

10 July 2024

Dear Licence Holder

Effective Control Principles

I am writing to advise you of upcoming changes to the application process for companies applying for a licence to operate pharmacy.

Following the High Court's judicial review decision in *New Zealand Independent Community Pharmacy v Te Whatu Ora – Health New Zealand and Ors* [2023] NZHC 1486 (CIV-2022-485-11), the Ministry of Health (the Ministry) has reviewed how the effective control provisions under section 55D(2)(a) of the Medicines Act 1981 (the Act) are applied.

The decision was appealed by the licence holder, but that appeal has now been withdrawn and the stay on the High Court decision is no longer in place. As a result, the interpretation of the effective control provisions has been updated in line with the High Court's decision.

The following principles will be used to guide assessment of an application, against the effective control aspects of the pharmacy ownership requirements of the Act:

Principle 1: Pharmacist(s) must own more than 50% of the share capital of the company.

Principle 2: Pharmacist(s) must have a majority of the voting rights on the board under the company's constitution or shareholders' agreement and must have the decisive casting votes in all board matters.

Principle 3: Pharmacist(s) must at all times make up the majority of the board's directors and must form the majority of the quorum for a shareholders' meeting.

Principle 4: Pharmacist(s) must have the ability to make the final decisive decision on behalf of the company, including casting the decisive vote on applicable matters in shareholder meetings.

Principle 5: Pharmacist(s) must be able to make decisions at the board level that can have an impact on the health and safety of pharmacy patients.

Enclosed is a copy of the published guidance for your reference. Future updates to this document will be published on the Medsafe website (www.medsafe.govt.nz).

We estimate about 400 of the approx. 1,100 licensed pharmacies may be affected. The extent of changes required will vary between pharmacies, and not all affected pharmacies will have to make significant changes.

Medsafe will engage with you through the licence application process, to assist you to demonstrate that you are able to meet the requirements of the Act. We encourage you to seek independent advice should you have any questions on how these principles apply to your company structure.

Please note that Medsafe is able to provide guidance on the licence application process, however is unable to provide regulatory consultancy services.

Implementation

Applications to renew an existing licence that expires on or after 1 January 2025 will be assessed against these principles. Application packs sent by Medsafe to renew licences from 30 September 2024 will contain updated application forms to reflect these principles.

Applications to amend an existing licence will be considered on a case-by-case basis. Where the application is received from 1 October 2024 and relates to a proposed change in the ownership structure, it will be assessed against these principles.

Applications for a new pharmacy premises (including relocations and changes of ownership) will be assessed against these principles from 1 October 2024.

Yours sincerely,

Michael Haynes
Manager & Licensing Authority, Medicines Control
Medsafe