

In Confidence

Office of the Minister of Health

Cabinet Social Wellbeing Committee

Pharmacy ownership

Proposal

- 1 This paper seeks Cabinet agreement to continue existing pharmacy ownership restrictions.

Relation to government priorities

- 2 This proposal supports implementation of the health system by providing stability for pharmacies while the new health entities (Te Whatu Ora - Health New Zealand and Te Aka Whai Ora - the Māori Health Authority) and processes are embedded within the primary and community health sector.

Executive Summary

- 3 This paper fulfils the requirement to report back on pharmacy ownership as part of the development of the Bill [SWC-18-MIN-0176 and SOC-15-MIN-0050].
- 4 The Medicines Act 1981 (the Medicines Act) restricts who may own a pharmacy by setting ownership requirements as a criterion for gaining a pharmacy licence. A pharmacy licence can only be granted to a company if a pharmacist has more than 50 percent of share capital and is in effective control of the company. Other rules restrict the number of pharmacies an individual can operate or hold a majority interest in.
- 5 The historical rationale for these restrictions has been the maintenance of a strong community pharmacy sector where consumer health interests are placed ahead of commercial interests. The avoidance of conflicts of interests for health practitioners and commercially driven market concentration are other factors traditionally cited in favour of restrictions.
- 6 Nonetheless, these restrictions are no longer consistent with the Government's expectations for good regulation, and do not fit well with the aims of the new therapeutic products regulatory scheme, such as enabling integrated and innovative models of patient care. They do not support the current objectives for the pharmacy sector, such as enhancing equitable access to medicines and pharmacy services, and fully utilising the unique skill set of pharmacists. As such, the Government consulted on reforms to ownership rules as part of the 2018-2019 consultation on the exposure draft of the Bill.
- 7 I have deferred bringing a proposal to Cabinet on this issue until now so that I could consider the impact of the wider health and disability system reforms and COVID-19 on the sector.

8 Despite the recognised issues with the current ownership rules, I propose retaining the status quo statutory settings as an interim measure under the Bill. This is because any change to the current model would create additional uncertainty for the sector while it is integrating major changes as part of the health and disability system reforms, and managing an essential part of the COVID-19 response. An existing exemption provision in the Medicines Act provides some flexibility to the rules in the short term.

Background

9 As part of developing a modern and comprehensive regulatory scheme for therapeutic products such as medicines and medical devices, the Bill will repeal and replace the Medicines Act. Currently, this includes repealing provisions in the Medicines Act that impose ownership requirements for pharmacies. A decision is required on this issue to enable the Parliamentary Counsel Office to appropriately draft the Bill.

10 The Medicines Act restricts who may own a pharmacy, by setting ownership requirements as a criterion for gaining a pharmacy licence. A pharmacist must hold more than 50 per cent of the shares of a pharmacy and may hold this majority share in up to five pharmacies. Medical practitioners are prohibited from holding an interest in pharmacy businesses. This latter restriction is intended to minimise conflicts of interest for prescribers of medicines.

11 Additionally, the Medicines Act contains a limited exemption provision that can modify or exempt individuals or companies from some of the rules by making an Order in Council (i.e., an individual or individuals who are not pharmacists could own a pharmacy if they made an application and it was granted). The exemption provision cannot be used to permit prescribers from holding an interest in pharmacy businesses or the five pharmacies cap.

12 The historical rationale for pharmacy restrictions has been the maintenance of a strong community pharmacy sector where consumer health interests are placed ahead of commercial interests. The avoidance of market concentration of pharmacy retailers is another factor traditionally cited in favour of restrictions.

13 Despite these historical justifications, the current restrictions are not fit for purpose. and do not align with the health system reform objectives of tackling the gap in access and outcomes, and ensuring consistent, high-quality care that is supported by innovation and new technologies to continuously improve services.

14 In December 2018, Cabinet agreed to public consultation on two options for pharmacy ownership with the intention that one of them would be included in the Bill [SWC-18-MIN-0176]:

14.1 option 1: strengthened accountability through pharmacist ownership and effective control

14.2 option 2: open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

15 The majority of submitters, particularly those within the pharmacy sector, supported option 1. They were also concerned about the impact that removing the majority ownership requirement would have on the quality of services and safety.

- 16 This paper fulfils the requirement to report back on pharmacy ownership and related licensing issues as part of the development of a new regulatory regime for the Bill [SWC-18-MIN-0176 and SOC-15-MIN-0050].

Analysis

- 17 In the medium to long-term, removing the pharmacy ownership restrictions would support the health and disability system reform objectives of tackling current gaps in access and health outcomes.
- 18 It would also support innovation and continuous service improvement through greater competition, and would put community pharmacies on the same footing as every other health profession within the scope of the Health Practitioners Competence Assurance Act 2003 (i.e., any health professional could own a pharmacy as they can with a general medical practice). A regulatory impact statement prepared in May 2021 supports this approach.
- 19 However, introducing significant change to the pharmacy ownership model in the short term would create additional uncertainty for the sector while it is integrating into the new health system. Major structural, accountability and funding changes are being implemented across the new health system and these need to be effectively embedded before any further matters such as pharmacy ownership are considered.
- 20 In addition, the health system, which includes the pharmacy sector, has been under pressure with the ongoing effects of the COVID-19 pandemic. A focus on the release of new COVID-19 antivirals and administering vaccines will continue for some time for pharmacies as New Zealand shifts to managing COVID-19 as an endemic and possibly seasonal illness.
- 21 Given the reasons above, I recommend continuing with the current arrangements in the Medicines Act that restrict pharmacy ownership in the short term, including the exemption mechanism.
- 22 Retaining the current exemption provision provides a mechanism to address some barriers to innovation in the delivery of pharmacy services in the period before further Cabinet consideration. Maintaining the status quo in the interim would not jeopardise the ongoing provision of safe and effective medicines and other therapeutic products.
- 23 This approach is likely to be welcomed by most pharmacy owners and their representative organisations as nothing will change for now.

Treaty of Waitangi

- 24 The current Wai 2575 Health Services and Outcomes Inquiry and The Ministry of Health's Te Tiriti o Waitangi Framework and *Whakamaua: Māori Health Action Plan 2020-2025* are relevant to, and will inform, further Cabinet consideration, including how pharmacy ownership restrictions affect equitable access to therapeutic products and pharmacy services. This is distinct to other provisions in the Bill that relate to how and where pharmacy activities can be performed (e.g., on marae), and to wider health sector principles in the Pae Ora (Healthy Futures) Act, and which are likely to positively impact access to health services for Māori.

Monitoring

25 There is already an extensive network of review, monitoring and evaluation mechanisms for the pharmacy sector. These mechanisms will continue and will be used to address any risks that arise in the interim, whether on the safety and quality of therapeutic products and pharmacy services, or community access to pharmacy services.

Financial Implications

26 There are no specific financial implications with this paper as it seeks to retain the status quo.

Legislative Implications

27 The Bill, as currently drafted, will repeal the Medicines Act upon commencement. To allow flexibility for future governments, I propose retaining the relevant parts of the Medicines Act addressing pharmacy ownership restrictions, as well as the current exemption provisions (and renaming the Act to reflect its narrower focus, if appropriate), while repealing the remainder of the Medicines Act on the commencement of the Therapeutic Products Act.

28 I do not support carrying these saved provisions directly into the Bill as it could mislead the sector on the decision taken.

29 s 9(2)(f)(iv)

Impact Analysis

Regulatory Impact Statement

30 A Regulatory Impact Statement (RIS) was prepared last year and the Ministry of Health has confirmed that it still applies. The RIS is attached at Appendix One.

31 While the RIS supports open pharmacy ownership, I have also considered the cumulative system and regulatory impact of the implementation of the health system reforms and this supports my view to retain the status quo for now. I am also cognisant of the need to allow time for the new health entities and processes to be embedded and for working relationships to be formed with the primary and community care sector. Finally, I have also considered the need to maintain our response to COVID-19 and other seasonal illnesses in the short term.

32 The Ministry of Health QA panel has reviewed the Impact Statement titled “Pharmacy ownership and licensing”, produced by the Ministry of Health and dated 20 May 2021. The panel considers that the Impact Statement meets the quality assurance criteria. The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed.

Climate Implications of Policy Assessment

- 33 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

Population Implications

- 34 I acknowledge that pharmacy ownership restrictions may have adverse impacts on Māori, Pasifika and rural and remote communities. It would be desirable to address inequities and limitations on service innovation as soon as practicable (i.e., once the health reforms and COVID-19 situation have stabilised).
- 35 Removal of all restrictions without careful planning in the context of the impacts of the new health reforms on the pharmacy sector, could lead to different or worse inequities (e.g., the sector could become monopolised by a small number of large, commercial operators). The risk of any reduction in access to, or quality of, pharmacy services in remote or otherwise vulnerable areas will be monitored, as discussed above in the implementation section. These risks are also somewhat able to be mitigated by retaining the exemption provisions in the Medicines Act.
- 36 The Bill provides new mechanisms that enable improvements in service innovation (e.g., around e-prescribing, locations where certain 'controlled activities' involving therapeutic products may take place, and a new regime for access to unauthorised medicines to meet a patient's clinical needs). These will address some of these inequities without requiring changes to pharmacy ownership rules initially.

Human Rights

- 37 The proposals in this paper are consistent with the New Zealand Bill of Rights Act 1990 and or Human Rights Act 1993.

Consultation

- 38 The Ministry of Health has consulted with the following agencies on the development of this paper: Ministry of Business, Innovation and Employment (MBIE), Treasury, Te Whatu Ora - Health New Zealand, Te Aka Whai Ora - Māori Health Authority Commerce Commission. The Department of the Prime Minister and Cabinet was informed.
- 39 MBIE has previously advised that they support removal of the restrictions, as this is likely to lead to improved access to medicines and pharmacy services.

Communications

- 40 The pharmacy and retail sectors are keenly interested in the future of ownership restrictions. Officials will support my office with developing the communications plan for public announcement.

Proactive Release

- 41 I intend to proactively release this Cabinet paper within the standard 30 business days. Redactions will be made to this paper pursuant to the Official Information Act 1982.

Recommendations

The Minister of Health recommends that the Committee:

- 1 **note** that this paper fulfils the requirement to report to Cabinet on a recommended approach to pharmacy ownership and licensing criteria [SWC-18-MIN-0176 and SOC-15-MIN-0050];
- 2 **note** that this paper is part of work to modernise New Zealand's therapeutics regulatory scheme, central to which is repealing the Medicines Act 1981, including pharmacy ownership and licensing criteria, and replacing it with the Therapeutic Products Bill;
- 3 **note** that while the removal of restrictions on pharmacy ownership in the medium to long term would enable innovation in delivery of services, in the short-term, it would create additional uncertainty for the sector while the new health entities and processes are embedded, working relationships are formed with the primary and community care sector and the response to COVID-19 is further managed;
- 4 **agree** that the current pharmacy ownership provisions, and the related exemption provisions, in the Medicines Act 1981 be retained by saving those provisions, and repealing all other parts of the Medicines Act, once the Therapeutic Products Bill is enacted, to allow time for pharmacies to embed changes under the new health system and continue addressing the ongoing impacts of COVID-19;
- 5 **authorise** the Minister of Health to instruct the Parliamentary Counsel Office to revise the Therapeutic Products Bill to reflect retention of the current pharmacy ownership provisions and the current exemption provision in the Medicines Act 1981 (including renaming the latter Act if necessary);
- 6 **note** that this paper will be proactively released within 30 days with any necessary redactions pursuant to the Official Information Act 1982.

Authorised for lodgement

Hon Andrew Little

Minister of Health