**In confidence**

Office of the Minister of Health

Cabinet Business Committee

# Therapeutic products and natural health products regulatory scheme: Establishing a new regulator and funding settings, offences and penalties; direct-to-consumer advertising of prescription medicines



## Proposal

1 This paper seeks decisions on: the form of the new therapeutic products and natural health products regulator (the regulator) to be established under the Therapeutic Products Bill, and funding mechanisms for the regulator; the inclusion of a civil pecuniary penalty regime in the Bill; and the regulation of direct-to-consumer advertising of prescription medicines.

2 I ask that Cabinet agrees to my recommendations:

2.1 that the regulator be established as a branded business unit within the Ministry of Health, with an independent statutory officer exercising the powers of the regulator

2.2 to include a civil pecuniary penalty regime in the draft Therapeutic Products Bill

2.3 to continue the current policy settings for well-regulated direct-to-consumer advertising of prescription medicines, and retain the provisions in the draft Therapeutic Products Bill for more modern enforcement tools.

## Relation to government priorities

3 This proposal helps to deliver on the Government's plan to develop a modern and comprehensive regulatory scheme for therapeutic products and natural health products, delivered by an effective, accountable and adequately-resourced regulator. In doing so, it contributes to the Government's commitment to build a stronger and sustainable health and disability system that delivers for all New Zealanders. It also supports our COVID-19 response and recovery.

## Executive summary

4 This paper seeks agreement on final policy decisions required for drafting instructions for revisions to the draft Therapeutic Products Bill (the Bill). The Bill provides for a new regulatory scheme to ensure all therapeutic products and natural health products are subject to appropriate levels of regulation, and enable improvements and innovation in Government and health priority areas.

*Establishing a new regulator and funding settings*

5 In 2018, Cabinet invited a report on the proposed institutional form of a regulator for the new regulatory scheme. This paper provides that report-back, along with an associated report-back on the funding approach. It also provides a report-back on themes from public consultation on the draft Bill.

6 As part of a new regulatory scheme for therapeutic products and natural health products, the Bill will establish a new regulator. The regulator will cover a broader scope of products and activities than the current regulator, Medsafe: for example, medical devices, advanced therapies, natural health products and clinical trials.

7 The regulator will be responsible for ensuring the safety, quality and efficacy or performance of regulated products across their lifecycle. It will design and implement proportionate and risk-based market authorisation pathways to support the timely availability of therapeutic products and natural health products. It will engage with international counterparts, industry sectors and other stakeholders (such as the healthcare sector and natural remedies sector, including traditional Māori healing or rongoā Māori). An appropriately-resourced and independent regulator is a critical component of the new regulatory regime to ensure timely access to safe and effective therapeutic products.

8 In addition to achieving the objectives of the Bill, the form of the regulator also needs to work as an integral part of the wider health and disability system and contribute to achieving a vision of pae ora/health futures for all New Zealanders.

9 Having regard to wider health and disability system transformation and the lessons from New Zealand's response to COVID-19, I recommend the new regulator be established as a branded business unit within the Ministry of Health, with an independent statutory officer appointed to undertake specific statutory functions of the regulator. The detailed functions of the new regulator will be included in a Cabinet paper seeking approval for final drafting instructions for the Bill, which I expect will be presented to Cabinet in October 2021.

10 Cabinet has previously agreed that the regulator should recover its costs through fees and levies where these costs are not met by Crown funding. I anticipate bringing the proposed cost-recovery model to Cabinet as part of the package of regulations relating to the new scheme.

11 To further secure the independence of the regulator, as well as ensure its ability to sustain and build regulatory capacity and capabilities, the regulator will need a degree of budgetary independence from the Ministry of Health. This can be achieved by Cabinet agreeing to a sustainable funding basis for the regulator, for example 'ring-fenced' funding for its activities.

12 s 9(2)(f)(iv) [redacted]

s 9(2)(f)(iv) [redacted]

*Offences and penalties*

13 In March 2016, Cabinet agreed that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings and infringement notices [SOC-16-MIN-0025]. Since then, a draft Bill has undergone public consultation (December 2018 – April 2019), and officials have subsequently considered whether civil pecuniary penalties would be appropriate as part of the scheme's compliance and enforcement regime.

14 I propose the draft Bill be amended to include a civil pecuniary penalty regime. While this was not included in the draft exposure version of the Bill, I consider the inclusion of civil pecuniary penalties supports the regulator to take enforcement action that is appropriate and proportionate, using fit-for-purpose tools and dependent on the circumstances of the conduct.

*Direct-to-consumer advertising of prescription medicines*

15 All medical advertising, including direct-to-consumer advertising of prescription medicines (DTCA-PM), has been regulated in New Zealand for nearly 80 years. There are currently strict controls in the Medicines Act 1981 and Medicines Regulations 1984.

16 Government regulation is complemented by self-regulation by both the advertising and therapeutic product industries. This consists of advertising and ethics codes that are binding on members, an industry-operated service to vet advertisements before placement, and a complaints adjudication procedure.

17 Medical advertising is also controlled through regulation and self-regulation of healthcare professions, and general consumer protection law.

18 This combination of government regulation and self-regulation by industries and professions has been progressively strengthened since the Medicines Act came into force. Compliance is very high.

19 DTCA-PM attracts strong opinion both in favour and in opposition. Robust empirical evidence of the health or economic impacts of DTCA-PM is scarce. There are weak to moderate arguments against DTCA-PM. There are weak to moderate arguments in its support. A thorough review of relevant literature shows that there is insufficient evidence to warrant changing the current policy and regulatory settings. This includes not being able to demonstrably justify the infringement of people's right to receive information that a partial or full prohibition of DTCA-PM would cause.

20 The Bill continues the current policy settings of allowing well-regulated DTCA-PM, and will provide the regulator with more modern and effective enforcement tools including advertising remediation orders and significantly increased penalties.

21 I propose that the current policy settings be continued, and the new enforcement tools provided in the draft Bill be retained.

## Background

### The current regulatory scheme for therapeutic products and natural health products and development of a new regulatory regime

22 Therapeutic products (principally medicines and medical devices, including biologics such as gene and tissue therapies) are used by all New Zealanders in their everyday lives and in all parts of the health system. They are also used to treat and prevent COVID-19.

23 Therapeutic products are currently regulated under the Medicines Act 1981, which is outdated. It takes a prescriptive and inflexible approach and has not kept pace with rapid advances in health technologies. There are significant gaps in coverage, such as in the regulation of medical devices and advanced therapy medicinal products. The response to COVID-19 has highlighted the limited regulation of medical devices and an outdated approach to regulating medicines.

24 In 2015, Cabinet agreed to repeal and replace the Medicines Act with a new Therapeutic Products Bill [SOC-15-MIN-0049]. In July 2021, Cabinet also agreed to include regulation of natural health products as part of the Bill [SWC-21-MIN-0109].

25 The Bill takes a modern regulatory approach and is comprehensive in coverage. As discussed below, there is broad support among stakeholders for a more modern and comprehensive regulatory scheme.

26 The Bill is well aligned with the Government's health and disability system reform, as it addresses significant gaps in one of the foundations of a well-functioning, patient-focused health and disability system. It will provide assurance of the safety, quality and efficacy or performance of therapeutic products across their lifecycle.

27 The Bill will address deficiencies in the regulation of New Zealand's domestic market for therapeutic products and natural health products, enable innovation in health services and support exporters by providing for better official assurance of products.

### Report back on consultation on the draft Bill

28 In December 2018, Cabinet invited the Minister of Health to report back on the overall outcomes of consultation on the exposure draft of the Bill and consultation document [SWC-18-MIN-0176]. This paper fulfils that report back, noting that key themes have been posted on the Ministry of Health's website since 2019 (see Appendix One).

29 Four hundred and forty-two submissions were received from a variety of stakeholders including consumers, industry professionals, health practitioners and their organisations, and health sector organisations. Submissions covered all the issues in the Bill and proposed regulatory scheme.

30 Stakeholders expressed general support for the purpose and principles of the Bill, recognising that successive governments have been working to enact reform in this area for nearly three decades.

31 Key themes expressed by submitters generally related to ensuring the enabling legislation appropriately balanced safety and compliance costs (eg, authorisation to conduct activities), promoted timeliness of the regulator and aligned internationally. This was particularly important for products and activities that are currently only lightly regulated, such as medical devices and clinical trials. Submitters provided feedback on the scope of products to be captured by the regime, for instance whether to include natural health products and sunscreens.

32 Contentious areas included pharmacy ownership restrictions, direct-to-consumer advertising of prescription medicines and access to unapproved medicines. All sectors wanted to know more about the scheme, much of which will be provided in secondary legislation that is developed after the Bill's commencement.

## Part 1 - Establishing a new regulator and funding settings

### The current therapeutic products regulator

33 The Medicines Act is administered by the Ministry of Health. In practice, therapeutic products are regulated by Medsafe, a branded business unit of the Ministry. Medsafe is accountable to the Director-General of Health, who is accountable to the Minister of Health.

34 Medsafe has approximately 60 staff and is relatively small by international standards — less than 10 percent of the size of equivalent regulators in Australia and Singapore. Medsafe is approximately 95 percent funded from fees.

35 While Medsafe has operated as an effective regulator, providing trusted and quality advice including during the COVID-19 pandemic, the Medicines Act does not provide it with the modern regulatory tools needed to ensure timely and safe access to therapeutic products that meet efficacy and safety standards, or to respond to market activity.

36 The Medicines Act places many core regulatory powers with the Minister of Health, which are exercised under delegation. This model does not enable an easy separation between performance and monitoring. It also makes the Minister responsible for technical decisions that have significant impacts on private interests, which ought to be directly conferred on a more appropriate entity.

### Previous decisions on entity form, and wider health system considerations

37 Cabinet has agreed that the objectives for a modern therapeutic products regulatory scheme would be best met by a regulator that can exercise regulatory powers and associated administrative powers effectively, is accountable and is able to engage internationally [SOC-15-MIN-0049].

38 In 2016, Cabinet agreed that the regulator should not be a Crown entity, and that further consideration be given to establishing it as a departmental agency or within the Ministry of Health [SOC-16-MIN-0025]. This decision was made on the basis of a regulatory impact analysis conducted by the Ministry of Health that examined three entity forms: a branded business unit within the Ministry of Health, a departmental agency and a Crown entity.

39 In 2018, Cabinet agreed this issue warranted further consideration and invited a report back on the proposed institutional form of the regulator [SWC-18-MIN-0176]. This paper fulfils that request.

40 This paper also considers which entity form would best align with recent decisions to transform the health and disability system [CAB-21-MIN-0092]. The form of the regulator should cohere with the Government's vision for the health and disability system — pae ora/healthy futures for all — and be able to contribute to its realisation.

41 The regulator's form should align with Cabinet's decisions that the Ministry will have strengthened stewardship responsibilities (including over regulatory functions). It should also align with Cabinet's decision to establish Health New Zealand as a Crown entity, the Public Health Agency as a branded business unit of the Ministry of Health, and the Māori Health Authority as a bespoke entity that includes features of a Crown entity [CAB-21-MIN-0092]. Although these new entities have a degree of separation from the core Crown, they will be expected to work together, and the risk of system fragmentation is being further managed through legislative and non-legislative mechanisms, including a Government Policy Statement for the health and disability sector.

42 Finally, the assessment of the form of the regulator has been informed by Cabinet's recent decision to include regulation of natural health products within the Bill [SWC-21-MIN-0109].

## Decisions on entity form should flow from proposed functions and the objectives of the regulatory scheme

### The new regulator will have an expanded role and a wide range of functions

43 Under the Bill, the regulator will have a broader scope than Medsafe does. It will exercise a full suite of modern regulatory functions, including market authorisation, licensing, monitoring, compliance and enforcement. It and the Ministry will jointly develop regulatory policy for therapeutic products and natural health products.

44 Given these broader functions, greater prominence and proposed cost-recovery arrangements, there will be high industry and public expectations for the regulator. A highly-effective regulator must have the credibility, trust, independence, capability and resources to deliver on the Government's objectives.

45 In deciding which form the regulator should take, I considered the criteria of independence[1], cost-effectiveness, transparency, accountability for decision-

[1] 'Independence' includes regulatory, operational, institutional, and budgetary independence. Operational independence allows a regulator to make decisions without undue industry or

making, ability to sustain regulatory capability and capacity, responsiveness and flexibility, trustworthiness and respectability, and the cost and timeliness of establishment.

46 I also had regard to the Government's wider health and disability system reform agenda and the lessons learnt from COVID-19. Ensuring coherence with decisions to establish new health entities and the future role of the Ministry in the new system is a significant criterion for assessing the most suitable form of the regulator. This required going beyond the three entity form options previously analysed in the 2016 regulatory impact statement and including a fourth option: an independent statutory officer within a branded business unit of the Ministry of Health.

**Options**

47 The options for the form of the new regulator that were considered are:

| Option | Description |
|---|---|
| Option 1:<br>Branded business unit (BBU) within the Ministry of Health | This is like the status quo, but it would have a wider role and responsibilities as provided by the Bill and proportionately more resources.<br>The statutory powers of the regulator would be vested in the chief executive of the Ministry of Health (ie, the Director-General of Health), and be delegated to appropriate staff within the Ministry. |



political interference, and in a manner independent from other actors within the health system such as the Director-General of Health, Director of Public Health, or the future Health New Zealand.

| Option | Description |
|---|---|
| Option 2:<br>BBU with an independent statutory officer (BBU + ISO)<br><br>***Recommended option*** | A branded business unit within the Ministry of Health, with an independent statutory officer who exercises the statutory powers of the regulator.<br>The independent statutory officer (ISO) would:<br>• be appointed by the Director-General of Health (DG)<br>• be a person who the DG is satisfied has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the regulator<br>• be an employee of the Ministry of Health (or be appointed as an employee of the Ministry)<br>• exercise their functions and powers as regulator independently of the DG and Minister.<br>• be subject to general policy directions given by the Minister of Health that are not inconsistent with the Bill, regulations, or other legislative instruments<br>• be accountable to the DG for the performance of their functions and duties and the exercise of their powers<br>• have arrangements in place to avoid or manage any conflicts of interest that may arise in the performance of functions and duties and the exercise of powers<br>• operate within the Government's and Ministry's strategic and policy framework<br>• supported by protected funding within the overall Vote Health<br><br>Examples of an ISO are the Director of Radiation Safety under the Radiation Safety Act 2016, and the Standards Executive under the Standards and Accreditation Act 2015. |
| Option 3:<br>Departmental agency with an independent statutory officer (DA + ISO)<br><br>*Alternative option* | An operationally autonomous agency hosted by, and legally considered part of, the Ministry of Health, established under the Public Service Act 2020.<br>The departmental agency would:<br>• be headed by its own chief executive, who would be directly responsible to the Minister of Health<br>• contain an independent statutory officer, who may or may not be the chief executive, who would exercise the statutory powers of the regulator<br>• receive corporate services from the Ministry of Health unless other arrangements were agreed by both chief executives.<br><br>If adopted, I propose that the agency operate within the Government's and Ministry of Health's overall strategic and policy framework (eg, Government policy statement), as therapeutic products are central to all aspects of the health system. |
| Option 4:<br>Crown entity | A separate Crown entity that gives effect to Government policy.<br>The entity would be directly accountable and governed by a board, and accountable to the Minister in relation to the letter of expectations. |

## Analysis of the options

48 Appendix Two summaries an analysis of the options. Stakeholder views on the entity form question are set out in the consultation section below.

## Options 1 and 4 considered and not recommended

49 Option 1, a BBU within the Ministry of Health would be the cheapest of the four options and easiest to implement. However, I consider that it would have insufficient independence from other actors within the wider health system, for example where different parts of the Ministry have to act as regulator and therapeutic product purchaser. A BBU is not recommended.

50 Option 4, a Crown entity, would structurally be the most independent option and would be governed by an appointed board. However, it would have several significant disadvantages.

51 The regulator being a Crown entity risks too much separation and fragmentation from the wider health sector, restricting the emergence of a culture of working with other health entities and across the public service. This model could also limit a collaborative approach with the Ministry of Health in international engagement, as distance from the core Ministry may impact the confidence of international counterparts, reducing the likelihood that they will share confidential product safety data with the regulator.

52 A Crown entity would also be the most expensive option to operate, because of board fees and separate corporate functions. As a cost-recovered entity, these costs would be borne by the sector and need to be justified by additional performance gains flowing from the entity's form. A board's added value to regulatory decision-making would be small compared with the expertise generated by technical committees provided for in the Bill, making it the least cost-effective of all options.

53 This analysis therefore continues to support Cabinet's decision that the regulator not be a Crown entity [SOC-16-MIN-0025].

### Options 2 and 3 both address functional criteria

54 Options 2 (BBU with ISO) and 3 (departmental agency with ISO) both provide a high degree of regulatory, operational and institutional independence. Each has some advantages and disadvantages:

| Option 2: BBU + ISO | Option 3: departmental agency |
|---|---|
| **Independence** | |
| Powers of the ISO are exercised independently of the DG of Health and Minister of Health. Conferral of legal powers on ISO makes independence clear.<br>DG of Health sets strategic objectives and priorities. While this may undermine the regulator's flexibility, for example in responding to pandemics or realising opportunities from technological developments, it would promote overall system coherence and is appropriate given centrality of pharmaceutical products to delivering key outcomes for the health and disability system (eg, equity, sustainability and patient-centred care).<br>The regulator's funding would need to be protected and not be used for other functions of the Ministry (except to meet the regulator's share of overheads). | Similar to a BBU+ISO but with the potential for greater independence (real and perceived), as the agency would be headed by its own chief executive, who would report to the Minister.<br>The regulator's funding would need to be protected and not be used for other function of the Ministry (except to meet the regulator's share of overheads). |
| **Coherence with wider health and disability system** | |
| A BBU+ISO would support system coherence, as it would be operating within the Ministry of Health and its strategic and policy frameworks, including *Whakamaua: the Māori Health Action Plan 2020–2025*.<br>Situating the regulator within the Ministry of Health would support the Ministry's system and regulatory stewardship roles as the Ministry could monitor the performance of the regulator more closely.<br>A closer working relationship between the ISO, DG and senior Ministry leaders will promote coherence in operating policies, information sharing and working with other Ministry staff. | As an operationally autonomous agency there is the potential that a departmental agency would increase fragmentation within the wider health and disability system. This is the case, even if the agency were not permitted to operate within its own strategic and policy framework or manage its own assets and liabilities.<br>The separate reporting relationship between the chief executive of a departmental agency and the Minister may reduce the incentive for the regulator to work with Ministry staff. |

| Option 2: BBU + ISO | Option 3: departmental agency |
|---|---|
| **Decision-making ability and accountability** | |
| Under BBU+ISO model, the statutory decision-making powers of the ISO are clearer than in a BBU model.<br>Lines of accountability to the DG and the Minister for the exercise of independent functions are also more clearly defined. | Greater decision-making ability over operational matters.<br>Agency chief executive directly accountable to Minister.<br>The ISO would be accountable to the agency chief executive and Minister for the exercise of independent functions.<br>The accountability of the agency to the Ministry for its contribution to overall system performance would be less clear in this model. |
| **Ability to sustain regulatory capability and capacity** | |
| No material difference in short term but may be weaker in long term as regulator builds new functions. Clear 'ring-fencing' of the regulator's funding would mitigate this risk. | Higher profile and autonomy and additional budgetary independence may facilitate attracting and retaining specialist staff required. |
| **Being seen as a trusted and respected regulator** | |
| Both models suitable as this outcome depends on regulator's performance. | |
| Being part of the core Ministry would provide status especially when engaging internationally.<br>Closeness to the core Crown may provide assurance to international counterparts (eg, around data sharing) and regulator could leverage of the Ministry's reputation, networks, and connections. | A chief executive may be seen to have additional status and independence, especially when engaging internationally. |
| **A responsive regulator** | |
| Tighter integration into the Ministry may allow the regulator to leverage off the wider Ministry in responding to challenges to the health and disability system. However, responsiveness to sector may be less strong than departmental agency. | Greater independence risks some divergence from wider system considerations. With greater operational autonomy, a departmental agency may be better placed to respond to changing sector demands and needs than a BBU+ISO. |
| **Cost and establishment** | |
| Less expensive, and arguably more cost-effective.<br>Less work to establish.<br>Less disruption to and demand on current Medsafe resourcing during establishment. | Slightly higher establishment and operating costs.<br>Would require the Public Service Commission undertaking a recruitment process to appoint the agency's chief executive. |

55 On an unweighted score, option 2 (ISO+BBU) and option 3 (departmental agency with an ISO) are effectively tied and both are viable options. However,

my preference for the ISO+BBU model is supported by the greater ability for this regulator form to contribute to the transformed health and disability system's vision of pae ora, given the centrality of therapeutic products to the health of New Zealanders. Establishing the regulator as a BBU+ISO is also likely to result in less disruption to the work of the current regulator in supporting New Zealand's response to COVID-19 and in its delivery of its other regulatory functions, for example those under the Misuse of Drugs Act 1975.

**Implementation**

56 The Ministry will lead the development of regulations and other secondary legislation necessary to complete the regulatory scheme, with significant technical support from Medsafe. This will take place over a 12- to-24-month period from the royal assent of the Bill. The transition period will need to be carefully designed to ensure the day-to-day work of Medsafe continues efficiently, and Medsafe will need more resources to continue its routine business while assisting with setting up the new regulatory regime.

57 Given the scale of implementation activities required to establish the new therapeutics regime (including for natural health products), I propose to bring a transition and implementation plan to a future Cabinet meeting.

58 In the interim, I seek agreement to prepare drafting instructions to give effect to Cabinet's decision on the form of the regulator, and to set out the functions of the regulator. These functions will reflect Cabinet's previous decisions on the objectives for the regulatory scheme and align with the principles and the purpose of the Bill. The detail of the functions section will be finalised by the Parliamentary Counsel Office.

59 I also seek agreement to include an objective for the regulator in the Bill. This will set the mandate for and the broad scope of the regulator's work, which will promote accountability, focus, legitimacy, predictability and consistency. It will also provide a clear statement of its purpose.

60 Establishment, operating and capital costs for the new regulator are discussed in financial implications below.

**Funding arrangements for the new regulator**

61 Approximately 95 precent of regulatory activities undertaken by Medsafe are cost-recovered from industry. All comparable regulators apply some measure of cost recovery, ranging from the Australian Therapeutic Goods Administration, which is 100 percent cost-recovered, to the US Food and Drug Administration which is 50 – 60 percent cost-recovered across a more restricted set of activities.

62 The usual practice is for fees to be applied to pre-market application processes, audits and inspections, and levies to cover other elements of post-market surveillance and monitoring. There are also variations in approach between medicines and medical devices. Natural health products will also need specific consideration.

63 Cabinet has agreed that the regulator will recover its costs through fees and levies where those costs are not met through Crown funding, and that these fees and levies will be reviewed within three years of the first being set [SOC-15-MIN-0049]. This decision was reflected in the exposure draft of the Bill,. The consultation document noted that the split between industry and Crown funding had not yet been decided, but that a significant proportion was likely to be recovered from industry.

64 In December 2018, Cabinet invited me to report back on the cost recovery policy for the new regulatory regime [SWC-18-MIN-0176]. The policy decisions I am seeking comprise the types of charges to be used for the regulator's activities.

**Stakeholder perspectives**

65 Many submitters on the draft Bill indicated that they intended to comment (or comment further) once specific cost recovery proposals were provided. Several submitters considered that industry should not pay charges, while many were broadly supportive, with the following points

65.1 the need for the regulator to have clear performance expectations and transparent reporting, particularly in relation to product approval timeframes, which many submitters considered should be prescribed in regulations

65.2 the need for waivers or reduced fees in situations (eg, orphan medicines[2] niche products and 'non-commercial clinical trials'), with appropriate safeguards to minimise the risk of 'gaming' the system

65.3 that industry should not be charged for policy development, the costs of establishing the new regime or the initial costs during the transition period.

**Proposed funding mechanisms across regulated activities**

66 In line with Treasury guidelines, I propose a funding regime that reduces reliance on funding from general taxation, places costs on regulated parties singly, by group, or generally, and recognises the public and merit goods from effective regulation of therapeutic products and natural health products.

67 I propose that the principles for the funding regime include:

67.1 Effectiveness – the level of funding should be fit for purpose and support a sustainable regulator

67.2 Efficiency – decisions to recover costs should be consistent with the efficient allocation of resources

67.3 Transparency – information on cost drivers and components of charges should be available to stakeholders

67.4 Consultation

[2] Orphan medicines are ones for treating conditions that affect a very small number of people, so would not be commercially viable to have approved in the normal way.

67.5 Equity – stakeholders should be treated equitably and impacts over time should be identified

67.6 Simplicity.

68 I propose that the activities needed for the effective administration of a therapeutic products and natural health products regulatory scheme be funded through the mechanisms shown in Table 1.

**Table 1: Proposed funding mechanisms**

| Activity | Fees | Levies | Crown funding |
|---|---|---|---|
| Policy advice | | | ✓ |
| International engagement and cooperation | | | ✓ |
| Guidance | | | ✓ |
| Development of regulations, rules and notices | | | ✓ |
| Approval, accreditation and certification activities | ✓ | | |
| Export facilitation:<br>- Developing export standards<br>- Developing and maintaining market access<br>- Export certification | ✓ | ✓ | ✓ |
| Monitoring and testing compliance | | ✓ | |
| Audits of individual businesses | ✓ | | |
| Investigations and enforcement action including prosecutions | | | ✓ |
| Drug abuse containment | | | ✓ |

69 It is too soon to seek decisions on the actual cost recovery model, as considerable work is needed to develop this model following the immediate policy decisions, and to incorporate Cabinet's recent decision to include natural health products in the regulatory scheme.

70 I anticipate bringing the proposed cost-recovery model (accompanied by a cost-recovery impact statement) to Cabinet in 2022, as part of the package of regulations relating to the new scheme. Public consultation would follow on this and on other regulations. The report-back on the cost-recovery model would also seek detailed decisions on whether to waive fees or levies in certain circumstances.



## Part 2 – Offences and penalties

71 In March 2016, Cabinet agreed that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings and infringement notices [SOC-16-MIN-0025]. Since then, officials have considered whether civil pecuniary penalties would be appropriate as part of the scheme's compliance and enforcement regime.

72 The therapeutic products and natural health products regulatory scheme is complex and covers a myriad of conduct and various industry participants

such as private individuals and body corporates, large and small. It provides for a regulator, which is discussed above.

73 The regulator needs a range of tools to effectively ensure compliance and take appropriate enforcement action, which includes targeting contraventions by corporates that are motivated by financial gain or an intention to build or retain market share.

74 To ensure these protections are effective and to give the new regime domestic and international legitimacy, a suite of enforcement tools is needed that are flexible, comprehensive, workable and allow a proportionate response.

75 The draft exposure Bill provides the regulator with a hierarchy of criminal enforcement tools to respond to and apply appropriate measures.

76 Further technical and minor drafting on offences and penalties in the draft Bill is needed, but no further policy decisions are required from Cabinet as the changes fall within the scope of the Cabinet decisions already taken. However, the addition of a civil pecuniary penalty regime does require a new Cabinet mandate.

**Civil pecuniary penalties**

77 Although Cabinet made no specific decisions on compliance and enforcement in December 2018 [SWC-18-MIN-0176], the paper noted that the Ministry of Health was considering whether civil pecuniary penalties would be appropriate for this scheme.

78 Civil pecuniary penalties are non-criminal monetary penalties imposed by a court after a trial. Table 2 illustrates their purpose and rationale for use in comparison with other enforcement tools.

**Table 2: Overview of enforcement tools and their rationale**

| Type of enforcement tool | Common rationale for use | Purpose |
|---|---|---|
| Criminal prosecution | To punish and denounce breaches of the law that are intentional, wilful or display a high level of negligence as to the possibility of harm. | Punitive |
| Civil pecuniary penalties | To punish and deter breaches of the law that may not involve fault or moral blameworthiness. | Punitive |
| Enforceable undertakings | Where a negotiated agreement can achieve an overall better change to individual/corporate behaviour to achieve an effective regulatory outcome. | Largely protective in nature – can become punitive if undertaking breached |
| Fines (infringement notices) | To punish and deter usually minor or technical breaches of the law. | Corrective-punitive |
| Administrative actions, e.g., licence suspension/ cancellation, additional conditions, recall orders etc | Intended to protect individuals, the community or the proper functioning of the regulatory system.<br>Note: some administrative actions (e.g., licence and product cancellation) can have as significant a commercial impact on an individual or corporation as a criminal or civil pecuniary penalty. | Protective |
| Other measures not discussed or not proposed for inclusion the Bill | Injunctions to stop or require certain conduct;<br>Public warning notices;<br>Suing for damages or to recover property for those who have suffered loss. | |

79 Reflecting the non-criminal nature of a pecuniary penalty, a trial is conducted under rules of civil procedure and evidence where liability is established on the civil standard of proof (the balance of probabilities), which is lower than the criminal standard of proof (beyond reasonable doubt).

80 The monetary penalty, which can be incurred by both individuals and corporate bodies, is a debt owed to the Crown and can be large — potentially higher than the fines available for many criminal offences.[3] The penalties are intended to punish and deter contraventions.

81 Both civil pecuniary penalties and criminal penalty provisions can apply to the same conduct, although a person cannot be tried for both. As such, the enforcement body would need to determine which form of action to commence.

[3] This is because, in imposing a criminal sentence, a court will generally consider all components of the punishment — including the stigmatising effect of a conviction itself — in setting the size of a fine.

**Analysis of civil pecuniary penalties**

82 Civil pecuniary penalties may be an appropriate enforcement tool where the conduct engaged in is in breach of the law and should be deterred, but where the conduct does not warrant the denunciatory and stigmatising effects of a criminal conviction (for instance, because the breach does not involve fault or moral blameworthiness). As with criminal provisions, a pecuniary penalty can serve to dissuade the defendant, or people more generally, from engaging in similar conduct in the future.

83 I am aware that pecuniary penalties are increasingly prevalent in regulatory regimes targeting commercial behaviour, as civil enforcement is more appropriate than criminal enforcement in most cases of non-compliance with the regulations. They were introduced in New Zealand in the Commerce Act 1986, and have been used in legislation such as the Biosecurity Act 1993, the Anti-Money Laundering and Countering Financing of Terrorism Act 2009 and the Financial Markets Conduct Act 2013.

84 Civil pecuniary penalties can make enforcement of commercial regulation more efficient and effective by avoiding lengthy and expensive criminal litigation, and they can also facilitate settlement. They can also be more appropriate where behaviour or misconduct stems from corporate culture, and it is challenging or unreasonable to expect the regulator to identify a specific individual who possessed the necessary criminal intent.

85 Likewise, if the value of the pecuniary penalty is set high enough it can also diminish any perverse incentive to accept such penalties as a ‘cost of doing business’. This is a highly relevant consideration in the context of the therapeutic products sector where there is a strong possibility of high profit levels through holding a patent or having a monopoly, and the market for goods is constrained.

86 The availability of both civil and criminal liability can also enable a more nuanced distinction in the nature of the offence and between different levels of culpability, which might assist with deterrence and enforcement. For example, the possibility of a large civil pecuniary penalty may motivate a party to seek a negotiated outcome such as an enforceable undertaking.

87 An enforceable undertaking might include other actions such as issuing a public notice, providing refunds to affected customers and agreeing to closer monitoring from the regulator. Rather than escaping punishment, an enforceable undertaking can secure a long-term change in behaviour that results in an effective regulatory outcome with less cost borne by the Crown (e.g., through legal fees and Court time).

88 Civil pecuniary penalties will not be suitable for all breaches of the law. Some breaches may be so flagrant or result in such harm that a criminal prosecution is the only justified course of action.

89 Conversely, other breaches will be minor and of a technical or administrative nature. A regulator should be able to deal with these lower-level breaches according to an appropriate enforcement model (e.g., a responsive regulation approach or the ‘Engage, Encourage, Educate, and Enforce’ model adopted

by Police during COVID alert levels and consistent with modern regulatory best practice).

90 As decisions will be highly fact-specific, I propose that the Bill be drafted to afford the regulator with discretion over which enforcement tool is appropriate.

91 An example of how graduated options might operate is set out in Table 3.

**Table 3: example of decision-making in selecting enforcement option**

| | |
|---|---|
| Factors favouring criminal prosecution<br><br>(Any or some of these might justify a criminal prosecution) | The accused acted wilfully or recklessly; the breach was extensive, repeated or systemic; the conduct was motivated by personal or corporate financial or market-share gain; the conduct resulted in wider harms (to community, Crown revenue, other suppliers, the regulatory system); the offender held a senior role in the company; the overall corporate culture; the community's interest in seeing such conduct punished criminally and the likelihood of securing a conviction (i.e. evidence available to prove offence beyond a reasonable doubt). |
| Factors favouring civil pecuniary penalty | The conduct was less significant than that which would warrant a criminal prosecution but there is still a need to punish the breach in order to denounce the conduct, or deter future behaviour, to compensate for harms or to act against any perverse incentives (e.g., fines as a cost of business) or undo unjust enrichment.<br>A factor may also be the challenge of securing sufficient evidence to prove the offence beyond a reasonable doubt. |
| Factors favouring infringement fine | The individual did not act wilfully or recklessly; the breach was small or one-off; the conduct was motivated by misunderstanding or misplaced compassion; the conduct resulted in little harm; the individual held a junior and non-governance role in the company; there is a low public interest in seeing such conduct punished criminally or the likelihood of securing a criminal conviction is low.<br>An infringement notice may also be appropriate where a speedy or immediate consequence to a technical or administrative breach will result in corrective behaviour. |

92 I consider that civil pecuniary penalties are a useful enforcement option particularly in relation to commercial conduct. I recommend that the Bill include this type of penalty, and as a maximum, incorporate pecuniary penalties for the conduct listed at Appendix Three. These would be an alternative to criminal prosecution or infringement fine.

93 The Ministry of Health will continue to work with the Ministry of Justice and the Parliamentary Counsel Office on the design of the compliance and enforcement regime.

**Part 3 – Direct-to-consumer advertising of prescription medicines**

94 Direct-to-consumer advertising of prescription medicines (DTCA-PM) is one type of advertising regulated under the Medicines Act 1981. Cabinet has

invited a report on whether the status quo should continue, or whether increased regulation is warranted [SWC-18-MIN-0176].

## Previous reviews

95 In 2000 and 2006 the Ministry of Health reviewed the regulation of DTCA-PM, in connection with proposals for a trans-Tasman therapeutic product regulator. No changes to policy or regulatory settings were made as a result.

96 The Bill, which was consulted on in 2019, continues the current policy settings for medical advertising, but provides for stronger regulatory powers and more effective enforcement tools, consistent with earlier Cabinet decisions [SOC-16-MIN-0025]. Consultation on the Bill sought views on this approach.

## Analysis

### How medical advertising is currently regulated

97 All advertising for medicines, medical devices and medical treatments — including DTCA-PM — is currently regulated through complementary government regulation and self-regulation by industry and professional organisations. This is summarised below, and detailed further in Appendix Four.

#### Government regulation

98 Medical advertisements have been comprehensively regulated in New Zealand for nearly 80 years. Current regulation is in the Medicines Act 1981, which prohibits misleading statements and specified types of claims or endorsements. The Medicines Regulations 1984 set controls specifically for prescription medicines. Only approved medicines may be advertised. Medical advertising is also regulated under consumer protection legislation, including the Fair Trading Act 1986 and the Consumer Guarantees Act 1993.

#### Self-regulation by the advertising and therapeutic product industries

99 As with all advertising, DTCA-PM is also regulated through an established framework of industry self-regulation.

##### *Advertising industry*

100 The Advertising Standards Authority develops and administers advertising codes that apply to all its members. These include the Therapeutic and Health Advertising Code, which contains requirements additional to those set in law. The Authority also operates an independent service to adjudicate on complaints from consumers or competitors. Decisions of the complaints board are publicly released.

101 The Association of New Zealand Advertisers provides an independent service to vet health-related advertisements before publication, to ensure they comply with the law and the Therapeutic and Health Advertising Code. It is a cost-recovered service paid for by advertisers. Participating media will not accept a health-related advertisement for publication unless it has been vetted.

***Therapeutic product industry***

102 The peak body for the pharmaceutical industry, Medicines New Zealand, has published an advertising code of practice for nearly 50 years, which is continually updated. Compliance with this code is a condition of membership.

**Compliance**

103 There are very few complaints to the Advertising Standards Authority about prescription medicine advertisements. Between 2012 and 2020, it received fewer than 3 complaints per year (0.4% of all complaints) relating to advertisements for prescription medicines. During that nine-year period, only four advertisements for prescription medicines were either found to be in breach of the code, or were altered by the advertiser before a decision was handed down.

104 Only minimal enforcement action is currently needed in relation to advertising of prescription medicines, suggesting that the combination of government regulation and self-regulation is effective. Medsafe investigates complaints or referrals about medical advertising, including those from the general public and from advertisers' competitors. In the five years to 2020, there were no complaints or referrals related to advertising of prescription medicines by the New Zealand supplier.

**The wider regulatory framework provides additional protection to consumers**

105 Regulation of DTCA-PM sits within the wider framework for regulation and self-regulation of the health sector. The Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights sets standards for communication, information, and informed choice.

106 The Health Practitioners Competence Assurance Act 2003 establishes Responsible Authorities for healthcare professions, such as the Pharmacy Council and the New Zealand Medical Council. The codes of ethics or standards of Responsible Authorities, and the codes of ethics for professional associations such as the New Zealand Medical Association and the Pharmaceutical Society of New Zealand, set expectations in relation to advertising and prescribing.

107 Whether it is appropriate and safe to prescribe a prescription medicine to a particular patient is a matter for the clinical judgement of the prescriber. The decision is their responsibility. Their training, continuing education and ongoing demonstration of competence underpin that judgement, which is made within the framework of professional standards, scopes of practice and prescribing standards.

**Views and evidence about direct-to-consumer advertising of prescription medicines**

108 DTCA-PM attracts attention, particularly when policy settings are reviewed, and there are strong arguments put forward both in support and in opposition to it.

109 There is vocal opposition to DTCA-PM from many representative organisations of healthcare professionals. Many, but by no means all, members share the same view. Two exceptions to this are the Pharmaceutical Society of New Zealand (representing pharmacists), and the Pharmacy Guild of New Zealand (representing pharmacy owners), both of which support continuing to allow regulated DTCA-PM.

110 The principal medicines industry body, Medicines New Zealand, strongly supports continuing the current regulatory regime for DTCA-PM. So do the advertising industry representative organisations. Officials consider that prohibiting DTCA-PM would be likely to have a negative impact on New Zealand's bilateral relationship with the USA, although this is something that officials assess would be manageable.

111 In general, businesses and industry organisations support continuing current regulatory settings. Individual healthcare professionals and general submitters hold a range of views from support, through mixed feelings, to opposition.

**Arguments made against DTCA-PM**

***Consumer information***

112 Manufacturers use DTCA-PM to sell more product. Advertisements are not balanced sources of information, and do not qualify benefit claims adequately or present sufficient information about risks. They can be emotive. In any case, consumers are not qualified to interpret information about prescription medicines, so advertising may undermine consumers' ability to make informed choices.

***Prescriber/patient relationship***

113 DTCA-PM can prompt patients to request a medicine they have seen advertised, regardless of its suitability. This puts pressure on prescribers to comply. It reduces the likelihood or effectiveness of alternative advice, such as to use a different product or make lifestyle changes. Overall, this damages the prescriber/patient relationship. DTCA-PM undermines the role of the prescriber as the 'learned intermediary' between pharmaceutical manufacturer and patient.

***Safe, effective and efficient use of medicines***

114 More prescribing of an advertised medicine can lead to unnecessary use of medication, which can have adverse health outcomes for patients and unnecessarily increase the pharmaceutical budget. DTCA-PM 'medicalises' healthcare, by encouraging patients to seek a pharmaceutical solution to a problem where other interventions might be more effective, or at least more appropriate as an initial step.

**Arguments made in support of DTCA-PM**

***Consumer information***

115 DTCA-PM can create a greater awareness of health conditions, and can promote earlier detection of diseases (e.g. through raising awareness of

symptoms that warrant further investigation). It can also promote health literacy, and reduce the information disparity between the pharmaceutical industry and the patient. Consumers have a right to receive information about medicines from manufacturers.

***Prescriber/patient relationship***

116 Advertising may encourage people to visit their family doctor where they wouldn't otherwise, and encourage them to ask questions when they visit. This can lead to earlier diagnosis of conditions, which can result in earlier treatment and less future pressure on the health system. This may be particularly relevant for ethnic minorities, people in lower socio-economic groups and those in poorer health.

117 Having a more informed society enables better conversations and relationships between patients and prescribers. It is part of a long-standing and widely-supported move towards a partnership model for healthcare, with consumers making active decisions about their healthcare. Informed choice and consent is at the heart of such decision-making.

***Safe, effective and efficient use of medicines***

118 If DTCA-PM does lead to patients asking for named medicines, and this does lead to more prescribing of that medicine, this could be meeting previously undiagnosed needs. The prescribing can be completely appropriate. Early intervention may have positive health outcomes, such as by preventing an otherwise untreated condition progressing to one that requires significant intervention.

119 Prescribers such as GPs report being confident in their ability to resist patient pressure to prescribe particular medicines, and adhere to professional standards for prescribing. They are well equipped for using consultations to address the full range of lifestyle and pharmaceutical measures for treating conditions.

**Evidence**

120 Any policy decisions about DTCA-PM need to be based on sound evidence. Many of the arguments for and against the practice are based on assertions rather than robust evidence. Much of the literature cited in support of a view, particularly for prohibiting DTCA-PM, consists of reviews rather than original research.

121 The Ministry of Health has recently reviewed research into the impacts of DTCA-PM, relying on studies that assessed self-reported behaviour and clinical interactions (rather than intent to seek information or ask for a prescription, hypothetical scenarios and reports on awareness of DTCA-PM or attitudes to it). Although results varied between studies, key findings are:

121.1 DTCA-PM rarely prompted patients to seek an appointment, but often prompted them to seek more information during a scheduled consultation. Other sources of information, such as prompts from family

and friends and information from the internet, are more likely to generate requests for a named product.

121.2 People with lower educational status, poorer health or from an ethnic minority are more likely to schedule an appointment for preventive care or a check-up as a result of DTCA-PM.

121.3 Sometimes DTCA-PM is correlated with an increase in prescribing for the promoted product. Sometimes it is not. It is very difficult to determine whether increased prescribing (and expenditure on medicines) is appropriate because it is treating conditions that had not been diagnosed, or constitutes unnecessary medication.

121.4 A minority of patients sought new or changed medication following exposure to DTCA-PM. Prescribers reported little or no pressure to prescribe as a result. A smaller minority of patients received the named product on request. No studies could assess whether that was appropriate for the patient's needs, or was unnecessary treatment.

121.5 Most patients and prescribers felt that DTCA-PM had no impact on their relationship. Some felt it improved the relationship, and only a minority reported negative outcomes.

121.6 Most studies are dated, and few reflect the rapid rise of DTCA-PM on the internet and the increasing use of social media to share information on medication.

**Global context**

122 It is often said that New Zealand and the USA are the only two countries to allow DTCA-PM. This would not in itself be a reason to change policy settings in New Zealand, but in any case it is not fully accurate. As with the United States, New Zealand allows named products to be promoted in DTCA-PM, in the same way as advertisements for any other legally-available product — naming it and making statements about its use and effectiveness.

123 Many other countries also allow DTCA-PM, but with only some information permitted. There are two main approaches. 'Disease-awareness' advertisements state that a product is available to treat a named medical condition or symptom. They do not name the product, but prompt the consumer to ask their doctor. 'Reminder advertisements' take the reverse approach — allowing advertisements to name a prescription medicine and give information on its strength, dosage, form and price, but not mention its therapeutic purpose, benefits or risks.

124 Maintaining the current policy settings, therefore, would not result in New Zealand adopting a position entirely alien to other countries, nor would it be likely to raise complications for engaging internationally on therapeutic product policy.

**The impact of the internet, including social media**

125 Maintaining the current policy settings is also appropriate given changes in the way consumers receive and engage with advertising generally. Consumers have always received medical information from a variety of sources, including friends, family and medical professionals. Now, the ubiquity of the internet means that consumers have access to more and more information, including from sources that are difficult — if not impossible — to regulate through domestic legislation. More than 85% of New Zealanders search for health information online. One overseas site alone, WebMD, receives more than 300,000 unique New Zealand visitors each month.

126 People in New Zealand see medical advertisements on websites, which is targeted to users based on their browsing history. In addition, social media is used to crowd-source information and advice about conditions and treatments, including prescription medicines. Even if DTCA-PM was prohibited in New Zealand, it would still be practically impossible to regulate either DTCA-PM or open access to medical information via the internet.

127 While practical difficulties alone are not a sufficient basis for not attempting to regulate a practice, the absence of data suggesting that DTCA-PM is creating a risk to individual or public health lessens the justification for further regulation.

**Proposed new regulatory framework**

128 The Bill contains an enhanced status quo. It continues the current policy of allowing tightly-regulated DTCA-PM, while modernising regulation including through:

128.1 a slightly broader scope of what constitutes an advertisement

128.2 being more clearly neutral as to any medium or channel (e.g. print, TV or internet)

128.3 a new provision for infringement offences

128.4 penalties that are graded according to the seriousness of offending and level of intent

128.5 significantly increased penalties.

129 A specific enforcement tool for advertising will also be available, as the regulator will be able to issue an ‘advertising remediation order’ in respect of any non-complying advertisement. This would require an advertiser to withdraw, retract or correct an advertisement, and do anything to prevent or reduce harm the advertisement might pose.

130 Under my proposal, the existing framework of self-regulation by the advertising industry, therapeutic product industry and healthcare professional organisations will continue.

## New Zealand Bill of Rights Act

131 The New Zealand Bill of Rights Act 1990 affirms the right of everyone to freedom of expression, including the freedom to seek, receive and impart information and opinions of any kind in any form. Full or partial prohibition on DTCA-PM would impinge on this right by limiting the ability for individuals to seek and receive information. Any justification for it would have to be supported by robust evidence showing that the prohibition met the threshold of being "demonstrably justified in a free and democratic society".

132 As noted above, reliable information about the behavioural impacts of DTCA-PM is scarce. Robust evidence on the health or economic outcomes of exposure to DTCA-PM is rare. The evidence that does exist shows that DTCA-PM is likely to have some health benefits, especially for minority communities. There may be negative health outcomes if overprescribing occurs, but evidence for that is weak. Claims of a negative effect on the prescriber/patient relationship are not well-founded.

133 Prohibiting DTCA-PM would be inconsistent with the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990. In particular, given the limited evidence available, it does not seem that the limitations on freedom of expression imposed by a prohibition would be proportionate, and therefore would not be justifiable in a free and democratic society.

## Treaty of Waitangi

134 There have been few studies of the potential impact of DTCA-PM on different population groups, however, the evidence that does exist indicates that DTCA-PM may improve equity of health outcomes for Māori by raising awareness of diseases and possible treatments.

135 Pharmac aims to eliminate inequities in access to medicines by 2025. As part of its work in this area, it has identified one of the drivers of medicine acceptability as patients/whānau being empowered with knowledge about medicines. One high-level outcome of *Whakamaua: the Māori health action plan 2020 – 2025* is for iwi, hapū, whānau and Māori communities being able to exercise their authority to improve their health and wellbeing.

## Is increased regulation of direct-to-consumer advertising of prescription medicines warranted?

136 The evidence to support full or partial prohibition of DTCA-PM is weak. The fact that few countries permit full-product DTCA-PM is not itself a compelling reason to prohibit the practice.

137 A complete prohibition on DTCA-PM would, in any case, be only partially effective. New Zealanders widely seek health information on the internet, and will continue to be exposed to DTCA-PM on overseas websites. This is likely to increase, as in the United States DTCA-PM using traditional media (TV, print, billboards, radio) is static or decreasing, but DTCA-PM via the internet is increasing markedly. If regulated DTCA-PM continued to be permitted in New Zealand, advertising on New Zealand internet sites would remain regulated.

138 In New Zealand, advertising of a product is completely prohibited only when the harm it causes clearly outweighs any benefits (eg, tobacco products). Advertising of products with a balance of benefits and risk (eg, alcoholic drinks, fast food) is regulated, but not prohibited. Advertising of complex products with significant impact on people's lifestyles (eg, financial products such as Kiwisaver) is also regulated but not prohibited. Prohibiting DTCA-PM would be inconsistent with the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990.

**Recommended course of action**

139 Healthcare, the practice of medicine, provision of medicines and management of medical information are big business. The pharmaceutical industry is the largest funder of medical research, and provides life-saving and life-changing medicines. It operates in New Zealand in an economy with open market settings. Every day, healthcare providers navigate the interface between their profession and the commercial realities of the health sector.

140 Continuing the regulatory and policy settings that have been in place and developed over the past 80 years would best meet the health objectives set out in this analysis. While I anticipate that this decision would disappoint many opponents to DTCA-PM, it will be supported by businesses that operate in compliance with the current regulatory regime.

141 I consider that an enhanced status quo would better achieve the desired outcomes than completely or partially prohibiting direct-to-consumer advertising of prescription medicines.

**Financial implications**

142 I am not seeking specific financial decisions in this paper; s 9(2)(f)(iv) [redacted]

143 Ensuring that the regulator's funding is protected and could not be used for other function of the Ministry (except to meet the regulator's share of overheads) would provide important budgetary independence for the regulator and underpin a sustainable regulatory regime in the longer term. It would also support accountability and transparency for Crown funding and other revenue from cost recovery by the regulator.

144 The new regulator will have a substantially larger scope of responsibilities than the current regulator. Its funding will need to be appropriately sized to reflect its new role and functions, and to ensure it can sustain its regulatory capabilities into the future. Some costs will be recovered via fees and levies, but additional Crown funding will be required.

145 s 9(2)(f)(iv) [redacted]

s 9(2)(f)(iv) [redacted]

146 s 9(2)(f)(iv) [redacted]

147 There are no financial implications with including civil pecuniary penalties in the Bill.

148 There are no financial implications from continuing with the same policy settings for DTCA-PM.

## Legislative implications

149 My recommendations will be implemented in the Bill, including stablishing the regulator and its functions, powers and duties; including civil pecuniary penalties; and retaining relevant provisions regarding DTCA-PM. The Bill currently has a category 5 (instructions to be provided to PCO in the year) on the 2021 legislation programme; however, I now propose that the Bill be introduced before the end of 2021. A full suite of secondary legislation will be required to operationalise the new therapeutic products and natural health products regulatory scheme.

150 Cost-recovery arrangements will be incorporated into regulation as part of the package of regulations relating to the new regulatory scheme.

151 At this time, I do not propose to make any changes to the existing regulatory regime established under the Misuse of Drugs Act 1975, the Psychoactive Substances Act 2013, or to Medsafe's current responsibilities under the medicinal cannabis scheme or residual role for radiation safety.

## Impact analysis

### Regulatory impact statement

152 Cabinet's impact analysis requirements apply to the proposals relating to the institutional form of the therapeutic products regulator and cost recovery for the regulatory regime, and to the inclusion of a civil pecuniary penalty regime. There are no accompanying regulatory impact statements, and the Treasury has not exempted the proposals from the impact analysis requirements. Therefore, it does not meet Cabinet's requirements for regulatory proposals.

153 On behalf of respective Ministers, the regulatory impact analysis team at the Treasury and Ministry of Health have agreed that supplementary analyses will be provided before the Cabinet Legislation Committee considers approving introduction of the Bill s 9(2)(f)(iv) [redacted]

154 The main decisions on the cost-recovery model will be made at a later date, and will be accompanied by a cost recovery impact statement then.

155 Treasury has confirmed that a regulatory impact statement is not required in relation to direct-to-consumer advertising of prescription medicines, as this proposal continues and updates the status quo.

#### Climate implications of policy assessment

156 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

#### Implications for Māori

157 To achieve the high-level vision of pae ora, it is essential that the regulator be designed, established, and operated in ways that meet the Crown's obligations under the Treaty of Waitangi. Equitable access to therapeutic and natural health products is a critical part of improving Māori health outcomes.

158 The Crown has an obligation to protect traditional Māori healing practices (rongoā Māori). Policy settings for the regulation of therapeutic products and natural health products will have an influence on partnership and participation in the systems that influence Māori health outcomes.

159 Establishing the regulator as part of the core Crown (e.g., a BBU+ISO), with links to the Ministry of Health, will promote alignment of the regulator's operation with key Ministry strategies, including *Whakamaua: Māori health action plan 2020–2025*.

160 There have been few studies of the potential impact of direct-to-consumer advertising of prescription medicines (DTCA-PM) on different population groups, though the evidence that does exist indicates that DTCA-PM may be more beneficial for Māori.

#### Implications for other population groups

161 There is some evidence that DTCA-PM is more beneficial for disadvantaged sectors of society (such as those with lower education levels or poorer health status), some ethnic minorities and women.

162 There are no specific population implications for the civil pecuniary penalty regime, as it would apply regardless of the legal personality of the defendant (e.g., legal or natural person) or, in the event of a natural person, their ethnicity.

### Human rights

163 The proposals in this paper are not inconsistent with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

## Consultation

*Establishing a new regulator and funding settings*

164 The Public Service Commission (PSC), Treasury, Department of the Prime Minister and Cabinet, the Ministry of Business, Innovation and Employment (MBIE), Parliamentary Counsel Office (PCO), Ministry of Justice and the Commerce Commission were consulted on the proposals in this paper.

165 On the advice of the PSC, this paper is now a report-back from the Minister of Health, rather than a joint paper with the Minister for the Public Service.

166 Agency input on the content of this paper was considered and adopted throughout. No substantive concerns were raised with either a BBU+ISO or departmental agency model. Advice provided by the Treasury on the Budget 2023 process for health was noted and the paper updated accordingly.

167 PCO raised significant concerns about the timeframes for drafting the final Therapeutic Products Bill and the planned timeline for the Bill's introduction to Parliament s 9(2)(f)(iv)

*Offences and penalties*

168 The Ministry of Health consulted with the following agencies in the development of this paper: Treasury, Ministry of Justice, Ministry of Business, Innovation and Employment, Commerce Commission, Department of the Prime Minister and Cabinet, and the Parliamentary Counsel Office. Changes have been made where necessary.

169 The Ministry of Justice provided initial feedback on the inclusion of civil pecuniary penalties in the Bill. The Ministry of Health will work closely with Ministry of Justice and PCO to refine the use of civil pecuniary penalties.

170 The Ministry of Health conducted public consultation on offences and penalties during consultation on the Bill in 2019, but did not seek specific comment on civil pecuniary penalties.

*Direct-to-consumer advertising of prescription medicines*

171 The Ministry of Health consulted with the following agencies in the development of this paper: the Ministry of Business, Innovation and Employment; Department of the Prime Minister and Cabinet; Commerce Commission and Ministry of Foreign Affairs and Trade.

172 The Ministry of Health conducted public consultation on the regulation of direct-to-consumer advertising of prescription medicines during consultation on the Bill in 2019. This built on earlier consultation on the topic in 2006 and 2000.

## Communications

173 There is considerable interest from industry and health sector stakeholders in the development of the new therapeutic products and natural health products

regulatory scheme. Further announcements will be made at the time the draft Bill is submitted to the House.

**Proactive release**

174 I intend to release this Cabinet paper when the Bill is introduced to the House, in accordance with guidance in Cabinet Office circular CO (18) 4.

**Recommendations**

The Minister of Health recommends that the Committee:

1 **note** that this paper is part of work to modernise New Zealand's therapeutic products and natural health products regulatory scheme, central to which is repealing the Medicines Act 1981 and replacing it with the Therapeutic Products Bill

2 s 9(2)(f)(iv) [redacted]

*Establishing a new regulator and funding settings*

3 **note** that Cabinet invited the Minister of Health and the Minister of State Services to report back on the recommended institutional form of the therapeutic products regulator and cost-recovery policy for the regulatory scheme [SWC-18-MIN-0176]

4 **note** that either a branded business unit or departmental agency, each with an independent statutory officer, would meet the Government's objectives for a regulator that is independent, transparent, accountable, able to sustain regulatory capability and capacity, responsive and flexible

5 **note,** however, that the branded business unit with an independent statutory officer is less likely to result in fragmentation in the sector and more likely to make a stronger contribution to system coherence and realising the Government's vision of pae ora/health futures for all New Zealanders

6 **agree** that the therapeutic products and natural health products regulator be established a branded business unit of the Ministry of Health, with an independent statutory officer

7 **agree** the Director-General must appoint a person as the independent statutory officer, as an employee of the Ministry of Health, after being satisfied that the person has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the role

8 **note** that, regardless of entity form, the regulator may require discretion to meet the market for remunerating specialist roles, and that this is justified by the cost-recovery arrangements

9 **note** the importance of ensuring that the regulator's funding is protected and cannot be used for other function of the Ministry (except to meet the regulator's share of overheads)

10 **note** that the principles guiding the development of the cost-recovery model will include effectiveness, efficiency, transparency, consultation, equity and simplicity

11 **agree** that the new regulatory scheme will be funded through Crown funding and cost recovery consistent with the division in Table 1 [para 68] as follows:

11.1 fees will be charged for approval, accreditation and certification activities, export certification and audits of individual businesses

11.2 levies will be charged for developing and maintaining market access, and monitoring and testing compliance

11.3 Crown funding will be applied to policy advice, legislative development, international engagement and cooperation, guidance, development of export standards, investigations and enforcement action including prosecutions, and drug abuse containment

12 **agree** that the cost-recovery model include provision for exemptions and waivers from fees and levies and that these may be granted on an individual or class basis

13 **agree** that the Minister of Health issue drafting instructions to amend the draft Therapeutic Products Bill to give effect to the Committee's decision over the entity form, and including the regulator's functions and objectives in the Bill

14 **invite** the Minister of Health to report back at a future Cabinet meeting in the second half of 2022 on the recommended cost-recovery model as part of the package of regulations relating to the new scheme, s 9(2)(f)(iv) [redacted]

15 **note** that in addition to costs associated with the transition to a new regulatory regime, the regulator will require a higher level of operational funding to match its increased regulatory role

16 s 9(2)(f)(iv) [redacted]

17 s 9(2)(f)(iv) [redacted]

18 s 9(2)(f)(iv) [redacted]

*Offences and penalties*

19 **note** that Cabinet previously agreed that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings and infringement notices [SOC-16-MIN-0025]

20 **agree** that a civil pecuniary penalty regime be included in the Bill

21 **note** that the Ministry of Health will continue to work with the Ministry of Justice to identify those existing offences within the Therapeutic Products Bill where the conduct engaged in is in breach of the law and should be deterred, but does not warrant the denunciatory and stigmatising effects of a criminal conviction

22 **agree** that the Minister of Health issue drafting instructions to the Parliamentary Counsel Office for the Therapeutic Products Bill to give effect to Cabinet's decision.

*Direct-to-consumer advertising of prescription medicines*

23 **note** that this paper fulfils the requirement to report to Cabinet on whether or not increased regulation of direct-to-consumer advertising of named prescription medicines is warranted [SWC-18-MIN-0176 and SWC-19-MIN-0088]

24 **note** that direct-to-consumer advertising of prescription medicines is effectively regulated in New Zealand now through existing provisions of the Medicines Act, general consumer protection legislation, self-regulation by the advertising industry and the therapeutic product industry, and both government regulation and professional standards for healthcare professionals

25 **agree** to retain the approach taken in the draft Therapeutic Products Bill, which is to continue the current policy settings for regulating direct-to-consumer advertising of prescription medicines, and provide the new therapeutic products regulator with updated regulatory tools.

Authorised for lodgement

Hon Andrew Little

Minister of Health

## Appendix 1: Key themes from submissions on the Therapeutic Products Bill

| Topic | Key themes |
|---|---|
| ***Medical devices*** | |
| Ensuring harmonisation with international regulation and device appropriate provisions | Submitters from the medical device sector are concerned to ensure that the new regulatory scheme for their products is aligned with international approaches and uses familiar concepts and terminology. |
| Transitioning into the scheme | The medical device sector raised concerns about the transition approach and the proposed timeframe. The sector also felt that either the regulatory scheme or Pharmac's procurement process should be delayed so they did not happen at the same time. |
| ***Clinical trials*** | |
| Cost and timeliness | Many submitters sought reassurance that the regulatory process would run in parallel with the ethics approval and be speedy, risk-based, and not stifle innovation through regulatory delays or a burdensome application process. DHB submitters were particularly concerned about potential impacts on observational studies and investigator-led trials. |
| Medical devices | Submitters commented on the requirement that clinical trials of medical devices would, for the first time, require approval by the regulator. Some were concerned to ensure that requirements were not onerous and duplicative of other processes. Others were very supportive and see the lack of this requirement as a significant gap in the current arrangements. |
| Technical matters | Submitters asked for the definition of *clinical trial* to be aligned with international norms, with some DHB submitters considering it was currently too broad and would capture some clinical practices. They also sought clarity on a number of specific issues. |
| ***Hospital settings*** | |
| Prescribing, compounding, dispensing, and administering | Many DHB submitters asked for more tailored arrangements to reflect the way medicines are handled within a hospital, including use of imprest supplies in hospitals and the way medicines are charted, prepared for administration, and then administered. |
| Medical devices made and put into service | Several submitters commented on the importance of the oversight of hospital practices including manufacturing devices for use in surgery so they are fit for purpose. |
| ***Health practitioner authorisations*** | |
| Ability of prescriber to dispense and supply | Some submitters expressed concerns about allowing health practitioner prescribers to dispense and supply medicines. These submitters emphasised the importance of separating prescribing from dispensing and supply, as this provides an additional clinical check of the prescription. They commented that the same requirements that apply to pharmacies should apply to health practitioners if they dispense and supply (ie, a licence). |
| Process for establishing a professions' authority to prescribe | There was general support for the proposal to establish the authority to prescribe via the relevant health practitioner profession's scope of practice (rather than listing professions that can prescribe within the Bill or regulations under it). There were a number of concerns and questions raised, which largely reflected confusion on what the change would mean and how it would be implemented. |

| Topic | Key themes |
|---|---|
| Ability for health practitioners to supply category 3 medicines | Reponses were mixed as to whether health practitioners (that are not prescribers) should be able to supply Category 3 (pharmacy) medicines.<br>Many submitters supported it as they considered it would improve access. A larger number of submitters did not think it would be appropriate. They expressed concerns that health practitioner practices do not have the same controls and monitoring as pharmacies (eg, temperature monitoring and oversight by the pharmacist of the medicines storage and supply). |
| Ability for health practitioner workers to supply category 3 medicines | While there was some support, the majority of submitters did not support allowing health practitioner workers (those working in a practice that are not registered health practitioners) to supply category 3 (pharmacy) medicines.<br>This was because they do not have the same training as pharmacy workers, the health practitioner would be unable to provide suitable supervision (as they are generally in a consulting room) and these premises are not licensed, so do not have the same standards and monitoring as pharmacies. |
| Sector specific concerns | Submitters from particular health care settings raised concerns about how the authorisations or requirements would apply to them and outlined the authorisations they consider they need. |
| ***Pharmacist & pharmacy worker authorisations*** | |
| Definition of dispensing | Submitters expressed concern that the definition of dispensing:<br>a) doesn't include reference to the clinical practice aspects associated with dispensing<br>b) defines dispensing as part of manufacturing |
| Supervision requirements for pharmacy workers | The authorisations for pharmacy workers were generally supported. There was some confusion regarding how the authorisations would apply to different pharmacy workers roles and requests for a lower level of supervision being allowed in particular circumstances. |
| ***Pharmacy regulation*** | |
| Enabling different distribution and supply arrangements | Submitters were generally supportive of enabling new pharmacy models as long as these were focused on promoting better patient outcomes.<br>There was some concern regarding whether medicines could be dispensed safely outside a pharmacy dispensary.<br>There was also concern that the Bill enables a split between the dispensing and advice activities within a pharmacy. |
| Remote pharmacist presence and supervision | Feedback was mixed. Overall, there was slightly more support for allowing remote pharmacist presence and supervision (with some submitters including caveats or limiting their support to particular situations). Reasons for support included advances in technology, opportunities for new models, and as a way to provide clinical advice to people that have difficultly accessing traditional pharmacy services.<br>Those that did not support it highlighted the importance of face-to-face consultation and direct oversight. |

| Topic | Key themes |
|---|---|
| Pharmacy ownership and licensing | The majority of submitters, particularly those within the pharmacy sector, supported the option of strengthened accountability through pharmacist ownership and effective control (including the five-pharmacy limit). They expressed concerns about the impact that removing the majority ownership requirement would have on the quality of services and safety. For some, support was contingent on removing the requirement that the pharmacist receive the majority of financial benefit. These submitters supported retaining a pharmacist ownership requirement based on stronger and clearer requirements for the pharmacist to have the majority of governance rights and effective control of the pharmacy.<br>Some submitters supported the option of open ownership with licence requirements targeted at pharmacist control of quality systems and practices and considered system controls more important than ownership for ensuring quality, and that replacing the ownership requirement with specified requirements for responsible pharmacists would increase efficiency and access and enable different pharmacy service models to develop. |
| Prescriber interest in pharmacies | Submitters generally supported retaining the restriction on prescribers from taking any interest in pharmacies. |
| ***Direct-to-consumer advertising of prescription medicines*** | |
| Direct-to-consumer advertising of prescription medicines (DTCA-PM) | DTCA-PM attracted a lot of interest in the consultation with strong views both for and against. Generally speaking, submitters from the advertising sector, industry sector, and parts of the pharmacy sector supported regulated DTCA-PM continuing whereas health practitioners and their representative groups did not. Consumers were both for and against, but generally were opposed to it.<br>The main arguments in favour of DTCA-PM were that advertisements are informative, empower consumers with knowledge, encourage dialogue with health practitioners, and enable informed choices about treatment options.<br>Arguments against DTCA-PM included that advertisements, by their very nature, are primarily aimed at encouraging consumers to buy products and can provide an unbalanced view of prescription medicines by emphasising benefits over harms leading to possible pressure on prescribers, unnecessary prescriptions, and potentially increased costs to consumers and the health system. Some submitters noted that although not generally the subject of DTCA-PM, prohibition is aligned with antimicrobial resistance initiatives. |
| ***Product approvals and changes to approved products*** | |
| Who can apply | Some submitters were concerned that the requirement for an approval-holder to be either normally resident in NZ, or a body incorporated in NZ, would have a negative impact on companies that are an affiliate of a multi-national or Australian company.<br>Some submitters were also concerned that they do not have a direct contractual relationship with the manufacturer, as that is usually managed through corporate headquarters. |
| Process for obtaining a product approval | While understanding that these will be set in legislative instruments under the Bill, submitters sought greater information and clarity about the processes and requirements for obtaining a product approval. |
| ***Access to unapproved medicines*** | |
| Requiring a Special Clinical Needs Supply Authority (SCNSA) for off-label use of medicines | Some submitters support the provisions in the draft Bill that would require a prescriber to complete a SCNSA as part of a prescription for an off-label use of a product (ie, when an approved product is being sought for a particular use, or a population, not covered by the approval). These submitters considered it would ensure patients received appropriate advice and care to make informed decisions in these situations.<br>The majority of submitters expressed concerns or indicated they did not support it. These submitters considered it would be impractical and burdensome in practice, particularly in hospitals. They highlighted a number of areas (eg, paediatrics) where off-label use of medicines is very common. |

| Topic | Key themes |
|---|---|
| Authorising only medical practitioners to issue a SCNSA | There was mixed support to the proposal to restrict the ability to issue a SCNSA for medicines not approved in New Zealand, to medical practitioners, but allowing other prescribers to prescribe the unapproved medicine for that patient once a SCNSA has been issued. There were some concerns that the requirement for a SCNSA would be too burdensome.<br>Some submitters, including those representing particular health practitioner prescriber groups, requested that all prescribers be able to issue SCNSA as long as the medicine is within their scope of practice.<br>These submitters considered the relevant health practitioner prescriber has the most knowledge regarding the medicines suitable for those conditions / diseases of their patients. Requiring the patient to go to a medical practitioner for a SCNSA when the required medicines was unapproved would add costs, and not add any clinical benefit. |
| ***Personal import authorisations*** | |
| Personal import | There was generally support for the proposal to disallow the personal import of category 1 (prescription) medicine by courier / mail, but permit for category 2 (pharmacist), 3 (pharmacy), & 4 (general sale) medicines and medical devices. There was some support for widening the prohibition to include category 2 and 3 medicines.<br>A few submitters opposed the prohibition on the personal import by courier / mail of prescription medicines due to concerns for patients or patient groups dependent on medicines not funded here.<br>Views on whether it would be appropriate to use permits to authorise personal import in particular situations were mixed, but were slightly more in favour. |
| ***Scope*** | |
| Merits review | Most submitters' comments related to the timeframes for the appeal process and views from some submitters that anyone should be able to appeal a decision, not just the aggrieved applicant. |
| ***Scope of products*** | |
| Exclusion of Natural Health Products (NHPs) | While submitters were not asked for feedback on the regulation of natural health products, some chose to comment. Some commented that they considered NHPs should be regulated under the Therapeutic Products regulatory scheme, while others commented that they should not. The Ministry is currently exploring options to regulate natural health products. |
| Sunscreens | With the exception of those from the cosmetics sector, submitters supported regulating products used as primary sunscreens. The cosmetics sector generally supported mandatory compliance with a standard but believed it should be able to choose to meet a US, European or ANZ standard. |
| Device-like products | There are a number of products that have similar characteristics and risks to medical devices, but have only a cosmetic, not therapeutic, purpose (eg, coloured contact lenses that have no corrective power and lasers for hair removal). Some countries regulate such products as a special category of device under their medical device regulatory schemes.<br>Submitters were asked whether they thought such products should be subject to strengthened regulation and many commented that they should be brought under the therapeutic products scheme. |

## Appendix 2: comparison of models for entity form

All measures are relative to a branded business unit (*status quo*).

0 = neutral/no change; + = improvement; - = less than status quo

| Criteria | Branded business unit (status quo) | Branded business unit with ISO | Departmental agency with ISO | Crown entity |
|---|---|---|---|---|
| Independence[4] | 0 | ++ | +++ | +++ |
| Cost-effective (size and scale – proportionate to problem) | 0 | 0 | - | --- |
| Transparency | 0 | + | ++ | +++ |
| Accountability – decision-making | 0 | + | ++ | + |
| Sustaining regulatory capability and capacity | 0 | + | ++ | ++ |
| Responsiveness and flexibility | 0 | + | ++ | ++ |
| Trusted and respected | 0 | ++ | ++ | ++ |
| Coherence within health system | 0 | + | - | -- |
| Cost and timeliness of establishment | 0 | - | -- | ---- |
| **Score (unweighted)** | | **8** | **9** | **4** |

[4] Four aspects drawn from the Productivity Commission report *Regulatory Institutions and Practices* 2014.

## Appendix 3: Offences that could incur civil pecuniary penalties

| Clause in Bill (exposure draft 2018) | Offence |
|---|---|
| 51 | Product approval required to import or supply |
| 52 | Sponsor's consent required to import approved product |
| 53 | Authorisation required for controlled activity |
| 55 | Persons in supply chain must comply with regulations |
| 81 | Prohibited product without authorisation |
| 83 | Advertising |
| 87 | Notifying regulator of suspicion of tampering |
| 88 | Misrepresentation about therapeutic product |
| 89 | Holding out |
| 92 | Misleading information in records |
| 116 | Sponsor of approved product must ensure compliance with approval |
| 117 | Sponsor must ensure compliance with product standards |
| 118 | Sponsor must comply with regulations |
| 153 | Licensee must ensure responsible person has authority and resources |
| 154 | Licensee must ensure health practitioner has authority and resources |
| 155 | Licensee or manager must not induce health practitioner to act unprofessionally |
| 157 | Protection of responsible person from retaliation |
| 159 | Licensee must ensure only authorised persons carry on pharmacy activities |
| 163 | Compliance with recall order |
| 167 | Compliance with advertising remediation order |
| 169 | Compliance with directions order |
| 171 | Compliance with product prohibition order |
| 197 | Misleading information to regulator |
| 198 | Compliance with investigative requirements |

| Clause in Bill (exposure draft 2018) | Offence |
|---|---|
| 199 | Obstructing regulator |

## Appendix 4: How medical advertising is currently regulated in New Zealand

All advertising for medicines, medical devices and medical treatments — including direct-to-consumer advertising of prescription medicines (DTCA-PM) — is regulated through complementary systems of government regulation and self-regulation by industry and professional bodies.

### Government regulation

Medical advertisements have been comprehensively regulated in New Zealand for nearly 80 years. The Medical Advertisements Act 1942 introduced a full set of regulatory measures for medical advertisements, laying the foundations for current controls.

#### Current regulation

The Medicines Act 1981 prohibits misleading statements, claims that a product has benefited the health of a person or class of persons, and endorsements by a health practitioner. There is tighter regulation of advertising relating to specified serious conditions.

The Medicines Regulations 1984 contain controls specific to advertising of prescription medicines. These include requiring a statement that the medicine is prescription-only, the name of each active ingredient, a statement that the medicine has both benefits and risks, and a statement about where to find out more about these.

All medical advertising is also regulated under consumer protection legislation. This includes the Fair Trading Act 1986, which requires that advertising is not misleading or deceptive, and the Consumer Guarantees Act 1993, which requires that goods match the description provided in advertising.

#### Enforcement

Only minimal enforcement action is needed in relation to advertising of prescription medicines. Medsafe investigates complaints or referrals about medical advertising, including those from the general public and from advertisers' competitors. In the five years to 2020 it conducted 462 investigations with an advertising component. Only 45 involved approved medicines, none of which related to advertising of prescription medicines by the New Zealand supplier.

### Industry self-regulation

As with all advertising, medical advertising is also regulated through an established framework of industry self-regulation.

#### Advertising industry

The Advertising Standards Authority (ASA) is a self-regulatory body with wide representation from the advertising sector. It administers the ASA advertising codes that apply to all of its members. These include the Therapeutic and Health Advertising Code, which is based on and supplements the advertising provisions in the Medicines Act and Medicines Regulations.

The ASA also operates an independent service to adjudicate on complaints from consumers or competitors. Decisions of the complaints board, which has public (majority) and industry representation, are made publicly available. Advertisers sometimes alter or withdraw advertisements after a complaint is made but before the board makes a decision.

The Association of New Zealand Advertisers (ANZA) — the peak body for New Zealand advertisers — provides the Therapeutic Advertising Pre-Vetting Service (TAPS), to ensure before publication that advertisements comply with both the law and the ASA Therapeutic and Health Advertising Code. It is a cost-recovered service paid for by advertisers. Participating media will not accept an advertisement for publication unless it has been vetted. In 2018 the ASA set up a complementary service to provide advice to advertisers and agencies on the content and placement of advertisements.

Self-regulation of medical advertising has been progressively strengthened. A 1998 Medsafe review of direct-to-consumer advertisements showed low compliance (33%) with regulatory requirements. In response ANZA introduced a voluntary advisory service for members. Although compliance with the law soon doubled (to 69%), this was not seen by Medsafe or the industry as sufficient. The voluntary advisory service was replaced in 2000 with the current pre-vetting service that members are obliged to use.

**Therapeutic products industry**

Therapeutic product industry groups have their own codes of practice. Medicines New Zealand (the peak body for pharmaceutical companies) has published an advertising code of practice for nearly 50 years, which is continually updated. The Medical Technology Association of New Zealand (the peak body for medical device companies) has a similar code of practice for advertisements. Both organisations make compliance with these codes of practice a condition of membership

**Compliance**

Complaints to the ASA about prescription medicine advertisements are minimal. Between 2012 and 2020, it received an annual average of 811 complaints about 538 different advertisements. Only 67 per year related to advertisements covered by the Therapeutic and Health Advertising Code, and of these fewer than 3 per year (0.4%) related to advertisements for prescription medicines.

Over the nine-year period, a total of four advertisements for prescription medicines were either found to be in breach of the code, or the advertiser altered the advertisement before a decision was handed down.

## The wider regulatory framework

Regulation of medical advertising sits within the wider framework for regulation and self-regulation of the health sector. The Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights sets standards for communication, information and informed choice.

The Health Practitioners Competence Assurance Act 2003 establishes Responsible Authorities for healthcare professions, such as the Pharmacy Council and the New Zealand Medical Council. Responsible Authorities' codes of ethics or standards set expectations for truthful advertising that upholds public trust in the professions, and acceptance of promotions by commercial entities including pharmaceutical manufacturers. Professional associations such as the New Zealand Medical Association and the Pharmaceutical Society of New Zealand also have codes of ethics with relevant provisions.

## Prescriber competency

Whether it is appropriate and safe to prescribe a prescription medicine to a particular patient is a matter for the clinical judgement of the prescriber. The decision is their responsibility. Their training, continuing education and ongoing demonstration of competence underpin that judgement, which is made within the framework of professional standards, scopes of practice and prescribing standards.