Submission on the therapeutic products regulatory scheme

To: Ministry of Health

Date: 1 May 2019

Commerce Commission submission on the therapeutic products regulatory scheme

Introduction

1. The Commerce Commission (the Commission) appreciates the opportunity to make a submission on the therapeutic products regulatory scheme (the scheme) consultation document and draft Therapeutic Products Bill (the draft Bill). We look forward to our ongoing engagement with the Ministry of Health (the Ministry) on this topic.

2. The Commission is responsible for enforcement of the Commerce Act 1986 and the Fair Trading Act 1986. It is in this context that we provide comment on matters raised in the consultation document and the draft Bill.

Executive summary

3. Broadly speaking, the Commission supports the establishment of a sector specific regulator (the TPR) for the therapeutics products sector.

4. Our submission is divided into three parts. The first part addresses a number of framework issues, in particular how the draft Bill will interact with the Fair Trading Act. The draft Bill places conduct under the jurisdiction of the TPR that, to date, in the absence of a sector specific regulator has fallen to be enforced by the Commission under the Fair Trading. We have set out our understanding of how the two regimes will work together.

5. We comment on:

    5.1. Our understanding of how the different purpose statements in the two statutes will work together, noting that if the intention of the draft Bill differs from our understanding, additional clarification would be of assistance to the Commission, the TPR and the courts;

    5.2. The need for information sharing powers between the Commission and the TPR and;

    5.3. The desirability of a consistent approach to penalties across the two regimes, providing consistent incentives and deterrence for similar conduct. To date, the Commission has taken the position that health credence claims are at the very serious end of offending. We propose that the offences and penalties provided under the draft Bill should reflect this established precedent.

6. The second part deals with specific matters relating to the Commerce Act 1986. Consistent with the purposes of the Commerce Act which are to promote competition for the long term benefit of end users we:

6.1. Recommend a fifth principle be added to clause 4 of the draft Bill including promotion of competition as one of the matters guiding the TPR's exercise of powers;

6.2. Draw attention to studies by international regulators such as the United Kingdom Office of Fair Trading considering regulation of pharmacy ownership and recommend that a fit and proper person ownership model is applied for pharmacy ownership to improve competition and reduce consumer costs;

6.3. Note the 2012 amendments to the Agricultural Compounds and Veterinary Medicines Act 1997 no longer restricting the sale of restricted veterinary medicines to veterinarians only and recommend that the Ministry ensure the scheme does not compromise the intent of these amendments.

7. The third part outlines recent examples of matters considered by the Commission in relation to products that are therapeutic products under the draft Bill. We also share our experience in relation to the proposed defences of reliance on information from another person and compliance with a specified standard.

8. In making this submission, the Commission is aware that pharmaceutical markets are subject to a range of market failures that do not afflict most other consumer goods e.g. consumers do not have enough information or scientific knowledge to make fully informed decisions on the effects of the products that they purchase. Furthermore, there are externalities associated with the consumption of pharmaceuticals e.g. overuse and drug resistance, pollution and anti-social behaviour, that may require regulation. These considerations are reflected in the Commission's submissions.

I. Framework issues

A sector specific regulator for therapeutic products

9. The draft Bill creates a sector specific regulator covering all therapeutic products with responsibilities that include oversight of behaviours (misleading conduct) around promotion of such products. For many of these products, the Fair Trading Act, through its general prohibitions on the making of false or misleading representations (made in trade) is the main legislation currently regulating such activity. The Commission welcomes the establishment of a sector specific regulator.

10. The different purpose statements of the draft Bill and the Fair Trading Act provide guidance that will help determine whether any particular misleading conduct falls within the jurisdiction of the TPR as the sector specific regulator or the Commerce Commission as the general regulator. Our understanding is that as general regulator we will no longer have responsibility for matters specifically placed within the ambit of the sector specific regulator.

11. Clauses 15 and 16 of the draft Bill, in conjunction with the purpose statement in clause 3, make it clear that any promotional activity relating to the therapeutic nature of therapeutic products or representing products as intended for use as a therapeutic product will, when the new Act is in place, fall within the ambit of the sector specific regulator.

12. There will still be some behaviours in relation to therapeutic products that will remain subject to the Fair Trading Act. As an example, we anticipate that promotional activity and claims in relation therapeutic products that address dimensions outside the ambit of personal or community health, such as country of origin, pricing matters, organic status and the like, will continue to be regulated under the Fair Trading Act.

13. Even so, there may be some areas where the nature of particular promotional behaviours may be such that there is an overlap, either because it is not entirely clear one way or another which regime applies, or because there is suite of behaviours, some of which are appropriately dealt with under one regime, some under the other regime.

14. Part 8: Subpart 4 of the draft Bill explains the relationship between the scheme and other Acts with which it interacts, including the Food Act, the Misuse of Drugs Act 1975, the Psychoactive Substances Act 2016 and the Radiation Safety Act 2016. However, Part 8: Subpart 4 does not include the Fair Trading Act.

Recommendation

15. We recommend defining the relationship between the scheme and the Fair Trading Act within in Part 8: Subpart 4. If our understanding of how it is intended the two regimes will work together differs from what is intended, it would be helpful for both regulators – the TPR and the Commission – for this to be clarified further.

Information sharing

16. Clause 209 of the draft Bill promotes cooperation between the TPR and several regulatory agencies by introducing an information sharing scheme. This allows the listed agencies to share information in relation to the performance or exercise of their functions, powers or duties. Additionally, the clause allows for the listed agencies to share information that they consider may assist one another in the performance or exercise of their functions, powers, or duties.

17. Clause 14 specifically defines the agencies that the TPR can share information with. These include the NZ Police, SFO, IRD and ACC. It also includes departments that relate to certain Acts including the Customs and Excise Act 2018 and the Food Act 2014. Notably, the Commission is not included in this list. We expect that the TPR will be unlikely to be able to voluntarily share information it holds. Additionally, the Commission will not likely be able to exercise its evidence gathering powers as the TPR will not be acting 'in trade'.

Recommendation

18. We expect that there will be overlap between the Commission and the TPR's work and that information will be required for the efficient and effective working of both regulators towards achieving their respective statutory purposes. Consequently, we recommend that the Commission be included in the list of agencies with which the TPR can share information.

Offences and penalties under the scheme and under the Fair Trading Act

Offences under the scheme

19. Breaches of clauses 83[1] and 88 under the draft Bill attract three levels of offences. These have different penalties:

    19.1. **Level A1** – if the person wilfully contravenes clause 83 or if the person knows that the representation is untrue under clause 88. A person who commits a level A1 offence is liable on conviction to, for an individual, imprisonment for a term not exceeding 5 years and a fine not exceeding $200,000; or otherwise, a fine not exceeding $1,000,000.

    19.2. **Level A2** – if the person recklessly contravenes clause 83 if the person is reckless as to whether the representation is untrue under clause 88. A person who commits a level A2 offence is liable on conviction to, for an individual, a fine not exceeding $100,000; or otherwise, a fine not exceeding $500,000.

    19.3. **Level A3** – otherwise than an A1 or A2 offence (this is a strict liability tier, which is where the conduct has simply occurred regardless of whether there was any intent or knowledge. This reflects the fact that anyone operating within the therapeutic products supply chain is obligated to find out what the requirements are and comply with them[2]). A person who commits a level A3 offence is liable on conviction to, for an individual, a fine not exceeding $70,000; or otherwise, a fine not exceeding $300,000.

Penalties for A1, A2 and A3 offences

20. The penalties for A1 offences are much higher than the penalties under the FTA and include the possibility for a custodial sentence. This reflects the inclusion of the intention requirement which is absent under ss 10 and 13 of the FTA. While intention can be considered as an aggravating factor under the FTA it does not give rise to an increased tier of offending as it does under the proposed regime.

21. The penalties for A2 and A3 offences are lower than the FTA penalties. A3 offences are strict liability (as are FTA offences under ss 10 and 13), but attract much lower penalties. Therefore, the same conduct could receive very different penalties under the FTA as under the therapeutic products regime.

---

1 If the contravention is in circumstances that are not infringement circumstances.

2 [199] of the consultation document.

Infringement offences and advertising remediation orders

22. The draft Bill provides that regulations can designate certain offences as infringement offences. This would enable immediate responses to lower-level breaches.

    22.1. Clause 250(2) provides that regulations must specify an infringement fee and infringement fine for each offence.

    22.2. Offences against clause 83 may be designated, in certain circumstances, as infringement offences.

    22.3. The infringement fine must not be more than the bottom tier criminal fine for the provision and the infringement fee must not be more than 5% of the bottom tier criminal fine.

23. Clause 166 also enables the TPR to make an advertising remediation order if satisfied that a person has distributed, or caused the distribution of, an advertisement for a therapeutic product in contravention of clause 83. Such orders can direct the advertiser to take actions such as retrieve the advertisement, remove it from a website or distribute a retraction.[3] These tools may allow the TPR to respond to breaches more nimbly and expeditiously than the Commission is able to.

Recommendation

24. We note that there are significant differences in enforcement penalties between the draft Bill and the FTA. The Commission submits that the new scheme should not introduce a lower penalty for comparable strict liability offences as compared to those penalties under the FTA. For comparative purposes, under s 40(1) of the FTA – offences committed by a body corporate can attract fines of up to $600,000 per offence while offences committed by individuals can attract fines of up to $200,000 per offence.

25. Introducing lower penalties under the scheme for strict liability offences (Level A3 offences) as compared to penalties for similar offences under the FTA (s 40 (1)) may result in inconsistent deterrence messages/compliance incentives. In previous therapeutic goods cases we have stated that ingestible / health credence claims (such as Nurofen) are at the very serious end of offending. Introducing a lower penalty for such behaviour under the scheme would undermine the Commission's general mandate and would not sit well with established precedent.

26. Additionally, therapeutic products are sometimes marketed across Australasia. In Australia, the Australian Competition and Consumer Commission has jurisdiction over therapeutic claims under general consumer law (equivalent to the FTA). This provides a further reason to align the new regime with general consumer law, to ensure Trans-Tasman consistency.

---

[3] We note that this is similar to orders which the Commission may seek under s.42 of the FTA. However, the draft Bill gives the TPR the power to unilaterally issue the remediation order rather than applying for the order through the Courts as the Commission must.

27. We also note that that infringement offences under the Fair Trading Act do not attract convictions. It is unclear whether infringement offences under the scheme would carry a conviction. We recommend that the Ministry clarify this point.

II. Competition issues

Principles-based framework

28. Clause 4 of the draft Bill outlines four principles guiding the TPR's exercise of powers under the scheme.

29. A principles-based approach will allow the TPR to facilitate supply of new medicines and medical devices. We support this approach, as it will mitigate the risk of the scheme failing to incorporate new medical technologies into the wider therapeutics sector. The Ministry has identified this as the main issue associated with the Medicines Act, stating in the consultation document that "[the Medicines Act] is ever less fit for purpose … dated, inflexible and hard to use … [with] significant gaps in coverage."[4]

30. The TPR will have substantial influence over the availability of therapeutic medicines and medical devices at all levels of the pharmaceutical and medical device supply chains: imports, manufacture, wholesale and retail. However, as currently proposed, the principles based framework does not require the TPR to consider competition when creating a new regulation or issuing a licence.

Recommendation

31. We recommend that a fifth principle be inserted into the draft Bill that requires the TPR to consider the promotion of competition in New Zealand markets when formulating regulations or granting new licences. This principle would be subordinate to the overall purpose of the Act. However, it could require the TPR to refer to a checklist before implementing a new regulation or issuing a new licence, such as the checklist found in the OECD's *Competition Assessment Toolkit*.[5]

Pharmacy ownership

32. The consultation document presents two options regarding pharmacy ownership. The first proposes to strengthen existing ownership rules (option 1). The second proposes removing existing pharmacy ownership restrictions under the Medicines Act; this would replace the status quo with a 'fit and proper person' standard for ownership (option 2).

33. In general competition brings a range of advantages to consumers (including on price, quality, range and service (PQRS)). Many of these align with the public policy goals of pharmacy regulation (which is to provide access to medicines at the lowest cost and

---

[4] Ministry of Health. "Therapeutic Products Regulatory Scheme Consultation Document" (December 2018) [*Discussion Paper*], at ix.

[5] OECD (2017), Competition Assessment Toolkit: Volume 1. Principles, www.oecd.org/competition/toolkit.

greatest range, with the best service, while compensating for potential abuse of the products). In pharmaceutical markets, which are characterised by information asymmetries and several externalities, regulation may be required to address these market failures. The direct ownership of pharmacies may be thought to be a check on the risk that commercial interests might override professional judgement and undermine these regulatory objectives.

34. We are not aware of any in-depth studies in New Zealand assessing whether pharmacist-owned pharmacies achieve public policy outcomes better than pharmacist operated pharmacies with non-pharmacist ownership. However, there is evidence found in international studies broadly relevant to the ownership issue that deregulation increases competition which leads to lower prices, increased opening hours and other consumer benefits.

35. The Harper Review explored Australian pharmacy location and ownership rules. The Review noted that these rules create barriers to entry to the retail pharmaceutical market and impose costs on consumers.[6] It recommended that the pharmacy ownership and location rules be removed in the long term interests of consumers.[7]

36. The Office of Fair Trading (OFT) conducted a market study on the control of entry regulations and retail pharmacies. The OFT considered that by relaxing locational entry restrictions, it should be expected that over time more firms would be expected to enter the retail market offering a wider range of services and opening times.[8] [9]

37. Consistent with the view of other competition agencies summarised above, we submit that deregulation of pharmacy ownership is likely to result in increased competition in pharmaceutical markets. Increased competition has been proven to deliver benefits to consumers. We expect that the remaining regulation around the pharmacists' practice will mitigate the risks to the public in the pharmaceutical sector.

Recommendation

38. We recommend adopting option 2 to improve competition and reduce consumer costs.

Supply of therapeutic products by veterinarians

39. In August 2012 the Agricultural Compounds and Veterinary Medicines Act 1997 was amended to allow non-prescribing suppliers that are "approved" by the Ministry for Primary Industries to sell veterinary drugs, including restricted veterinary medicines

---

[6] Ian Harper & Ors. *Competition Policy Review,* March 2015, p 189. See also p 180.

[7] Ibid., at 57.

[8] OFT, 'The control of entry regulations and retail pharmacy services in the UK', January 2003. See 1.09 – 1.24.

[9] The OFT market study also showed that competition may be distorted if some players gained market dominance and were incentivised to vertically integrate and align their product range with the supply of owners. This limited availability of less requested products to consumers. However, we note that in New Zealand such conduct may be captured by the relevant provisions under the Commerce Act.

(RVMs). This resulted in the sale of RVMs being no longer restricted to veterinarians. However, a prescription is still required to be written by a veterinarian if RVMs are being supplied.

40. We understand that, under clauses 61, 62, 66 and 67 of the draft Bill, the intention is that a patient with a prescription for therapeutic medicine can have that prescription filled by another health practitioner or veterinarian that did not write the prescription. This would enable patients to choose which provider supplies therapeutic medicines that have been prescribed to them to maintain and encourage competition among suppliers of therapeutic medicines to humans and animals.

41. From discussions with the Ministry of Health, we understand that the words "for a patient of, at the request of, another health practitioner/veterinarian", for example in clause 66(2)(1)(a)(ii), is intended to mean a situation where a patient presents a prescription written by a health practitioner/veterinarian to another health practitioner/veterinarian for supply. We do not consider that it is sufficiently clear that the reference to a "request" of another health practitioner/veterinarian means a "prescription" written by another health practitioner/veterinarian. It suggests that a specific request in addition to the prescription may be required.

42. Further, if our understanding is correct that a "request" refers to a prescription, then clauses 61(3)(b)(ii) and 66(2)(a)(ii) appears redundant. As currently worded, these clauses allow another health practitioner/veterinarian to issue a new prescription where the patient presents a prescription from another health practitioner/veterinarian for the same therapeutic products.

Recommendation

43. We recommend that the Ministry consider the effect of the scheme on the Agricultural Compounds and Veterinary Medicines Act to ensure that the recent 2012 amendments are not impacted.

44. We also submit that:

    44.1. The words "for a patient of, at the request of, another health practitioner/veterinarian" in clauses 61, 62, 66 and 67, be amended to make it clear that this relates to a situation where a patient is seeking therapeutic medicine by using a prescription written by another health practitioner/veterinarian; and

    44.2. the Ministry considers whether sections 61(3)(b)(ii) and 66(2)(a)(ii) are required in the draft Bill.

III. Consumer issues

45. This part outlines recent examples of matters considered by the Commission in relation to products that are therapeutic products under the draft Bill. It also discusses the

Commission's experience in relation to the proposed defences of reliance on information from another person and compliance with a specific standard.

Recent examples considered by the Commission

Natural health products

46. The Commission has received complaints about and taken enforcement action in relation to natural health products (NHPs) in the past.

47. NHPs are specifically carved out from the therapeutic products regime[10] in anticipation of a separate natural health products regulatory regime. It is likely that until such a scheme is designed regulation of claims made about NHPs will continue to fall to the Commission.

48. However, some NHPs may still fall within the scheme where they represent themselves as having a therapeutic purpose or effect. Clause 88 of the draft Bill prohibits a person from making a misrepresentation about a therapeutic product. As a consequence, NHPs representing themselves to be therapeutic products may be caught within this prohibition. An example of complaints received by the Commission is Red Seal's 'Pharmacy Strength' range, which represented itself to be a therapeutic product. Such a representation would likely constitute a breach of clause 88.

49. We understand that it is intended that, to the extent that promotional claims are made about the therapeutic properties of NHPs, those claims will be the responsibility of the TPR.

Medical devices

50. The Commission has in the past investigated products that fall within the draft Bill's definition of 'medical devices'. The Commission has investigated complaints about several such devices, including:
    - the Pain Eraser Pen (promoted as a device that alleviates pain);
    - Slimming Insoles (promoted as a product that eases weight loss);
    - Ba-Ba Beads (amber that was promoted as having calming properties); and
    - Ecoworld and HRV (water filtration systems that claim to cure various ailments).

51. We understand that the above matters will fall within the definition of 'medical devices' under the draft Bill and will be the primary responsibility of the TPR. We consider this to be appropriate given the likely specialist expertise of the TPR and we particularly support the inclusion of medical devices in the draft Bill.

Sunscreen

52. The absence of a single compulsory standard for the testing of SPF in New Zealand has meant that sunscreen manufacturers have been able to sell products in the New Zealand market which have been tested under one of several international SPF standards. Many

[10] Clause 16(3) of the draft Bill.

of these standards differ in their approach to SPF testing and can produce variable results. This complicated the Commission's enforcement of accurate SPF claims as traders can rely on SPF testing carried out under any internationally recognised standard.[11] This also puts the New Zealand out of step with Australia which does have a mandatory sunscreen standard.

53. We understand that sunscreens will be included under the scheme by introducing regulations which explicitly define sunscreen as a therapeutic product. This would enable the TPR to mandate a standard for SPF testing. A dedicated sunscreen regulator which can enforce compliance with a mandatory standard would introduce significant benefits and could remedy this issue.

Over the counter medications

54. We have previously investigated claims under the FTA that concern over the counter medications, such as Nurofen. These cases often involved 'twin products', that had the same active ingredients but were marketed for different purposes or targeting different ailments.

55. We understand that such claims would likely fall under the new regime and the jurisdiction of the TPR.

Defences and the FTA

56. The draft Bill outlines defences to contraventions of the scheme under Part 7. These include:

    56.1. **All reasonable steps** - it is a defence if the defendant took all reasonable steps to ensure the contravention was not committed (applies to both clauses 83 and 88).

    56.2. **Reasonable excuse** - it is a defence if the defendant has a reasonable excuse for engaging in the conduct that constituted the contravention (applies only to clause 83).[12]

    56.3. **Reliance on information from another person** - it is a defence if the contravention was due to the defendant's reliance on information given to the defendant by another person and the other person was not a senior manager, a worker, or an agent of the defendant and in the circumstances, it was reasonable for the defendant to rely on that information. (applies to both clauses 83 and 88).

    56.4. **Compliance with specified standard** - in a prosecution for an offence of contravening a provision where compliance with a specified standard is

---

[11] Commerce Commission's Enforceable Undertakings with Johnson and Johnson New Zealand Limited.

[12] However, for a contravention that occurs in relation to a therapeutic product, this clause does not apply if the defendant is the sponsor of, or a person in the supply chain for, that product.

required by regulation, it is a defence if the conduct that is alleged to contravene the provision complied with the compliance standard.

57. The defences of 'reliance on information from another person' appears to be similar to the defence of reasonable reliance under s 44(1)(b) of the Fair Trading Act.

58. We anticipate that the defences of 'reasonable excuse' and 'all reasonable steps' are likely broader than the defences under the Fair Trading Act. The defences proposed would likely provide the defendant with the opportunity to explain the offending having reference to countervailing or explanatory factors.

    58.1. Under the Fair Trading Act these factors would be considered as mitigating factors in the defendant's favour. However, they would not amount a defence unless the excuse constituted a reasonable mistake under s 44(1)(a) or the act or default of another person per s 44(1)(c) under the FTA.

59. In relation to the defence of 'compliance with a particular standard', the Commission's past work on sunscreens may be informative. This, along with other of our work involving the application of standards, identifies potential concerns about how standards may be applied; in particular around the frequency with which products are tested and the currency of test results that may be relied upon. The lack of a reasonableness element has the potential to create an overly broad defence.

Recommendation

60. We recommend that the Ministry carefully consider how this defence would operate in practice to avoid creating an unintentionally broad defence.

Contact details

61. We thank the Ministry for this submission opportunity and would be pleased to provide any further assistance that you may require. If you have specific questions on this submission please contact John Stewart, Advocacy Adviser on 04 924 3706 or john.stewart@comcom.govt.nz in the first instance.