

Medicines Amendment Regulations (No 2) 2002

Pursuant to section 105 of the Medicines Act 1981, Her Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations or bodies appearing to the Minister to be representatives of persons likely to be substantially affected, and acting on the advice and with the consent of the Executive Council, makes the following regulations.

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1 Title

- (1) These regulations are the Medicines Amendment Regulations (No 2) 2002.
- (2) In these regulations, the Medicines Regulations 1984¹ are called “the principal regulations”.

¹ SR 1984/143

2 Commencement

These regulations come into force on the 28th day after the date of their notification in the *Gazette*.

3 Interpretation

- (1) Regulation 2(1) of the principal regulations is amended by inserting, after the definition of **approved immunisation programme**, the following definition:

“**approved school** means an approved school referred to in regulation 27 of the Pharmacy Regulations 1975.”

- (2) Regulation 2(1) of the principal regulations is amended by revoking paragraphs (a) and (c) of the definition of **dispensary technician**.

- (3) Regulation 2(1) of the principal regulations is amended by revoking the definition of **pharmacy graduate**, and substituting the following definitions:

“**pharmacy graduate** means a person—

“(a) who is not a pharmacist, but who—

“(i) has a degree in Pharmacy or a diploma in Pharmacy from an approved school; or

“(ii) has a degree or a diploma from a school of pharmacy outside New Zealand; and

“(b) who is actively taking steps towards registration as a pharmacist under section 13 of the Pharmacy Act 1970

“**pharmacy student** means a person who is undertaking, but who has not yet completed, the course and examinations leading to a degree in Pharmacy or a diploma in Pharmacy from an approved school

“**pharmacy technician** means any person who has—

“(a) a National Certificate in Pharmacy (Technician); or

“(b) an overseas qualification recognised by the Council of the Pharmaceutical Society of New Zealand as equivalent to the National Certificate in Pharmacy (Technician)

“**pharmacy technician student** means a person who is undertaking, but who has not yet completed, training and examinations leading to a National Certificate in Pharmacy (Technician).”

- (4) Regulation 2(1) of the principal regulations is amended by adding the following definition:

“**student** means a pharmacy student or a pharmacy technician student.”

4 Dispensing of prescription medicines

- (1) Regulation 42(1) of the principal regulations is amended by inserting, after the words “a pharmacy graduate,”, the words “a pharmacy technician, a student,”.
- (2) Regulation 42 of the principal regulations is amended by inserting, after subclause (1), the following subclause:

“(1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:

“ ‘

“(a) dispensary technicians:

“(b) pharmacy graduates:

“(c) pharmacy technicians:

“(d) students.’ ”

5 New regulation 43 substituted

The principal regulations are amended by revoking regulation 43, and substituting the following regulation:

“43 Director-General may waive certain requirements

Despite the requirements in regulations 41 and 42, the Director-General may, in special circumstances and at his or her discretion,—

“(a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and

“(b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.”

6 New regulation 63 substituted

The principal regulations are amended by revoking regulation 63, and substituting the following regulation:

“63 Restriction on, and supervision of, compounding medicine

- “(1) A dispensary technician must not undertake any process of compounding a medicine.
- “(2) The following persons may compound a medicine, but only if under the direct personal supervision of a pharmacist:
- “(a) pharmacy graduates:
 - “(b) pharmacy technicians:
 - “(c) students:
 - “(d) despite subclause (1), dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939.”

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 the 28th day after the date of their notification in the *Gazette*, amend the Medicines Regulations 1984 (“the principal regulations”).

Regulation 3 amends regulation 2(1) of the principal regulations by—

- changing the definition of dispensary technician to take account of the new definition of student and to remove reference to persons undertaking the course leading to a Dispensary Assistant’s Certificate, because that course is no longer available:
- substituting a new definition of pharmacy graduate, requiring a graduate to be actively taking steps towards registration as a pharmacist in order to come within the definition:
- inserting definitions of pharmacy student, pharmacy technician student, and student.

Regulation 4 adds pharmacy technicians and students to the list of persons who may dispense prescription medicines under regulation 42(1) of the principal regulations. *New regulation 42(1A)* provides that dispensary technicians, pharmacy graduates, pharmacy technicians, and students may only dispense when under the direct personal supervision of a pharmacist. This aligns the supervision requirement

for pharmacy graduates with the supervision requirement in regulation 37(1) of the Pharmacy Regulations 1975.

Regulation 5 substitutes a *new regulation 43* into the principal regulations. *New regulation 43* extends the Director-General's discretionary power of waiver (which previously applied only to requirements relating to the dispensing of prescription medicines that are set out in regulation 42). The power now includes the discretionary power to waive, in special circumstances, the requirements in regulation 41 (which relates to the form of prescriptions).

Regulation 6 substitutes a *new regulation 63* into the principal regulations. *New regulation 63* relates to restrictions on, and the supervising of, compounding medicine. Under *new regulation 63(1)*, dispensary technicians continue to be restricted from undertaking any process of compounding a medicine. Under *new regulation 63(2)*, pharmacy graduates, pharmacy technicians, and students may compound medicine, but only if they are under the direct personal supervision of a pharmacist. *New regulation 63(2)(d)* provides that, despite the restriction on dispensary technicians compounding medicines in *new regulation 63(1)*, dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939 may compound medicines under the direct personal supervision of a pharmacist.

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