For the purpose of conducting any animal research work in accordance with a code of ethical conduct; or

(d) To or by a veterinarian in the course of practice.

(3) Subclause (1) (b) does not apply to the importation of a needle or syringe—

(a) For a therapeutic purpose specified in section 4 of the Medicines Act 1981; or

(b) To or by a dentist in the course of practice.

**14. Penalty for offences against regulations**—Every person who commits an offence against regulation 11 or regulation 12 or regulation 13 is liable on summary conviction to a fine not exceeding $500.

*Revocation*

**15. Revocation**—The Health (Needles and Syringes) Regulations 1987 (S.R. 1987/414) are revoked.

MARIE SHROFF,
Clerk of the Executive Council.

## EXPLANATORY NOTE

*This note is not part of the regulations, but is intended to indicate their general effect.*

These regulations, which come into force on 1 October 1998, set out the legal requirements of the Needle and Syringe Exchange Programme. The programme aims to minimise the risk of the spread of blood borne infection through the shared use of needles and syringes principally among intravenous drug users. These regulations provide for the sale of new (and therefore clean) needles and syringes by pharmacists, pharmacy employees, approved medical practitioners, and authorised representatives, as well as providing for the safe disposal of used needles and syringes. These regulations revoke the Health (Needles and Syringes) Regulations 1987.

As with the earlier 1987 regulations, the starting point is section 13 of the Misuse of Drugs Act 1975. This section makes it an offence to possess needles and syringes for the purposes of any other offences against that Act. *Regulation 10* of these regulations provides a defence where it can be shown that the needle or syringe was obtained in accordance with *regulation 3 or regulation 4 or regulation 5*.

*Regulation 3* deals with pharmacists and pharmacy employees. A pharmacist or pharmacy employee may sell new needles and syringes in accordance with the regulations. Pharmacists and pharmacy employees do not need to be approved by the Director-General of Health, although the Director-General may prohibit specified pharmacists or pharmacy employees from selling needles and syringes in certain cases.

*Regulations 4 and 5* deal with approved medical practitioners and authorised representatives. As was previously the case, they must be approved by the Director-General before they may sell new needles and syringes. However, these regulations also make explicit the circumstances where the Director-General may revoke that approval. *Regulation 5* also provides that an authorised representative, in addition to selling needles and syringes from his or her usual place of business or the usual place of business of the agency by whom the representative is employed, may sell needles and syringes from any other place or vehicle approved by the Medical Officer of Health. This allows authorised representatives to sell needles and syringes from mobile vehicles or temporary facilities.

The requirement that the needles must be of a kind, and packaged and labelled in a manner, approved by the Director-General continues in *regulation 7*.

*Regulation 8* specifies the procedure for the setting of fees and costs in relation to the sale of needles and syringes. Under this regulation, the Director-General must consult with such interested persons as the Director-General thinks fit before he or she fixes any fee or cost. Previously, the Director-General was required to consult with certain specified bodies.

*Regulation 9* requires pharmacists, pharmacy employees, approved medical practitioners, and authorised representatives who sell needles or syringes under these regulations to accept for disposal used needles or syringes, if they are returned in the appropriate package and in accordance with the directions on that package.

*Regulation 11* prohibits the use, or offer for use, of used needles and syringes.

*Regulations 12 and 13* prohibit the importation, sale, or supply of needles and syringes otherwise than in accordance with these regulations.

A number of exemptions apply to the offences created in *regulations 11 to 13*.

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