



## THE MEDICINES REGULATIONS 1984, AMENDMENT NO. 5

CATHERINE A. TIZARD, Governor-General

### ORDER IN COUNCIL

At Wellington this 16th day of March 1992

Present:

HER EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

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 and bodies that appeared to the Minister to be representatives of persons likely to be substantially affected, and by and with the advice and consent of the Executive Council, hereby makes the following regulations.

### REGULATIONS

**1. Title and commencement**—(1) These regulations may be cited as the Medicines Regulations 1984, Amendment No. 5, and shall be read together with and deemed part of the Medicines Regulations 1984\* (hereinafter referred to as the principal regulations).

(2) These regulations shall come into force on the 17th day of April 1992.

**2. Interpretation**—Regulation 2(1) of the principal regulations is hereby amended by inserting, after the definition of the term “appropriate quantitative particulars”, the following definition:

“‘Approved immunisation programme’ means a vaccination programme—

\*S. R. 1984/148

Amendment No. 1: S.R. 1985/228

Amendment No. 2: S.R. 1988/61

Amendment No. 3: S.R. 1990/221

Amendment No. 4: S.R. 1991/134

- “(a) Pursuant to the National Immunisation Schedule of the Department of Health; or  
 “(b) Approved by the Director-General or a Medical Officer of Health.”

**3. Prescriptions not required in certain cases**—(1) Regulation 44 of the principal regulations is hereby amended by adding the following paragraph:

“(o) A person or body authorised to distribute, or a person authorised to administer, the prescription medicine in an approved immunisation programme.”

(2) Regulation 44 (n) of the principal regulations is hereby consequentially amended by adding the expression “; or”.

**4. Administration of vaccines in approved immunisation programmes**—The principal regulations are hereby amended by inserting, after regulation 44, the following regulation:

“**44A.** (1) Any medical practitioner or other person who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.

“(2) The Director-General or a Medical Officer of Health may authorise any person to administer a vaccine for the purposes of an approved immunisation programme if that person, following written application, provides documentary evidence satisfying the Director-General or the Medical Officer of Health, as the case may be, that that person—

“(a) Can carry out basic emergency techniques including resuscitation and the treatment of anaphylaxis; and

“(b) Has knowledge of the safe and effective handling of immunisation products and equipment; and

“(c) Can demonstrate clinical inter-personal skills; and

“(d) Has knowledge of the relevant diseases and vaccines in order to be able to explain the vaccination to the patient, or to the parent or guardian of the patient who is to consent to the vaccination on behalf of the patient, to ensure that the patient or the parent or guardian of the patient can give informed consent to the vaccination.

“(3) Subject to subclause (4) of this regulation, any authorisation given by the Director-General or a Medical Officer of Health under subclause (2) of this regulation shall be valid for a period of 2 years and shall be subject to such conditions as the Director-General or the Medical Officer of Health, as the case may be, thinks fit.

“(4) An authorisation given to any person under subclause (2) of this regulation may be withdrawn at any time before its expiry if the Director-General or a Medical Officer of Health is satisfied that the authorised person has failed to comply with any condition specified by the Director-General or the Medical Officer of Health under subclause (3) of this regulation.”

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 17 April 1992, amend the Medicines Regulations 1984.

*Regulation 2* defines the term "approved immunisation programme" for the purposes of the principal regulations.

*Regulation 3* exempts the distribution and use of vaccines in approved immunisation programmes from the requirements of Part VII of the principal regulations which relate to prescriptions.

*Regulation 4* allows any medical practitioner or other person authorised by the Director-General of Health or a Medical Officer of Health to do so, to administer a vaccine in an approved immunisation programme other than pursuant to a prescription written by a medical practitioner.

*Subclause (2)* sets out the requirements to be met by a person seeking authorisation to administer a vaccine.

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These regulations are administered in the Department of Health.