

Cabinet Social Wellbeing Committee

Minute of Decision

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Amendments to Fees Specified in the Medicines Regulations 1984

Portfolio Health

On 20 October 2021, the Cabinet Social Wellbeing Committee:

- 1 **noted** that Medsafe has undertaken a fees review in order to meet an undertaking with Audit New Zealand and as part of its obligations to manage its memorandum account;
- 2 **noted** that the fees review identified a need for increases in fees, with some requiring only a Consumer Price Index increase while others a more substantial increase to address cost recovery requirements;
- 3 **agreed** to the amendment of the maximum fees set in regulation 61 and Schedule 5A of the Medicines Regulations 1984 to allow for the below fee review proposals to be implemented;

Regulation 61	Fee Type description	Old fee (maximum)	New fee (maximum)
(1)	Schedule 5A licences	See below	
(4)	Fee for any other application made under section 21 for the consent of the Minister under section 20 of the Act (new medicines other than new novel medicines)	\$43,875	\$79,877
(5)	New related products	\$5,500	\$5,731
(6)	Provisional consent under section 23	\$8,437	\$85,202
(7)	Changed medicine notifications	\$3,200	\$3,334
Schedule 5A	Licence application fees		
2	Licence to manufacture medicines	\$13,750	\$14,328
	Licence to pack medicines	\$845	\$880
	Licence to sell medicines by retails	\$845	\$880
	Licence to sell medicines by wholesale	\$1,054	\$1,123
	Licence to hawk medicines	\$845	\$880
	Combined licence to pack and sell by retail	\$300	\$313
(lances (2) (2) and (9) (10)	Licence to operate a pharmacy	\$1,030	\$1,097

Clauses (2), (3) and (8)-(10) have no change to the fee

4 **agreed** that a new regulation is drafted allowing significant changed medicine notifications to be charged as new medicines, with the Regulation 61A waiver also applying;

IN CONFIDENCE

5 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to implement the above changes through amendments to the Medicines Regulations 1984.

Rachel Clarke Committee Secretary

Present:

Hon Grant Robertson Hon Kelvin Davis Hon Carmel Sepuloni (Chair) Hon Andrew Little Hon Poto Williams Hon Kris Faafoi Hon Damien O'Connor Hon Willie Jackson Hon Jan Tinetti Hon Dr Ayesha Verrall Hon Meka Whaitiri Hon Aupito William Sio Hon Priyanca Radhakrishnan

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Officials present from: Office of the Prime Minister

Officials Committee for SWC

Office of the SWC Chair