1991/134

THE MEDICINES REGULATIONS 1984, AMENDMENT NO. 4

CATHERINE A. TIZARD, Governor-General

ORDER IN COUNCIL

At Wellington this 22nd day of July 1991

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. 4, 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 29th day of August 1991.

*S.R. 1984/143
Amendment No. 1: S.R. 1985/228
Amendment No. 2: S.R. 1988/61
Amendment No. 3: S.R. 1990/221

2. New regulations substituted—The principal regulations are hereby amended by revoking regulation 61, and substituting the following regulations:

"61. **Fees**—(1) The fees for the licences listed below shall be as follows:

	$
"(a) Licence to manufacture medicines	3,800
"(b) Licence to pack medicines	300
"(c) Licence to sell medicines by retail	50
"(d) Licence to sell medicines by wholesale	300
"(e) Licence to hawk medicines	70
"(f) Combined licence to pack, and to sell by retail, medicines	300.

"(2) The amount to be deposited with the Medicines Review Committee pursuant to section 13 (2) of the Act shall be $9,000.

"(3) The fee to accompany an application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be $15,300 where any active ingredient of the medicine that is the subject of the application is not generally available as at the date of that application.

"(4) The fee to accompany any other application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be $7,800.

"(5) The fee to accompany an application made under section 21 of the Act (as applied by section 96 (1) of the Act) for the Minister's consent under section 20 of the Act in relation to a related product shall be $5,500.

"(6) The fee to accompany an application made under section 23 of the Act for the Minister's provisional consent shall be $5,000.

"(7) The fee to accompany a notice deposited with the Director-General under section 24 of the Act shall be $1,600.

"(8) The fee to accompany an application made under section 30 of the Act for the approval of a clinical trial, and of the persons (in that section called investigators) who will conduct that trial, shall be $2,800.

"(9) For the purposes of section 70 (4) of the Act, the fee for a copy of a certificate of an analyst, or (as the case may be) a copy of a report made by an analyst in respect of a sample, shall be $60.

"(10) For the purposes of section 97 (1) of the Act, the fee for procuring a sample of any medicine and submitting it for analysis shall be $600.

"(11) For the purposes of subclause (3) of this regulation, 'not generally available' means not legally available other than pursuant to an exemption granted under any or all of sections 25, 26, 27, 28, 29, 30, 31, 32, 32A, or 33 of the Act.

"61A. **Waiver and refund of fees**—(1) The Director-General may, in a particular case or class of cases, waive or refund, in whole or in part, any fee otherwise payable under regulation 61 of these regulations.

(2) In exercising his or her powers under subclause (1) of this regulation, the Director-General shall have regard to—

"(a) The time reasonably required to consider any application made or notice given under the Act:

"(b) The degree of complexity involved in considering any such application or notice:

"(c) The interests of public health in New Zealand.

"61B. **Fees inclusive of goods and services tax**—The fees fixed by these regulations are inclusive of goods and services tax under the Goods and Services Tax Act 1985."

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 29 August 1991, prescribe a new and increased scale of fees payable under the Medicines Act 1981. A number of fees are prescribed for the first time. All of the fees prescribed are inclusive of goods and services tax and may, in certain circumstances, be waived or refunded by the Director-General of Health.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette:* 25 July 1991.
These regulations are administered in the Department of Health.