From: Jonathan Chilton-Towle [mailto:jct@pharmacytoday.co.nz]
Sent: Monday, 9 May 2016 11:19 a.m.
To: Kirsty Taylor-Doig <Kirsty.Taylor-Doig@parliament.govt.nz>
Subject: Questions for Jonathan Coleman re Theraputic Products Bill

Hi Kirsty

I have a media query for you regarding the recently released Theraputic Products Bill discussion papers

http://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

I'm hoping to get some comment from Dr Coleman around the removal of pharmacy ownership restrictions discussed in the papers.

My questions are:

1. Why do you feel pharmacy ownership restrictions are not needed?
2. What benefits will removing these restrictions have?
3. Some pharmacists I have spoken to about the proposed changes are quite concerned about the changes. Major concerns seem to be removing ownership restrictions will A) devalue their profession and B) result in large corporates forcing current pharmacist owners out of business. How do you respond to these concerns?
4. In the discussion documents it mentions that new regulations will "prohibit prescribers from benefitting from their prescribing activities through an investment in pharmacies, but not prevent sensible integrated service initiatives from developing". How will this work? Will prescribers be allowed to own pharmacies under the new rules and, if so, how will they be stopped from profiting from this?

My deadline is 4pm, Thursday

Kind regards,

Jonathan Chilton-Towle | Journalist
Pharmacy Today
The Health Media
Phone 09-488 4294
M 027-825 2539
Email jct@pharmacytoday.co.nz

Proud co-hosts of the 2016 Pharmacy Awards.

Response
Can be attributed to Andi Shirtcliffe, Chief Advisor - Pharmacy

1. Why do you feel pharmacy ownership restrictions are not needed?

The most important role of the licensing regime is ensuring safety, access and quality of services. Any regulatory requirement or restriction needs to relate to these outcomes to minimise unnecessary regulation.

In looking at how best to regulate the licensing of pharmacies, the Ministry of Health started from the ground up. It became apparent early on that the main concerns of safety, access and quality could be effectively and efficiently addressed directly through the licensing framework. Ownership was an indirect and less effective tool. Compliance with Ownership restrictions consumes the time and effort of both Pharmacists and the Regulators, without gains in safety. Also, opening the ownership structures can enable pharmacies to structure their businesses in more efficient ways to focus on services, rather than ownership compliance.

This also has the advantage of meeting Health Strategy objectives of being more people centred.

2. What benefits will removing these restrictions have?

Some of the benefits of removing ownership restrictions include facilitating pharmacists to focus on safety, quality and supply through more innovative services. There is less resource invested on compliance costs, and pharmacists can focus on what they do best, which is supplying high value services to the community.

The Ministry's recognises that our Pharmacists are highly qualified but can be underutilised. We want to find ways of being smarter about how we utilise this valuable workforce.

3. Some pharmacists I have spoken to about the proposed changes are quite concerned about the changes. Major concerns seem to be removing ownership restrictions will A) devalue their profession and B) result in large corporates forcing current pharmacist owners out of business. How do you respond to these concerns?

Concerns about professional values and quality of service have been at the forefront of considerations for the Ministry of Health. The Ministry has engaged closely with the industry and consumers to ensure that the changes both support a high professional standard of service to consumers and facilitate greater access.

To this end it's been agreed that all licences will require the engagement of a responsible pharmacist for the day-to-day operation of the pharmacy (as we have now), as well as having the pharmacist on premises (as we have now), while introducing the new role of a Supervisory Pharmacist responsible for ensuring compliance with licence conditions and implementation of professional standards. The Ministry of Health will work with industry and consumers to ensure the new Supervisory Pharmacist role meets the needs of the consumers and profession.

One argument that's been made against changing the ownership rules was that under the current system unethical or unprofessional behaviour could be contained because the owner had an Annual

Practising Certificate and was therefore subject to discipline under the HPCA. The same will apply to the Supervisory Pharmacist under the proposed regulatory changes.

Corporate and private pharmacies already exist together. The Ministry of Health wants to make sure that the public continues to receive high quality pharmacy care, regardless of the ownership model used. Competition in markets is a factor which can help keep costs lower and develop better services to compete for business. This combined, with the Supervisory Pharmacist role, should enable a more dynamic pharmacy industry focusing more effectively on high quality professional services and business innovation.

4. In the discussion documents it mentions that new regulations will "prohibit prescribers from benefitting from their prescribing activities through an investment in pharmacies, but not prevent sensible integrated service initiatives from developing". How will this work? Will prescribers be allowed to own pharmacies under the new rules and, if so, how will they be stopped from profiting from this?

Currently the regulator can and does grant exemptions to this prohibition, for example where a doctor invests in a pharmacy geographically distant to where they practice so as to have no benefit derived from their prescribing practice. This exemption will continue.

The ability to enable sensible integrated service initiatives is important to achieving better people centred health care. In terms of how this will work we don't have all the answers yet, but want to allow the regulator to consider how the professions can work more closely. The Ministry of Health will work with industry stakeholders and the public to achieve these objectives.

ENDS

FW: Deregulation of Pharmacy
Ibolya Rumi to: 'Briefings@moh.govt.nz' 31/05/2016 01:15 p.m.

1600949 , routine min please

-----Original Message-----
From: Ibolya Rumi
Sent: Tuesday, 31 May 2016 11:57 a.m.
To: [s9(2)(a)]
Subject: RE: Deregulation of Pharmacy

Dear [s9(2)(a)]

On behalf of Hon Dr Jonathan Coleman, Minister of Health, thank you for your email of 31 May 2016 about deregulation of your profession.

The Minister has asked Ministry of Health officials to advise him on the matters you have raised. Please be aware that due to the large volume of correspondence we receive, a personal reply to your email may take some weeks.

Kind regards

Ibolya Rumi
Acting Private Secretary - Health
Office of Hon Dr Jonathan Coleman

sc/Comm H/Primary Health Pharmacy
(3)
John

-----Original Message-----
From: [s9(2)(a)]
Sent: Tuesday, 31 May 2016 10:10 a.m.
To: Office of Dr. Jonathan Coleman
Subject: Deregulation of Pharmacy

Dear Dr Coleman,
this is the first time I have been spurred into action to voice my opinion on any political matter, but this is an area I am very passionate about.
My husband and I have been qualified pharmacists for over 30 years and have dedicated our lives to helping the community we serve.
We have both spent time working as pharmacists in London and have experienced first hand how unprofessional many of the retail stores were as the owner was not a pharmacist.
As soon as you have an owner of a business who is solely in the game to make money the balance of ethics change.
I realise this would not happen in all situations but it will happen in more than you probably realise.
As owner operators ourselves we have an invested interest and genuinely care about our customers and it is not all about doing everything to make money.
For example just this morning my husband went and picked up one of our staff members (was out of his way) to take her to work as her car had broken down. Somehow I cannot see a non pharmacist owner of a business allowing this to happen !
My husband and I would like the opportunity to meet with you to discuss why you want to deregulate our profession and to listen to our side of the argument, having worked in both a regulated and deregulated pharmacies.
We have already met with our local MP Simon O'Connor and he may have already discussed our meeting with you .However I would like you to get a better understanding of why we care so much . We are not alone in our

thinking and it is not about protecting our financial situation but rather about protecting our patients /customers.

Kind regards

[s9(2)(a)]

Ministerial	Ref. 1600949
H Number:	H201602259
Govt Relations contact:	John Bell
Phone:	04 816 2233 (ext. 2233)
Received by Ministry:	02.06.2016
Due date Minister's office:	30.06.2016
New due date if extended:	
..... /	
Peer reviewer's name:	John Doyle
Date of review if by email:	24.06.2016
..... /	
For the Director-General of Health / date	

Mrs [s9(2)(a)]

Dear [s9(2)(a)]

Thank you for your email of 31 May 2016 about the regulation of pharmacies.

The most important aspect of the pharmacy licensing regime is ensuring safety, access and quality of pharmacy services. The regulations must relate to these outcomes to minimise unnecessary regulation.

Under the new regime the restrictions on owners being pharmacists are being removed. In their place a new a Supervisory Pharmacist role is being created responsible for ensuring compliance with licence conditions and implementation of professional standards. This role is designed to ensure the commercial incentives do not compromise pharmacy standards or patient safety. The Ministry of Health is committed to working closely with key industry stakeholders and consumers to ensure the new Supervisory Pharmacist role meets these needs.

Ownership restrictions have been assessed as an indirect and less effective tool than directly placing controls on a licence. Compliance with ownership rule restrictions consumes the time and effort of both pharmacists and the Regulator, without gains in safety. Benefits of removing ownership restrictions include facilitating pharmacists to focus on supplying high value services to the community.

Thank you for sharing your concerns.

Yours sincerely

Hon Dr Jonathan Coleman
Minister of Health

From: [s9(2)(a)]
Sent: Thursday, 30 June 2016 11:36 p.m.
To: Hon. Dr. Jonathan Coleman <Jonathan.Coleman@parliament.govt.nz>
Subject: Ammendment of the Medicines Act of 1981

Dear Dr Coleman

I have read recently in the media that you are preparing a bill to 'free up' pharmacy ownership under the 1981 Medicines Act to other interested 'fit and proper' parties. I may wish to ask you what do you mean by 'fit and proper'? We as pharmacy owners have put plenty of time, effort and money into purchasing and running pharmacies to the best interest of the health profession the first and foremost our patients. Although we strongly think that this will not be to the best interest of the profession or patient as non-professional parties may be interested in the ownership of pharmacies. I would like you however to indicate clearly the group of 'fit and proper' people that may be interested, as there could be a supermarket interest, and online interest and worse big co-operates. I hope you mean medical doctors by 'fit and proper' and I hope you could include that in, rather than leaving it to the interpretation.

Regards
[s9(2)(a)]

Ministerial	Ref. 1601110
H Number:	H201602729
Govt Relations contact:	John Bell
Phone:	04 816 2233 (ext. 2233)
Received by Ministry:	05.07.2016
Due date Minister's office:	19.07.2016
New due date if extended:	
..... /	
Peer reviewer's name:	Sue Scott/Nive Sharat Chandran
Date of review if by email:	14.07.2016
..... /	
For the Director-General of Health / date	

Mr [s9(2)(a)]

Dear [s9(2)(a)]

Thank you for your email of 30 June 2016 about proposed changes to the pharmacy licensing regime.

The most important aspect of the pharmacy licensing regime is ensuring safety, access and quality of pharmacy services. The regulations must relate to these outcomes to minimise unnecessary regulation.

Concerns about professional values and quality of service have been at the forefront of considerations for the Ministry of Health. The Ministry has engaged closely with the industry and consumers to ensure that the changes both support a high professional standard of service to consumers and facilitate greater access.

Under the new regime, the restrictions on owners being pharmacists are being removed. In their place, a new Supervisory Pharmacist role is being created, which will include responsibility for ensuring compliance with licence conditions and implementation of professional standards. This role is designed to ensure commercial incentives do not compromise pharmacy standards or patient safety. The Ministry is committed to working closely with key industry stakeholders and consumers to ensure the new Supervisory Pharmacist role meets these needs.

The Ministry wants to make sure that the public continues to receive high quality pharmacy care, regardless of the ownership model used. Competition in markets is a factor which can help keep costs lower and develop better services to compete for business. This, combined with the Supervisory Pharmacist role, should enable a more dynamic pharmacy industry focusing more effectively on high quality professional services and business innovation.

'Fit and proper' and 'good repute' are not defined by the Medicines Act 1981. However, they are terms commonly used in law. Because the details of the changes to pharmacy ownership in the new Therapeutic Products Bill have not yet been finalised, it is not possible to state definitively how fit and proper/good repute provisions will be defined and monitored. However, the principles that will be followed will be similar to those currently in use.

Ministry officials intend to undertake further consultation with stakeholders about the new licensing proposals under the Therapeutic Products Bill prior to preparing an exposure draft of the Bill and a discussion document.

Thank you for writing.

Yours sincerely

Hon Dr Jonathan Coleman
Minister of Health

Therapeutic Products Regulation – Pharmacy Licensing

DISCUSSION DOCUMENT

PURPOSE

1. This purpose of this paper is to seek feedback on some **early draft** options for the licensing of pharmacies in New Zealand. Your feedback, along with input from feedback provided on the Pharmacy Action Plan, will help to inform components of the exposure draft of the new Therapeutic Products Bill.

BACKGROUND

CURRENT ARRANGEMENTS

2. Medicines are made available to the public under rules set out in legislation (currently the Medicines Act 1981 and Medicines Regulations 1984) designed to ensure that effective products are made available safely for indicated use.

3. Pharmacies must be licensed. The Medicines Act 1981 and Medicines Regulations 1984 set out the requirements, restrictions and prohibitions for obtaining a pharmacy licence, issued by Medicines Control under delegation from the Director General of Health.

FUTURE ARRANGEMENTS

4. The Medicines Act 1981 is being repealed by a Therapeutics Products Act. There will be a range of opportunities and methods for the public and sector to inform this process. An exposure draft of a Therapeutic Products Bill will be released for public consultation in mid-2016. That process enables an early draft of the Bill to be improved based on public and sector feedback ahead of the introduction of the Bill to Parliament. The exposure draft of the Bill will be accompanied by a description of the likely content of the regulations and subordinate instruments.

5. This document should be read as a whole. The option to change licensing restrictions gives rise to arguments that may be addressed through other regulatory mechanisms or interventions that are also discussed. Comments on all aspects of this paper are welcome.

STRATEGIC OBJECTIVES

6. The new regime is being designed to meet the needs of the health and disability support sector now and into the future, to give effect to Government's expectations for regulatory

systems and mindful of the global settings for therapeutic products. Reflecting this context the objectives for the regime are that it:

- meets expectations of risk management and assurance of acceptable safety
- results in efficient and cost effective regulation
- is flexible, durable, up-to-date, and easy to use
- ensures high-quality, robust and accountable decision-making
- is able to sustain capable regulatory capacity
- supports New Zealand trade and economic objectives
- is trusted and respected
- supports consumer access and individual responsibility for care.

HIGH LEVEL OBJECTIVES FOR A LICENSING REGIME

7. In addition to our overarching legislative objectives a licensing regime should specifically meet these high level objectives, which can be viewed as a simplification of the above. The options presented in this paper will be measured briefly against these objectives:

Outcomes	Objectives
Safety	Ensures high quality care without compromising patient safety Improves health outcomes for people Ensures accountability is appropriate and transparent
Access	Enables people to obtain the therapeutic products they need in a timely way Supports patient choice and convenience where possible
Efficiency	The regulator's roles can be practically administered Innovation in health care is enabled Health care providers are able to comply with regulations

SUMMARY

INTERVENTIONS: OPTIONS AND ANALYSIS

8. The discussions are broken into major themes and subsections which focus on a list of questions below. The discussion tables set out:

    - The broad regulatory question for discussion.
    - A short explanation of the issue.
    - A table of various regulatory approaches that could be taken from highly regulated to least regulated. Followed by questions to stimulate discussions. (NB - not all options will be feasible or desirable. Preferred options are highlighted in the colour of the column they are in).
    - A brief assessment of the options against the high level criteria to stimulate discussions.
    - Current legislative settings for comparison.

SUMMARY OF QUESTIONS:

To licence or other form of regulation

- Should we license pharmacies, or consider some other mechanism for supporting the safe storage and supply of medicines?

Restrictions and prohibitions on pharmacy licences

- Should prescribers be prohibited from owning pharmacies?
- Should all pharmacies be majority owned by pharmacists?
- Should the role of the Responsible Person[1] be expanded and protected to address changes to the restrictions above?

General licence terms

- Should a licence term be restricted to 12 months, or be more flexible?
- Should a pharmacist be required to be on pharmacy premises at all times?

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[1] A **responsible person** (as currently defined by section 2 of the Medicines Act 1981), "in relation to a licensee corporation, means an agent or employee of the corporation who is a pharmacist or a person approved by the licensing authority as the responsible person for the purposes of the licence". Section 51 requires that responsible persons are obligated to have sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines that they are licensed to supply.

The Pharmacy Council Code of Ethics 2011 defines a **charge pharmacist** as "the pharmacist who is present in the pharmacy from which pharmaceutical services are provided, and at any particular time is responsible for the overall control of the provision of pharmaceutical services from the place".

TO LICENCE OR, OTHER FORM OF REGULATION

Should we license pharmacies, or consider some other mechanism for permitting the sale of medicines?

9. Medicines are potentially harmful products, so it is important to have a system in place that assures safe storage appropriate oversight of sales and appropriate dispensing. For example, an alternative to licensing premises could be to allow all pharmacists to store and dispense medicines, so long as they comply with conditions that are placed on the medicines.

Pharmacy licensing					
Question	Option 1 (Most regulated)	Option 2	Option 3	Option 4 (Least regulated)	Considerations for discussion
Should we license pharmacies, or consider some other mechanism for permitting the sale of medicines?	Yes – We should have a licensing regime in the primary legislation with a regulator responsible for issuing licences. All terms for obtaining a licence should be in primary legislation.	Yes – We should have a licensing regime in the primary legislation with a regulator responsible for issuing licences. The regulator must consider specific terms for granting a licence but should have flexibility in doing so.	Partly - We should have a soft approach to approving pharmacies using notification systems whereby applicants provide evidence that they meet a minimum standard set within a code or guideline.	No – We should not have a licensing regime for pharmacies. As an alternative - Authorised Prescribers and pharmacists can sell and dispense medicines so long as they comply with dispensing and storage requirements for those medicines. Professional bodies may provide additional guidance on sale and dispensing.	What are the risks that we are managing – do these vary? Are the risks such that a licensing regime is necessary? What level of flexibility is necessary to ensure individual safety and workability for the Regulator? What effect does licensing have for providing assurance for DHB contracting? Should licensing be restricted to physical premises or should there be scope for mobility?
Strategic objectives					
Safety	Allows for the setting of terms for storage, practice and service.	Allows for the setting of terms for storage, practice and service.	Reduced government oversight, increased risk for people.	Potentially riskier – less accountability to government.	
Access	Ensures safe access, public confidence.	Ensures safe access, public confidence.	Increased ease of regime may increase access.	May lead to greater access options.	
Efficiency	Higher regulatory compliance costs, inflexible.	More flexible, easier to change in future if required	May lead to reduced time and costs for pharmacies and regulator.	May lead to new market innovations and efficiencies.	
Current regulation					
	Status Quo (mix option 1 and 2)				
The Medicines Act creates framework for licensing of pharmacies. The majority of the licensing requirements are set in the primary legislation for pharmacy licences (ss17, Part 3 Licences, S51,52, 55A, 55B, 42, 55C, 55E, 55F, 42C) and regulations providing further requirements on applications (e.g. regs 45, 45A, 46, Form 7 Schedule 2).					

RESTRICTIONS AND PROHIBITIONS ON PHARMACY LICENCEES

10. Currently there are a variety of restrictions placed on who is able to obtain a pharmacy licence. Many countries have reviewed similar restrictions. The Australian Government received an independent review of competition policy from Professor Ian Harper in June 2015 that stated of pharmacy regulations that ownership and location rules should be removed in the long term interests of consumers, and that they should be replaced with regulations to ensure access to medicines and quality of advice regarding their use that do not unduly restrict competition. The recommendation has only been noted by the Australian Government.

11. Placing more emphasis on the point of health care service, while holding licensees accountable in New Zealand should facilitate more innovative and integrated health care services.

12. There are arguments however that current prohibitions and restrictions:

    a. Prevent financial incentives influencing decisions that may compromise patient care

    b. Facilitate professional oversight that aligns business and health incentives and helps maintain high standards

Should prescribers be prohibited from owning pharmacies?

13. Currently prescribers are prohibited from having an interest in pharmacies, unless approved to do so by the regulator. This prohibition is based on the view that a prescriber who holds an interest in a pharmacy could direct someone to that pharmacy in a way that;

    a. reduces choice

    b. is an abuse of relationship for financial gain

    c. may result in additional costs to the patient

    d. compromises the patient's care.

14. These risks may be better managed through other regulator tools, or interventions as discussed in the table.

15. It is also arguable that the prohibition inhibits integration of health care services as any shared business services or interests must be carefully managed so as not to trigger the prohibition.

Prescriber Interest in pharmacy					
Question	**Option 1** (Most regulated)	**Option 2**	**Option 3**	**Option 4** (Least regulated)	**Considerations for discussion**
Should prescribers be prohibited from owning pharmacies?	Yes. Keep the prohibition but can take a pharmacy interest with the approval of the regulator.	Partially. Special rules are created for prescribers seeking to have an interest in pharmacies.	No. Prescribers are required to communicate their interests in pharmacies to patients where there may be a perceived conflict of interest and must disclose to the regulator where they have an interest in a pharmacy.	No restriction specifically directed to prescribers.	What risks are created by prescribers having interests in pharmacies? Can these risks be addressed through other means? What evidence is available to support pros and cons of prohibition?
Strategic objectives					
Safety	Manages the potential or perceived conflict for prescribers.	Unlikely to be significant change. Professional and ethical duties already imposed.	Unlikely to be significant change. Professional and ethical duties already imposed. Patients can make informed choice.	No requirement to inform the patient or regulator may reduce trust of health care professionals	
Access	No Change	More integrated health care service may bring about greater access.	More integrated health care service may bring about great access.	More integrated health care service may bring about great access.	
Efficiency	May inhibit development of integrated health services.	May allow for integrated health services depending on special rules.	Facilitates integrated health services. Reduces burden on regulator to monitor previous prohibitions.	May create new risks for regulator that are difficult to monitor.	
Current regulation					
	Status Quo				
The Medicines Act *1981, s42C* Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies					

Should all pharmacies be majority owned by pharmacists?

16. Currently pharmacies must be more than 50% pharmacist owned, and pharmacists cannot have majority stakes in more than five pharmacies.

17. There has been a significant growth in ownership models that have corporate pharmacy frameworks. The benefits of aligned businesses and shared services has included greater efficiencies and improved quality standards.

18. An important consideration for any changes to the status quo is understanding what the key drivers are for high quality service and standards, and what impact and role pharmacist 'control' has (or should have) on those services.

19. In the 'expanded responsible person' question below we consider whether requiring a special pharmacist in an unrestricted licensee framework to; maintain, oversee and develop professional service standards and adherence to license requirements, would address some of the arguments for keeping the status quo.

20. A more restrictive option is also considered below, where only pharmacists are permitted to obtain licences.

Pharmacist majority interest and limit to number of pharmacies					
Question	**Option 1 (Most regulated)**	**Option 2**	**Option 3**	**Option 4 (Least regulated)**	**Considerations for discussion**
Should all pharmacies be majority owned by pharmacists?	A pharmacist is required to have complete (100%) ownership of a pharmacy. There is a restriction on the number of pharmacies that can be owned by a pharmacist.	A pharmacist is required to have majority (>50%) ownership of a pharmacy. There is a restriction on the number of pharmacies that a pharmacist can have a majority ownership interest in.	A pharmacist is not required to have complete or majority ownership of a pharmacy. There are no regulatory restrictions on the number of pharmacy licences that an operator can hold. A specific Responsible Person role is established for developing, maintaining, and overseeing the professional service standards and legal and license requirements.	A pharmacist is not required to have complete or majority ownership of a pharmacy. There are no regulatory restrictions on the number of pharmacy licences that an operator can hold.	How does an individual's safety vary by licence ownership? How can risks associated with perceived or actual corporate interference of pharmacy service be managed? Does the responsible person have to be a pharmacist?
Strategic objectives					
Safety	Variable change, May depend on individual pharmacist.	No change	Ensures a further level of professional standards compliance.	Perceived or actual undue influence of corporate management on pharmacists compromising care.	NB fit and proper persons/companies test to be retained.
Access	Variable, will depend on business viability and business management skills of pharmacist.	No change	May create better access via new business models, and integration	May create more access via new business models, and integration	
Efficiency	May be increased time costs for pharmacist.	No change	Less resource spent by regulator and corporate pharmacy groups to operate within legal restrictions on business structure.	Less resource spent by regulator and corporate pharmacy groups to operate within legal restrictions on business structure.	
Current regulation					
		Status Quo			
The Medicines Act 1981, ss51,55A,55D,55E, 55F					

Should the role of the Responsible Person be expanded and protected?

21. A responsible person is already required to be identified in a licence as the person the regulator can contact who is available and can take action or direction immediately in relation to those pharmacies they are named as responsible person for.

22. The draft proposition here is that the role of the Responsible Person be extended, at least in relation to contexts where there is less than 50% pharmacist ownership of a licence, to:

a. Take responsibility for maintaining and developing the professional service and practice standards of the pharmacies for which they are the Responsible Person.

b. Take responsibility for ensuring the licence owner is aware of and complies with their licence obligations.

c. Keep corporate pressures removed and divisible from health service obligations, both from a professional and legal perspective. Ensuring the pharmacy standards of service are not compromised by any commercial means, by the licence holder or anyone else - notify and report any such interference to the regulator.

d. Understand all aspects of pharmacy business and practice to enable them to communicate actions and changes that may be necessary relating to guidelines, codes, or directions from the Regulator.

e. Consulted by non-pharmacist licence holders in matters relating to pharmacy and pharmacist services, by pharmacists, or activities carried out at pharmacies that could be perceived as health services.

23. The cycle of accountability is such that the licensee owner(s) will want to ensure that the Responsible Person dutifully carries out their responsibilities, including all employees comply with appropriate service standards, and that commercial pressures do not interfere with those services, because to do so risks the loss of their licence.

24. Although not discussed here, we note and would seek to retain and clarify in the Bill, the prohibition and penalty against anyone interfering with pharmacist's delivery of health services to a consumer.

Responsible Person (in context of majority pharmacist ownership requirement removed)					
Question	Option 1 (Most regulated)	Option 2	Option 3	Option 4 (Least regulated)	Considerations for discussion
Should the role of the Responsible Person be expanded and protected?	Primary legislation sets out the responsibilities, skills and qualifications required of a Responsible Person to be named on all licences.	Primary legislation sets out the responsibilities, skills and qualifications required of a responsible person to be named on a licence with less than 51% pharmacist ownership, or a network of more than 5 pharmacies.	A responsible person must be identified on a licence – no special responsibilities beyond status quo.	No responsible person required as part of licence. All accountability sits with the licence holder – up them to make arrangements as they see fit to manage compliance with legislature and maintenance with standards	What risks do we want the RP to manage? What special skills (if any) are required for the RP? Is an authority required to create or certify the RP? Does the RP need to be a pharmacist?
Strategic objectives					
Safety	Better alignment of responsibility and accountabilities should ensure greater safety in larger pharmacy business models.	Better alignment of responsibility and accountabilities should ensure greater safety in larger pharmacy business models.	In this context of reduced pharmacist interest in pharmacies. The perceived or actual corporate influence may be that safety is compromised.	In this context of reduced pharmacist interest in pharmacies. The perceived or actual corporate influence may be that safety is significantly compromised.	

Access	Possible increase due to increase in different ownership models possible.	Possible increase due to increase in different ownership models possible.	Possible increase due to increase in different ownership models possible.	Possible increase due to increase in different ownership models possible.	
Efficiency	May be more restrictive than necessary, especially for small pharmacy groups or sole owners.	Less resource spent by regulator and corporate pharmacy groups to operate within legal restrictions on business structure.	Less resource spent by regulator and corporate pharmacy groups to operate within legal restrictions on business structure.	Less resource spent by regulator and corporate pharmacy groups to operate within legal restrictions on business structure.	
			Current regulation		
			Status Quo		
The Medicines Act 1981, s51 Grant of licences (1) (d) that, in the case of an application made by a natural person on his own behalf, the applicant, or, in the case of an application made on behalf of a body corporate, every person proposed to be a responsible person for the purposes of the licence applied for, has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines in which it is proposed to deal:					

GENERAL LICENCE TERMS

Should a licence term be restricted to 12 months, or be more flexible?

25. Currently pharmacy licences are restricted to 12 months only. Permitting the regulator to extend the licence period for pharmacies with an established record of safe practice, may help save time and costs for pharmacies and the regulator.

Licence Duration					
Question	**Option 1 (Most regulated)**	**Option 2**	**Option 3**	**Option 4 (Least regulated)**	**Considerations for discussion**
Should a licence term be restricted to 12 months, or be more flexible?	Duration of licence set in primary legislation to 1 year.	Regulator given discretion in primary legislation to set duration for 1-3 years based on proven safety and compliance record set in regulations.	Regulator given discretion in primary legislation to set duration for 1-3 years based on safety – and regulator able to set safety criteria to be met for longer duration licences.	No limitation on duration of licence granted. Duration at full discretion of regulator.	What kind of safety record might warrant a longer duration licence? Who is best placed to decide safety criteria for a longer duration licence? What about the possibility of mobile licences?
			Strategic objectives		
Safety	No change	Potentially slight risk increase.	Potentially more risk	Potentially more public risk	
Access	No Change	No change	No change	No change	
Efficiency	No change	Greater regulator efficacy and pharmacy efficacy.	Greater regulator efficacy and pharmacy efficacy. Decrease in certainty.	Potentially greater regulator efficiency. Significant decrease in certainty for pharmacies.	
			Current regulation		
	Status Quo				
The Medicines Act 1981, s53 Duration of licences, restricts a Pharmacy licence to 1 year.					

Should a pharmacist be required to be on pharmacy premises at all times?

26. Currently a pharmacist is required to be on pharmacy premises at all time. Should the regulator have a wider discretion to have flexibility in relation to those licence conditions?

Pharmacist presence					
Question	**Option 1 (Most regulated)**	**Option 2**	**Option 3**	**Option 4 (Least regulated)**	**Considerations for discussion**
Should a pharmacist be required to be on pharmacy premises at all times?	Yes	Yes, but Some flexibility around the degree of presence, set in regulations.	Largely, but the regulator is given discretion to refine the terms of presence in a licence, or via reference to a code or standard.	No. The presence or otherwise is left to the discretion of pharmacist themselves / so long as they comply with any conditions placed on dispensing (which may actually require presence of a pharmacist anyway)	Is it better to place a requirement on the pharmacist to be present or supervising dispensing, or place it on the licence? What drives the greater safety outcomes? How might this operate in the context of a mobile licence? Could supervision be provided remotely, e.g. via video call?
Strategic objectives					
Safety	No change	Unlikely to be significant change.	Unlikely to be significant change.	May be increase in risk or uncertainty – depending on whether point of dispensing still requires a pharmacist or pharmacist supervision.	Should a term be incorporated into a licence that any interference with a pharmacist's health service and legal obligations for dispensing may result in loss of licence?
Access	No Change	No change	No change	No change	
Efficiency	No change	Pharmacists may have greater certainty around flexibility.	Pharmacists may have greater certainty around flexibility.	Potentially shifts regulator focus. Places greater responsibility at point of sale.	
Current regulation					
	Status Quo				
The Medicines Act 1981, s42A Every pharmacy must be under supervision of pharmacist					

MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20160264

Security classification: In-Confidence

File number: AD62-14-2016
Action required by: comment by 15 March 2016

Therapeutic Products Regulation: Draft Cabinet Paper

To: Hon Dr Jonathan Coleman, Minister of Health

Copy to: Hon Peter Dunne, Associate Minister of Health

Purpose

To provide a draft of the *Therapeutic Products Regulation: further policy approvals* cabinet paper for your comment and a copy of the draft Regulatory Impact Statement for your information prior to the final versions of these papers being considered by the Social Policy Committee on 30 March 2016.

Key points

- The attached paper *Therapeutic Products Regulation: further policy approvals* seeks agreement from Cabinet to issue drafting instructions on a range of discrete matters to be contained in the Therapeutic Products Bill.
- Since meeting with you on 10 February 2016 to discuss the content of the paper officials have had further discussions with a range of stakeholders and other government agencies.
- These consultations have largely confirmed the approaches that were discussed with you. That said, this paper draws your attention to the following matters:
  - *Clinical trials* – there will be consultation with ethics committees, the Health Research Council and the research community on the proposed approach and detailed matters prior to the release of the exposure draft.
  - *Cell and tissue therapeutic products regulation* – the Ministry's view remains that all these products should be within the scope of the regulatory regime in order to provide the ability to respond to any emerging issues in the future and to avoid difficult definitional boundaries. However, it is critical that this does not have any negative impact on the availability of organs for immediate transplantation, or associated clinical systems and processes. It is therefore proposed that, at the outset of the regime, minimally-manipulated tissue for immediate transplantation not be subject to any pre-market regulatory requirements (such as approvals and licences), beyond those that apply now as part of clinical practice.
  - *Prescribing and dispensing* – the paper proposes that final approval of prescribing authority should rest with the Minister of Health.
  - *Pharmacy licensing* – the paper proposes that there should continue to be limitations on prescriber interests in pharmacies.
- In respect of the institutional form of the regulator, the Ministry has had considerable discussion with the Treasury about the merits of the three options and the proposal that a decision on form be taken in two steps. Treasury does not support the two-step approach as proposed by the Ministry.
- We seek your comments on the draft paper by 15 March 2016 with a view to providing you with a final paper by 18 March 2016 and for lodgement in CabNet by 24 March. The paper is due to be considered by the Social Policy Committee on 30 March 2016.

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MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20160264

Therapeutic Products Regulation: Draft Cabinet Paper

Recommendations

The Ministry recommends that you:

a)	**Provide** comment on the attached draft cabinet paper by 15 March 2016 so that final papers can be prepared for you to lodge in CabNet by 24 March 2016.	**Yes / No**
b)	**Note** that the attached regulatory impact statement is a draft that has not yet been assessed by Treasury against their quality assurance criteria.	
c)	**Note** that Cabinet agreement to this paper, and issuing of drafting instructions to Parliamentary Counsel Office promptly is important in order to meet your preferred timetable of introduction to the House in late 2016.	
d)	**Confirm** that you wish to seek a decision from Cabinet that the regulator not be established as a Crown Entity and that both the Departmental and Departmental Agency options be left open until October	**Yes / No**
e)	**Note** that Cabinet approval is sought to release the three cabinet papers (two from November 2015 and the attached paper) and associated Regulatory Impact Statements, with any necessary redactions by May 2016.	

Hamiora Bowkett
Acting Chief Strategy and Policy Officer
Strategy and Policy

Minister's signature

Date:

Database number: 20160264

Therapeutic Products Regulation: Draft Cabinet Paper

1. The attached draft cabinet paper covers the issues discussed at your meeting with officials on 10 February 2016. It proposes policy settings on the matters listed below:
   - Clinical trials
   - Cell and tissue therapeutic product regulation
   - Prescribing and dispensing
   - Pharmacy licensing
   - Import and export
   - Offences and penalties framework
   - Interface with the Hazardous Substances and New Organisms Act
   - Regulator form
   - Placement of provisions.
2. Cabinet decisions on these matters will enable further drafting instructions to be issued to the Parliamentary Counsel Office for the Therapeutic Products Bill. An exposure draft of the Bill is due for release later in 2016.
3. This report draws your attention to a number of issues in which you expressed particular interest on 10 February, or where interagency consultation has resulted in a slightly different approach than that discussed with you.

Introductory context

4. You emphasised to officials that it would be helpful for the paper to recap the rationale for the new regulatory regime and its key interfaces with other regulatory regimes. This material is contained in paragraphs 6-10 of the draft paper.

Clinical trials

5. The proposals for changes to the clinical trials regime are as discussed with you (that is, covering all products, ensuring sufficient powers for the regulator, and making the most of the enabling legislative framework). Officials are aware that the ethics committees have an interest in the proposals as does the Health Research Council and the wider research community. Engagement with these stakeholders ahead of the exposure draft being released is planned. This will support implementation of the new regulatory regime in respect of aligning processes between the regulator and the ethics regime and developing and testing options for where the relevant scientific committees should sit.

Cell and tissue therapeutic product regulation

6. As the Ministry has further developed the regulatory framework for these products it has tested the requirements that should apply to the different types of cell and tissue therapeutic products. These products vary in the degree of manipulation they have had and in the way they are used in clinical practice. At the least-manipulated end are organs for immediate transplantation and at the most-manipulated are cellular-based therapies. Between these extremes are banked tissue, and blood and blood products.
7. The Ministry continues to hold the view that all these products should be within the scope of the regulatory regime, however it also considers that the regime should enable the least manipulated tissues to not be subject to pre-market requirements such as product approval and activity licences. These controls will not add beneficial requirements to current processes and risk impacting negatively on the delivery of transplantation services. There may well, however, be developments in

the future (such as organs grown for transplant, or new infectious disease risks) that would mean that it would be beneficial to apply some pre-market controls and the regulatory regime should provide for this potential. Sector stakeholders are relatively comfortable with this approach provided that there are process requirements governing how any decisions to put pre-market regulatory requirements in place are made. The Ministry is supportive of this and it can be addressed by appropriate legislative placement and by using the accountability framework already agreed by Cabinet.

Prescribing and dispensing

8. In discussion of the proposal to move controls on prescribing to the Health Practitioners Competence Assurance (HPCA) Act 2003 you asked where final approval of prescribing authority would rest. Officials noted that they were considering whether this should rest with the Minister of Health or the Director-General of Health. The draft cabinet paper proposes that this power rest with the Minister of Health and notes that, under the general power of delegation in the State Sector Act, the power could be delegated if the Minister wished. This is consistent with the other powers under the HPCA Act.

Pharmacy licensing

9. As discussed with you, officials have tested further the policy on prescriber interests in pharmacies with relevant stakeholders and within the Ministry. As a result the draft cabinet paper proposes that the legislation contain a focussed prohibition on prescribers benefitting from their prescribing decisions through investment in pharmacies (as opposed to the current Medicines Act restriction on prescribers taking any interest in pharmacies, unless an exception is granted by the regulator). This approach aims to avoid the perverse incentives that may arise from prescriber interests in pharmacies while not impacting negatively on the development of integrated services (it would allow, for example, shared systems, staff, and working space).

Regulator form

s9(2)(f)(iv)

S9(2)(f)(iv)

Release of Cabinet papers

17. The Ministry has been considering the next steps of stakeholder engagement. Stakeholders are very interested in the developing regulatory regime and have been engaging constructively with the Ministry on its development. It would facilitate further engagement for the Ministry to be able to share the advice that has been provided to Cabinet in the attached paper and those considered by Cabinet in November 2015. The attached draft cabinet paper proposes that these three papers and associated Regulatory Impact Statements, with any necessary redactions, be released by the Ministry by May 2016.

Process matters

18. This paper is due to be considered by the Social Policy Committee on 30 March. A final paper for your approval will be provided by 18 March for lodgement in CabNet by 24 March. To facilitate meeting this timeframe your feedback is sought on this draft by 15 March.
19. The attached Regulatory Impact Statement is still under discussion between officials and has not yet been assessed by Treasury against their quality assurance criteria. This will be completed in time for lodgement on 24 March.

END.

DRAFT FOR MINISTER 11 MARCH 2016

In Confidence

Office of the Minister Health

Chair, Cabinet Social Policy Committee

Therapeutic Products Regulation: further policy approvals

Proposal

1 That Cabinet agree to further drafting instructions being issued for the Therapeutic Products Bill. The Bill is due for introduction in late 2016.

Executive Summary

2 Further to Cabinet decisions in November 2015 on the strategic context for the therapeutic products regulatory regime and key elements of the new regime, this paper seeks decisions on several discrete issues in order that further drafting instructions can be issued. The issues and key proposals on each are set out briefly below. These proposals have been developed to give effect to the objectives agreed by Cabinet for the regulatory regime, including that it be high quality, cost effective, and sustainable.

2.1 **Clinical trials** – alignment with international norms in respect of scope (trials of all types of products to be covered) and regulatory powers (sufficient to provide adequate protection).

2.2 **Cell and tissue therapeutic product regulation** – all such products (including tissue for immediate transplantation and xenotransplantation) should be within the scope of the regime with the ability for the most minimally manipulated tissue (eg, organs for transplantation) to be exempted from pre-market controls.

2.3 **Prescribing and dispensing** – legislative controls on prescribing authority should sit under the Health Practitioners Competence Assurance Act 2003 and under the jurisdiction of the Responsible Authorities established by that Act. Final approval of prescribing authority should rest with the Minister of Health.

2.4 **Pharmacy licensing** – pharmacies should continue to be licensed. Requirements to be met before a licence is granted should focus on ensuring the integrity of the supply chain for therapeutic products and upholding professional pharmacy standards. Restricting ownership of pharmacies to pharmacists is not required to meet these objectives. Controls will continue to be required, however, to limit prescriber interests in pharmacies.

2.5 **Import and export** – these activities require regulatory oversight via licensing and notification respectively. In addition the regulator should

continue to be able to issue export certificates where these are requested by exporters.

2.6 **Offences and penalties framework** – a hierarchy of tools is required – criminal offences, enforceable undertakings, and infringement notices.

2.7 **Regulator form** – a Crown Entity is not supported. Further work is being done on the options of a Departmental Agency and the Department, and on the design of supporting infrastructure. I will seek final decisions by October 2016.

2.8 **Interface with the Hazardous Substances and New Organisms Act** – simple changes are needed to address a current gap with respect to the environmental risks of finished dose form medicines.

2.9 **Placement of provisions** – officials will work to take account of advice from the Legislation Design Advisory Committee and the Parliamentary Counsel Office about the content of third tier regulatory instruments.

3 The next step for the Bill is the development and release of an exposure draft for consultation. To facilitate engagement in this process I recommend:

3.1 That this paper, those considered by Cabinet in November 2015, and the associated regulatory impact statements, be released by the Ministry (with any appropriate redactions) before May 2016.

3.2 That I approve the release of the exposure draft and an accompanying consultation document.

Background

4 In November 2015 Cabinet agreed to repeal and replace the Medicines Act 1981 and its Regulations with a new therapeutic products regulatory regime. It agreed the objectives of the regime, the key means to achieve those objectives, and the main elements of the regulatory scheme; drafting of the Bill has commenced. It also:

4.1 noted that the Minister of Health will report to Cabinet and seek agreement on the most appropriate [pharmacy] licensing arrangements for the Bill following sector consultation on the Draft Pharmacy Action Plan

4.2 noted that the Minister of Health would report to the Social Policy Committee during March 2016 on further policy issues with a view to further drafting instructions being authorised; these include prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework and the form of the regulator

4.3 noted that the Ministry of Health will discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments further with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and that the Minister of Health will report back on the outcome if any changes are proposed.

(SOC-15-MIN-0050 and SOC-15-MIN-0049 refer)

5 These matters and other issues are discussed in this paper.

Overview of the new regime

6 To recap, the regime seeks to address significant weaknesses and gaps in the Medicines Act 1981. That Act will be replaced with a comprehensive, modern regulatory regime. This regime is being developed following the decision to cease work on the joint regulatory regime with Australia (ANZTPA). The objectives agreed by Cabinet for the regime reflect the needs of the health sector now and into the foreseeable future, international regulatory and market settings (and New Zealand's unique market), and the Government's expectations for regulatory regimes.

7 The new regime will assist with delivering the proposed new New Zealand Health Strategy and in particular its aim for a Smart System. This theme in the strategy aims for the system to be well placed to take advantage of new technologies. These developments need to be underpinned by a robust regulatory framework that provides assurance of the safety, quality and efficacy or performance of products and sets out roles and responsibilities in relation to them. The new regulatory regime for therapeutic products is one of the actions in the proposed New Zealand Health Strategy's Roadmap of Actions (Action 27(b)). The strategy will also be considered by this Committee on 30 March 2016.

8 Cabinet has agreed that objectives of the regulatory regime for therapeutic products will be best met by:

8.1 an enabling legislative framework

8.2 regulatory requirements that reflect international norms, standards and frameworks

8.3 a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable, and able to engage internationally.

9 The therapeutic products regulatory regime will sit alongside regimes regulating food, psychoactive substances, natural health products, controlled drugs, human tissue, hazardous substances and new organisms, and health practitioners. Care is being taken to ensure the regimes work together, are fit-for-purpose, and that there is clarity for industry and practitioners as to their requirements.

9.1 **Food** and **psychoactive substances** are regulated by the Food Act 2014 and the Psychoactive Substances Act 2013 respectively. These statutes are clear that food and psychoactive substances do not include any substances used as medicines under the Medicines Act 1981. These arrangements will be updated and carried into the new therapeutic products regime.

9.2 **Natural health products** will be regulated under the Natural Health Products Act (once passed) which provides that a natural health product may not be, or contain, a scheduled medicine. That Bill also requires the

therapeutic products regulator to consult the Natural Health Products Authority before scheduling a natural substance as a prescription or pharmacy medicine. There are likely to be products that could be sold as natural health products or medicines and the person bringing the product to market will choose which regime to comply with according to their assessment of where they want to position their product in the market and compliance costs. The Natural Health and Supplementary Products Bill is currently before Parliament.

9.3 **Controlled drugs** are regulated under the Misuse of Drugs Act 1975. The controls under that Act will remain in place and work will be done to streamline detailed requirements, such as those in respect of labelling, as subordinate instruments are developed.

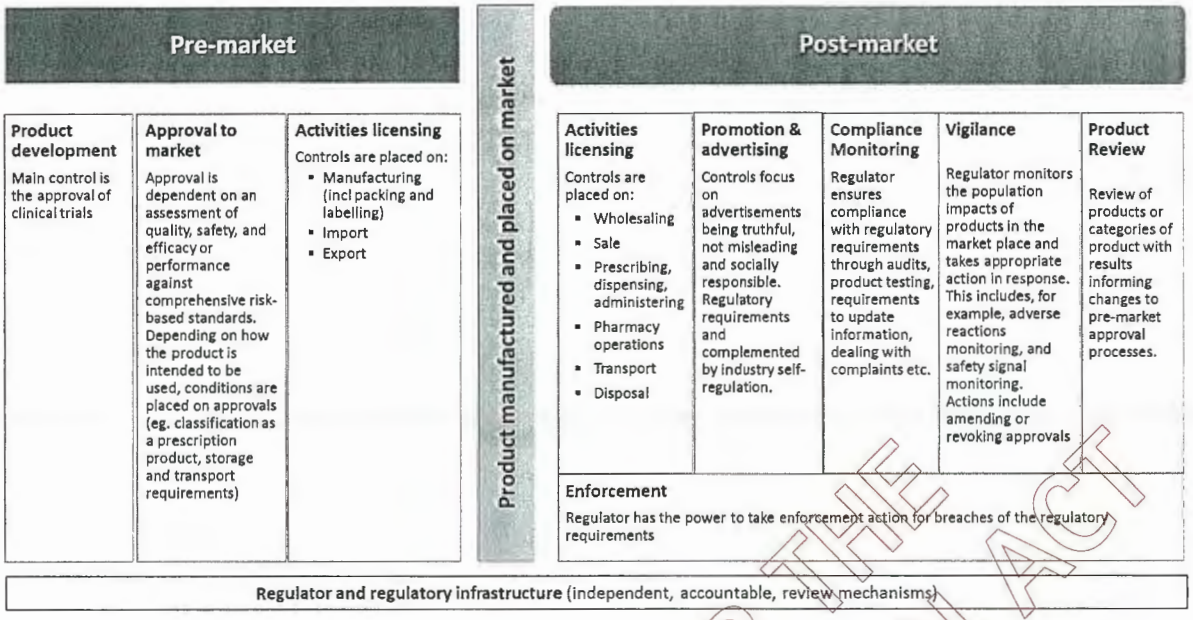
9.4 **Human tissue** use and collection is regulated under the Human Tissue Act 2008 and is primarily concerned with ensuring appropriate consent has been obtained for the use of tissue from deceased persons. It also controls trade in tissue from both living and deceased donors and is intended to ensure that the gift status of tissue is preserved. Importantly, the Human Tissue Act prevents trade in tissue without a ministerial exemption. Currently there is no process for gaining a ministerial exemption and it is therefore difficult for legitimate products to be available for patient treatment. The new therapeutic products regime will enable the approval of cell and tissue therapy products from a safety perspective, which could form the basis for a Ministerial exemption from the trading provisions of the Human Tissue Act for all approved cell and tissue therapies.

9.5 **Hazardous substances and new organisms**, that may also be therapeutic products, have an interface with Hazardous Substances and New Organisms Act 1996. This interface is discussed in this paper.

9.6 **Health practitioners practice** is regulated under the Health Practitioners Competence Assurance Act 2003. This interface with respect to prescribing practice is discussed in this paper.

Comment

10 Cabinet has agreed that, consistent with international approaches, the therapeutic products regulatory regime will regulate all therapeutic products (medicines, medical devices, cell and tissue therapeutic products and hybrids) across their lifespan. The diagram below shows the main control points and Cabinet has agreed this basic structure of pre- and post-market controls, approvals, licences, monitoring and enforcement.



11 This paper proposes arrangements for:

11.1 clinical trials

11.2 cell and tissue therapeutic product regulation

11.3 prescribing and dispensing

11.4 pharmacy licensing

11.5 import and export

11.6 offences and penalties framework

11.7 regulator form

11.8 interface with the hazardous substances and new organisms act

11.9 placement of provisions.

12 It is useful to recall that arrangements for these topics are being designed consistent with the overall objectives for the regime that Cabinet has agreed. Namely that the regime will:

12.1 meet expectations of risk management and assurance of acceptable safety

12.2 result in efficient and cost effective regulation

12.3 be flexible, durable, up-to-date, and easy to use

12.4 ensure high-quality, robust and accountable decision-making

12.5 be able to sustain capable regulatory capacity

12.6 support New Zealand trade and economic objectives

12.7 be trusted and respected

12.8 support consumer access and individual responsibility for care.

Clinical trials

13 Clinical trials can offer a number of social and economic benefits to New Zealand. New Zealand is a desirable location for conducting trials because of the high quality of our infrastructure, people and facilities. Looking forward the new regime needs to build on these strengths and facilitate trials being conducted here while ensuring that appropriate standards are met for the quality of the research and the safety of the participants. Currently clinical trials are regulated under the Medicines Act 1981 and the ethics regime under the New Zealand Public Health the Disability Act 2000 in parallel but separate processes.

14 In order to conduct trials two approvals may be needed: one in respect of the ethics of the research trial is needed in all cases, and the other in respect of the science only for certain types of medicines and uses. Medsafe issues the scientific regulatory approval on the advice of the relevant committee of the Health Research Council. An ethics committee will consider the ethical standards, which are set out National Ethics Advisory Committee (NEAC) guidelines and the procedural requirements contained in the Standard Operating Procedures for Health and Disability Ethics Committees.

15 Ethics processes are outside the scope of the therapeutic products regulatory regime, however it is worth the Committee being aware that NEAC is currently undertaking a comprehensive review of its guidelines. With both regimes under review, there is significant scope for increasing the cooperation and coordination between the regulatory and ethics approval processes for clinical trials. A more seamless application process for clinical trials will serve to enhance New Zealand's international competitiveness in attracting investment and research and development in the therapeutic products sectors. I have instructed officials to work to streamline and improve the efficiency of the two processes.

16 The therapeutic products regulatory regime will focus on the scientific elements of the clinical trial process. In keeping with the overall objectives for the regime, changes are needed to current arrangements in respect of scope and regulatory powers.

Scope

17 Currently the only clinical trials that require regulatory approval are those testing new medicines. In a comprehensive regulatory regime there is no case for not covering clinical trials of all therapeutic products, including all medicines (and specifically those that already have marketing approval, but are being trialled for new uses), medical devices, and cell and tissue therapeutic products. There will also need to be clarity over what constitutes a clinical trial, particularly the distinction between innovative clinical practices where new approaches are being used but formal investigational research is not being carried out.

18 This is the norm internationally and, as with the rest of the regulatory regime, it will be important for the regulatory requirements to be commensurate with the risk any particular trial poses: a graded system will be developed.

Regulatory powers

19 The new regime needs to enable the regulator to set the requirements to be met for approval to be granted, approve trials, set and change conditions on approvals, require reporting and information, inspect trial sites, audit the trial, take action to ensure safety and enforce compliance, and revoke or suspend approval.

20 The detailed technical requirements to be met before approval can be granted will follow international norms. In keeping with the objectives of the regime, requirements will be commensurate with risk. Low-risk trials are expected to require simple notification for approval and higher-risk trials an assessment (full or partial) by the regulator. There will also be a requirement for every trial to have an identified person who resides in New Zealand during the course of the trial to be responsible for meeting all the conditions of the approval, and a requirement for registration on an approved registry. These requirements will need to address issues such as the long-term commitment to participants, including ensuring that they continue to receive treatment for the full period of benefit. The Ministry will work with agencies such as PHARMAC in developing the requirements.

21 The time taken for regulatory approval of trials is critical to industry and short approval times support New Zealand's attractiveness as a trial destination. I propose that the current timeframe for considering applications for trials remain at a mandatory maximum of 45 *working* days. For future flexibility, including coordination with ethics timelines (which is currently 35 *calendar* days – a difference of 20 days) this should be set out in a subordinate instrument. This period is comparable with other jurisdictions.

22 Cabinet has already agreed that the regulator will have the ability to establish expert advisory committees and that it must establish a committee (or committees) for certain purposes. Under this structure, I propose that the regulator be required to establish a committee which could provide advice, as needed, on clinical trials. The relationship between this committee and the existing Health Research Council committee will be examined as part of the implementation.

Impact

23 Like other areas of the regime, the changes will be most significant for the currently largely unregulated sectors: medical devices and cell and tissue therapeutic products. Covering these products is, however, entirely consistent with international norms for protecting the public and important for maintaining New Zealand's standing as a high quality location for conducting trials. I expect sector interest in the detail of the clinical trial proposals during public consultation and the Ministry will engage with key stakeholders (eg, the Health Research Council and its committees, the Health and Disability Ethics Committees and the research community) before that time.

Cell and tissue therapeutic product regulation

24 Cell and tissue therapeutic products are derived from living cells and tissues of human or animal origin. These products span whole tissues that are part of established clinical practice (eg, kidney transplants and skin grafts) through to

innovative and substantially manipulated cellular therapies (eg, demineralized bone matrix for repair, dental pulp-derived stem cells for tooth regeneration).

25 New Zealand does not currently have specific regulation for cell and tissue therapeutic products. Although some products, such as innovative cellular products at the clinical trial stage and various blood products, are regulated as medicines.

26 The cell and tissue therapeutic product sector is a mix of non-profit entities (universities and health services) and commercial companies. Although volumes are generally low, there is a wide range of cell and tissue products on the market, the market is characterised by significant innovation internationally (eg, stem cells used for cardiac muscular repair) and continued growth is expected in this industry.

27 Since Cabinet's decisions in November 2015 the Ministry has been working with the sector to test whether the overall regulatory approach (summarised in the diagram at paragraph 10) needs any particular modification for cell and tissue therapeutic products. The overall conclusion of that work is that all these products should be included in the regulatory regime and that regulatory requirements will need to be graded according to the degree of manipulation of the tissue and will need to accommodate the realities of donation and transplantation services. This would mean that:

27.1 **Minimally-manipulated tissue for immediate transplantation** (eg, kidney transplants) would not require an approval before use; neither would retrieval or transplantation be licensed activities. This approach acknowledges that these are not 'products' in the conventional sense. Kidneys, hearts and other minimally manipulated tissue for immediate transplant can have a wide variation in physiological functioning (quality) and in potential for disease transmission (safety). There are long waiting lists for these tissues and a need to maximise their availability. The decision to use these tissues is a clinical one, there are protocols in place to guide practice (including informed consent requirements) and decisions often need to be made quickly. Additional pre-use regulatory controls (such as approvals and licences) are not considered necessary or desirable at present as they may impact negatively on transplant services without adding safety benefits. That said, these tissues should be within the scope of the regulatory regime in order to avoid creating difficult boundary issues with other tissue products and to provide the ability for regulatory requirements to be applied in the future should that be necessary to respond to technological developments (such as organs grown for transplant), new public health issues (such as new infectious diseases that warrant regulatory controls and that can be screened for within the timeframes necessary for transplant). A suitable mechanism will be developed through the drafting process in consultation with Parliamentary Counsel.

27.2 **Minimally-manipulated tissue that is stored** (eg, banked bone) would not require an approval before use. An activity licence covering matters such as infectious disease testing, storage, labelling, and transport would be required and some post-market controls would apply.

27.3 **Tissue that is more than minimally-manipulated** (eg, expanded mesenchymal stem cells to repair cartilage) would require approval, activity licences and post-market controls would also apply. These products are akin to medicines in many ways and similar controls are appropriate.

27.4 **Blood and blood products** would continue to be subject to full regulatory controls under the therapeutic products regulatory regime.

28 The Ministry will continue to work with the sector on the detailed requirements, the specific impacts on their work, and cost implications. The sector has been assured that the requirements will be risk-appropriate and reflect the characteristics of cell and tissue therapeutic products and will facilitate legitimate import and export of these products. The transplantation sector is relatively comfortable with the inclusion of minimally-manipulated tissue for immediate transplantation within the scope of the regime, provided that there are process requirements governing how any decisions to put regulatory requirements in place are made. I am supportive of this being a requirement and note that this can be addressed through the design of legislative instruments (such as having a regulation-making power that enables classes of product to be exempted from requirements) and through using the accountability framework already agreed by Cabinet.

29 Those dealing with products that are not currently regulated (such as the NZ National Eye Bank, NZ Blood Service's bone and tissue bank, and small tissue banks) will face additional compliance costs. These may be difficult for small, and/or not-for-profit bodies. Similar issues were faced in Australia when regulation of tissue banks was introduced there in 2011 and the Australian Government provided time-limited funding (until March 2016) to offset direct regulatory costs for publicly-funded and not-for-profit entities. These arrangements were designed to ensure the ongoing supply of donated tissue products for transplant. I am equally conscious of the need to maximise the availability of these products in New Zealand and officials will advise me of the likely impact on the sector and potential mitigations as the details of the regime are designed during 2016.

Import and export

30 Import and export controls for therapeutic products are discussed later in this paper. It is useful to note here however that the controls will not be placed on the import and export of minimally-manipulated tissue for immediate transplantation as this would impact unnecessarily and negatively on the New Zealand – Australia transplantation programme.

Xenotransplantation

31 Xenotransplantation is the practice of using live animal cells in human therapy. This technology is developing and there are clinical trials underway in New Zealand. Xenotransplantation is controversial with some people, and the Medicines Act 1981 currently contains specific provisions regulating xenotransplantation trials that ensure there is a high level of scrutiny of these trials and ministerial approval of applications. While not an issue yet, as xenotransplantation products have not developed beyond clinical trials, there is a

gap in the Medicines Act in respect of xenotransplantation products that may emerge from trials to be marketed. It is proposed that xenotransplantation be included within the scope of the therapeutic products regulatory regime to ensure complete coverage of products using this technology.

32 As a separate matter I will bring advice to Cabinet before June 2016 proposing that an Order-in-Council be made to extend the current controls in the Medicines Act on clinical trials until after the therapeutic products regulatory regime is in place. Currently these controls will expire in September 2016.

Prescribing and dispensing

33 Currently the Medicines Act 1981 and the Medicines Regulations 1984 control who may prescribe prescription medicines and any conditions on prescribing. Repealing and replacing these instruments provides an opportunity to assess whether the current arrangements for prescribing are fit-for-purpose for the delivery of health and disability support services into the future.

34 Any proposed changes to the prescribing parameters of practitioners need to bring about benefits to patient care, result in improved health outcomes, or equivalent health outcomes with improved patient convenience or more appropriate use of the workforce.

35 The classification of a therapeutic product is the process of specifying conditions on public availability, for example, whether a product should only be available via a health practitioner. Only certain health practitioners can prescribe prescription therapeutic products because they have the qualifications, training and competence to do so. The competence and registration of health practitioners is the remit of the Responsible Authorities (eg, Medical Council, Nursing Council) under the Health Practitioners Competence Assurance Act 2003 (HPCA Act). In that light I propose that, through the Therapeutic Products Bill, controls on prescribing shift to the HPCA Act. This approach better recognises the role and jurisdiction of Responsible Authorities for the competence and practise of the regulated professions.

36 Under this approach the detail of who is authorised to prescribe prescription therapeutic products (including any conditions for certain prescriber groups) will shift into the relevant scopes of practice developed and Gazetted by Responsible Authorities under requirements in the HPCA Act.

37 Scopes of Practice bound the roles of health practitioners and the HPCA Act contains mechanisms for establishing and changing scopes of practice. These will require some amendments to ensure sufficient oversight of prescribing.

38 The current prescribing authorities and parameters will be directly translated into this new approach. Likewise, for registered health practitioners who do not currently have prescribing authority, no changes are proposed.

39 The process to establish a new, or significantly change, a Scope of Practice for prescribing will then be:

39.1 Responsible Authorities establish, through a period of consultation, the appropriate parameters of prescribing activity (including training and qualifications).

39.2 The Ministry considers the proposal in line with the strategic objectives of the health system.

39.3 The Minister of Health makes a decision whether to approve the parameters of prescribing proposed for inclusion in a Scope of Practice. Under the general power of delegation in the State Sector Act this ability could be delegated if the Minister wished.

40 The Ministry has consulted the Responsible Authorities and key representative groups on this proposal. The majority of stakeholders and Responsible Authorities supported the option of using the scope of practice detail to identify those that are authorised to prescribe.

41 In consultation, Responsible Authorities noted that there will be a need for stringency in how Scopes of Practice are drafted and for greater transparency in the consultation process. They also identified the risk that some Responsible Authorities may seek to advance their own profession and this will need to be managed. These issues will be addressed as the changes are implemented. This will include guidance on how Scopes of Practice should be drafted and expectations set as to how the provisions of the HPCA Act that detail how Scopes of Practice are developed and consulted upon are given effect. The Medical Council has decided to await the draft Bill before providing a position.

42 On the basis of consultation with the sector, mechanisms will be developed to facilitate the continuation of delegated prescribing and the use of Standing Orders (where prescription medicines can be administered in defined circumstances in the absence of a prescription, for example, by paramedics). These matters will be set out in regulations. I will be bringing a paper proposing that Nurse Practitioners be given the ability to issue Standing Orders to the Committee for consideration in April 2016.

43 It is proposed that dispensing arrangements and obligations continue to be set in regulations. The content of regulations will reflect current practice needs and appropriate safety controls.

44 An amendment Bill is currently being redrafted by Parliamentary Council Office to give effect to the two reviews of the HPCA Act. Officials are working to ensure consistency between that amendment Bill and the amendments proposed for inclusion in the Therapeutic Products Bill.

Pharmacy licensing

45 Cabinet agreed in November 2015 that, as is the case currently, operating a pharmacy will be prohibited except when done under a licence. In making this decision I advised Cabinet that further work would be done on licensing arrangements and that my initial view was that the current restrictions on pharmacy ownership are not necessary to achieve safety objectives. This paper reports back on pharmacy licensing arrangements.

Pharmacy in New Zealand

46 New Zealand has more than 3400 practising pharmacists and over 980 community pharmacies. Around 75 percent of pharmacists work in community pharmacy, dispensing over 50 million prescriptions each year and providing advice on medicines and the management of minor ailments, from a network of distributed and highly accessible community pharmacies.

Pharmacy licensing

47 Pharmacy licensing is a critical part of ensuring the integrity of the supply chain of therapeutic products and Cabinet has agreed to continue the international norm of licensing this activity. Currently, the regulator has the ability to:

47.1 issue a licence

47.2 set conditions on licences

47.3 require information

47.4 assess whether the applicant for a licence is a fit-and-proper person or, if a corporate, of good repute to hold a licence.

48 I propose that these arrangements continue in the new regulatory regime.

49 In addition, the Medicines Act 1981 contains the requirement that a pharmacy must be majority owned by a pharmacist (51 percent) and that a pharmacist can hold a majority stake in up to five pharmacies. As stated in my previous advice to Cabinet these ownership restrictions are unnecessary to ensure the integrity of the supply chain and manage risks to public health.

50 Pharmacy licence ownership restrictions are an anomaly in New Zealand's licensing system. Licences do not normally seek to restrict business owners, but rather regulate the risk of an activity via conditions. Conditions on a licence rather than ownership restrictions better manages risks and enables a competitive market.

51 To ensure that professional standards of pharmacy practice are upheld I propose that the regulator require pharmacy licence applicants to name a pharmacist who will have responsibility for advising owners on, and overseeing, the implementation of professional pharmacy standards and licence conditions. This role would be additional to the current requirement that a Responsible Pharmacist is identified as responsible for the day-to-day operations within the pharmacy. The working title for this new role is Supervisory Pharmacist.

52 Both the Supervisory Pharmacist, and the Responsible Pharmacist, will be accountable to the licence holder who, in turn, would be accountable to the regulator. A breach of professional practice standards within a pharmacy may result in enforcement action against the licence holder. It may also result in disciplinary action for the Responsible or Supervisory Pharmacist through the Health Practitioners Disciplinary Tribunal established under the Health Practitioners Competence Assurance Act.

53 In practice, in a small pharmacy, an individual pharmacist could be the Supervisory Pharmacist and Responsible Pharmacist. Where the owner(s) (which could be an individual, a trust, or a corporate body) holds multiple pharmacy licenses a single Supervisory Pharmacist should be named across all their licenses where there is consistency across standards being overseen, to enable a single point of contact for this role for the owners and the regulator.

54 To ensure that the Supervisory Pharmacist is able to effectively perform their role, the regulator should be able to impose conditions on a licence with respect to:

54.1 requiring licence owners to ensure the Supervisory Pharmacist is adequately resourced to perform their role across a number of pharmacies

54.2 managing risks that may arise if a Supervisory Pharmacist is responsible to different pharmacy owners.

55 The Medicines Act 1981 also contains provisions restricting prescribers from taking any interest in pharmacies, unless granted an exception by the regulator. This restriction is designed to prevent prescribers benefitting financially from their prescribing decisions. I support the intention of this policy, but note that the current settings may negatively impact on the development of integrated health services. I propose that a more focussed prohibition on prescribers benefitting from their prescribing decisions through investment in pharmacies is developed that also enables prescribers and pharmacies to develop more patient-centred and integrated services (for example, shared systems, resources, staff, and working space). The arrangement would apply to all prescribers, including pharmacist, nursing, and other prescribers.

56 I also propose that:

56.1 consistent with Cabinet's decisions in respect of licences for other activities (such as wholesaling), pharmacy licences may be issued for up to three years (as opposed to the current annual licensing) where there is evidence of suitable quality systems and standards

56.2 the regulator be able to set appropriate conditions to manage the risks associated with different distribution and supply models for therapeutic products and different models of pharmacy practice. This includes, for example, not tying licences to fixed physical premises, and setting minimum pharmacy standards to be met under a licence.

57 As a related matter, I note that pharmacy licensing decisions and access to public funding for providing pharmacy services are separate matters. I do not propose making any change to this division of roles. Pharmacy licensing will be the jurisdiction of the therapeutic products regulator, while funding decisions are made by District Health Boards according to the needs of their local populations. The granting of a pharmacy licence does not carry any entitlement to a services contract. Officials will work to ensure the pathway and processes for funding decisions are clear to licence applicants.

58 Officials have engaged thoroughly with the pharmacy sector on these proposals (including through the Pharmacy Action Plan consultation process) and will

continue to do so as the Bill is drafted and details developed. To date the sector has shown a close interest in these issues and is keen to engage more closely as detailed regulations are developed.

Import and export of therapeutic products

59 Therapeutic products are freely-traded global commodities. Parts of the manufacture and packing process may occur at different locations and supply chains are complex. The internet also allows consumers to have direct access to suppliers in different jurisdictions. It is important for the therapeutic products regulatory regime to have import and export controls that appropriately manage the risks to patient safety, protect New Zealand's reputation and support New Zealand's trade and economic objectives.

60 The risks of not having adequate controls at the border are:

60.1 low-quality or counterfeit products entering the New Zealand supply chain

60.2 not meeting international commitments

60.3 reputational – for New Zealand-manufactured products and more broadly for New Zealand Inc.

61 These risks vary depending on the circumstances and so does New Zealand's interest in regulating them.

Import controls

62 Imported therapeutic products are intended for supply to the New Zealand market. If those products are counterfeit, adulterated or do not meet regulatory safety and efficacy requirements, they could pose a direct safety risk to New Zealand consumers. The current arrangements do not adequately manage this risk as prosecutions can only be made once an actual sale has occurred or an intention to sell has been established. It also means that information about who is importing therapeutic products, in what quantities and where that product is going is not collected and collated at the border.

63 It is proposed that importation become a licensed activity: importation without a licence would be an offence and enable intervention before those products get into the New Zealand supply chain. Collecting more information at the border will ensure that there is a more complete picture of the therapeutic products that come into the country and will also assist with the traceability of those products in the event of recalls. Import licences are required for products that pose comparable risks including prescribed foods, psychoactive substances, hazardous waste and those containing ozone-depleting substances. This approach is consistent with what happens in other jurisdictions and it will help New Zealand to meet its World Health Organization commitments in assisting to prevent the manufacture and sale of substandard and counterfeit medicines[1].

[1] The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1999).

64 These benefits need to be balanced against the costs and the likelihood of risks materialising given that within the supply chain for publicly-funded medicines there are already a number of control points at which issues with imported products can be detected. I therefore propose an arrangement where the system for import licences is as automated and streamlined as possible. Officials are working on an approach that would require minimal additional data entry and there should be no justification for industry passing on substantial costs to consumers or the health system. Import licensing will be a significant change for the medical devices and cell and tissue industries, but may be welcomed by compliant and trusted suppliers as it will protect the integrity of the market.

65 I propose to retain the current ability for individuals to bring in small quantities of therapeutic products for personal use, so long as they have met regulatory requirements. Currently the requirements relate to prescription medicines and an individual needs to have an authorisation from a prescriber in order to receive imported goods. A similar arrangement will be contained in the new regime. The regulator will also have the ability to intervene if the volume of product is too high (over 3 months' supply) or if particularly high-risk products are being imported.

Export controls

66 New Zealand manufacturers export their products to other markets and there is some transactional export where products from overseas are imported (potentially repackaged or labelled) then exported again. The issues of concern relate to protecting New Zealand's reputation and to support the domestic industry; namely, that:

66.1 Some companies may be acting as 'middlemen' in transacting (importing then exporting) unapproved and possibly low-quality products through New Zealand sometimes to nations with less ability to pay for products (eg, the Pacific Islands). These products may pose a risk to the well-being of these consumers.

66.2 Therapeutic products may be exported (including transactional export) either claiming or implying New Zealand regulatory approval.

66.3 It is damaging to New Zealand's wider reputation if it is seen as a source or transit point for low-quality or counterfeit product.

66.4 New Zealand may not be meeting its international commitments.

67 I propose regulatory controls to address these risks while not imposing burdensome requirements or impeding the flow of therapeutic products to Pacific countries for legitimate reasons.

68 I propose that the regime require notification of exports of therapeutic products accompanied by evidence that those products meet the regulatory requirements of the receiving country. Notification of exports is already a requirement in some cases for medical devices and will be for natural health products, but is not for medicines. Notification alone for all therapeutic products would improve information at the border, but would do little to mitigate the reputational risks associated with low-quality products. Adding a requirement that the exporter supply evidence that the product meets the standards of the importing country

would provide some assurance that the exported product meets minimum standards. Requiring that all exported products be approved by the regulator would place too much of a burden on the export-only industry and on the regulator. If overseas jurisdictions wish to seek the advice of the New Zealand regulator on the safety of a particular product they could do so.

69 In addition, I propose to continue the current ability for the regulator to issue export certificates on request. These certificates are currently required by some jurisdictions receiving products manufactured in New Zealand and the New Zealand-based exporter can obtain these from the regulator. Export certificates provide an assurance that the product can be marketed in New Zealand and New Zealand currently follows the international norm for issuing certificates (set by the World Health Organization's Certification scheme on the quality of pharmaceutical products moving in international commerce).

70 No changes are proposed to current requirements in respect of the import and export of controlled drugs.

Parallel importation

71 For therapeutic products, parallel importation would effectively mean the importation and marketing of products by a supplier that does not hold a regulatory approval for those products. Even if they appear to be the same as an approved product, the quality and safety of these products could not be assured and it would be impossible to hold the approval holder to account for them. The ability to parallel import with minimal regulatory control in Europe has resulted in counterfeit medicines in the legitimate supply chain on several notable occasions.

72 Parallel importing of medicines is prohibited now as a result of requiring regulatory approvals. The same arguments apply to medical devices and cell and tissue therapeutic products in that there needs to be a clear link between the supplier and the manufacturer. Parallel importing will therefore be prevented for them under the new regime when they also require approvals.

73 There is currently a specific exemption in the Medicines Act that allows the Crown to parallel import medicines without the usual approval processes. The Crown has contemplated using this when available stocks of key medicines were running out. It has also provided useful leverage for PHARMAC when suppliers have threatened to withdraw vital products during commercial negotiations. I propose that the new regime include a credible mechanism to make it possible for the Crown to source alternative supplies of therapeutic products in appropriate circumstances.

Offence and penalty framework

74 Cabinet was advised in November 2015 that the legislation would include flexible modern offences and penalties, aligned with recent similar legislation (such as the Food Act and the Health and Safety at Work Act). The proposed enforcement tools will allow the regulator a wide range of options, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances.

75 I propose a hierarchy of enforcement tools:

75.1 Tiered criminal offences, generally in three levels covering 1) negligent or reckless conduct; 2) conduct that poses a risk to human health, but is not negligent or reckless; and 3) less serious non-compliance with regulatory requirements. There will be separate categories of offence for misconduct by licence-holders (such as a failure to abide by the code of good manufacturing practice) and for the unlicensed carrying out of a restricted activity (such as manufacturing medicines without a licence) with penalties calibrated to the type of licence.

75.2 Enforceable undertakings, which allow the regulator to accept an undertaking from a license-holder, in lieu of more severe enforcement action. Such undertakings are then enforceable in the courts and offer an interim step before suspension or cancellation of licenses, or even criminal charges.

75.3 Infringement notices, which will allow instant fines for low-level offending.

Regulator form and vestment of powers

76 The choice of institutional form and the supporting infrastructure are important to achieving the objectives of the regime; noting that the new regulatory regime will be different to the status quo in the following ways:

76.1 it will be more comprehensive and have greater reach

76.2 the regulator will have greater regulatory independence and commensurately greater accountability

76.3 it will be larger (though still modest by international standards).

77 As Cabinet was advised last November, there are three options for the form of the regulator: Department (a unit of the Ministry of Health – the status quo); Departmental Agency (an operationally autonomous agency with an independent chief executive, accountable to a Minister and hosted within the Ministry), or a Crown Entity (a separate entity with a board accountable to the Minister).

78 The most appropriate form is that which best supports:

78.1 independence – the regime will be most effective when regulatory and budgetary independence is supported by operational independence[2].

78.2 accountability – the corollary of independence is accountability and Cabinet has agreed a set of accountability arrangements for the regulator. These include separate reporting of financial and non-financial performance.

78.3 establishing and maintaining capability and capacity – recalling that this was a key reason for joining forces with Australia under ANZTPA, all

[2] The Productivity Commission's definitions of these terms is used here. Namely that, *regulatory independence* is the degree to which the regulator can set and adjust regulatory requirements; *budgetary independence* is the degree to which the regulator is protected from political or sector pressure through funding arrangements; and *operational independence* is the degree to which the regulator has operational independence or a broad discretion to exercise a range of powers.

efforts need to be taken to support sustainable capacity. With respect to institutional form, the key issue is how the regulator is perceived by technical staff and the international regulatory community as a credible operator and a desirable place to work. The regulator needs to be well positioned to attract and retain staff, engage international expertise (eg, on committees) and participate in the international regulatory community (eg, information-sharing, staff development, and work-sharing initiatives).

78.4 a positive regulatory culture – highlighted by the Productivity Commission as a critical factor for effective regulation. The Commission identifies the importance of good foundational leadership.

78.5 organisational effectiveness and efficiency – includes consideration of cost, impact of size, ongoing cost effectiveness and connections within the Ministry and the wider health sector.

78.6 flexibility to incorporate other functions – the degree to which the options provide flexibility for the regulator to oversee other regulatory functions (eg. Psychoactive Substances Act, and the Radiation Protection Act). Administration of the upcoming Natural Health Products regulatory regime could also be done under the auspices of the therapeutic products regulator. This is not the approach being taken now, but may be desired in the future (for example after the 5 year review of that regime).

79 It is also important for the Committee to be aware that, as part of an internal change programme, the Ministry of Health is examining the optimal delivery of its broad set of regulatory functions. This will include the fit between other responsibilities (such as the regulation of services) and the new therapeutic products regulatory regime.

80 At this point the Ministry considers that the key decision to enable as complete a draft as possible of the Bill to be released is whether the regulator should be a Crown Entity or not. Should a Crown Entity be the preferred approach, the draft Bill should contain provisions in respect of its functions and powers.

81 The key difference between a Crown entity and the Department and Departmental Agency options is its status in relation to the Crown. Departments and Departmental Agencies are part of the legal Crown while Crown Entities are outside the legal Crown. Initial analysis concludes that being part of the legal Crown has advantages in respect of delivering the regulatory regime objectives. In particular that it will facilitate domestic and international engagement – factors identified as important to effective regulation and for sustaining capacity.

82 Alongside this consideration, the analysis identifies that the Crown Entity model would be the most expensive to establish and maintain and that it may be harder for a Crown Entity to incorporate other functions. A completely separate organisation also risks weakening the connection between the Ministry and the regulator to the detriment of both organisations.

83 I recommend therefore that the therapeutic products regulator not be established as a Crown Entity.

84 A decision between the remaining two options turns on the need for operational independence, the contribution organisational form can make to sustaining capacity, and the fit with the Ministry's other functions, including its regulatory functions.

85 Initial analysis shows that the Departmental Agency form offers a number of advantages in respect of operational independence and sustaining capacity. It is, however, a new institutional form that, while designed for this type of function, has not yet been used for a regulator. The Departmental model could support the objectives of the regime. It is a known structure but it brings least as a matter of form and would require more to ensure that the objectives were met in an enduring way.

86 In light of this uncertainty, I propose that a decision on the form of the regulator be delayed until later in the year when further analysis has been carried out on the fit with the Ministry's wider functions. I propose managing any uncertainty in the interim by providing a clear signal that the regulator will have operational independence, clear accountability arrangements, and that all efforts will be taken to ensure sustainability: these are the factors of importance to stakeholders. I also propose that the decision on the form of the regulator be taken by October 2016 in order that there is no undue delay to the development of the regulatory regime.

87 In order that the drafting of legislation is not impacted, the Therapeutic Products Bill should be drafted so as to keep open the options of Departmental Agency and Department. This can be done by vesting the relevant powers in the chief executive as defined in the State Sector Act. That Act defines chief executive as the head of a department or a departmental agency.

Interface with the Hazardous Substances and New Organisms Act

88 If a therapeutic product contains a new organism (including genetically modified organisms) or a hazardous substance it falls within the jurisdiction of the Hazardous Substances and New Organisms Act 1996 (HSNO) and the new regime. Two issues have been identified in respect of this interface:

88.1 the approvals process for new organisms

88.2 the environmental risks of finished dose form therapeutic products that contain substances hazardous to the environment.

<u>Approval process for products containing a live new organism</u>

89 If a medicine contains a live new organism, an approval is required from two regulators – Medsafe and the Environmental Protection Authority (EPA). Separate applications are made to both agencies with the EPA assessing the environmental and public health risks while Medsafe assesses the efficacy, consumer safety and risk to the general public. Currently, only one relevant human medicine has been approved by the EPA for use in New Zealand (Pexa-Vec), with that approval restricting use of the medicine to a clinical trial. The medicines industry has indicated that the dual processes for medicines are a barrier to market entry and deter clinical trials. There is also a potential risk of

duplication in the current process as both agencies assess public health and safety risks.

90 I suggest that the new therapeutics regulator and the EPA continue to work together to ensure the application process for therapeutic products containing new organisms is efficient and effective, including minimising where appropriate the transactions required. This would recognise the separate roles of each agency in an applications process while streamlining it from the applicants' perspective. The new therapeutics regulator would require sufficient flexibility to be able to work with the EPA, which already has the ability to develop an appropriate operational arrangement with the new regulator.

Regulating products containing hazardous substances

91 The HSNO regulations exempt finished dose form medicines from the HSNO Act; and the Medicines Act only empowers the prohibition of medicines that represent an unacceptable risk to public health. Officials advise this interface is generally working well. However, there is no regulation to control the disposal of medicines and there is no legislated mandate under the HSNO Act or the Medicines Act to prohibit the importation and distribution of medicines in a finished dose form that contain an environmentally hazardous substance.

92 Were a product to be identified that might have a high environmental risk in the future, it would be unacceptable that New Zealand regulators are unable to adequately respond to such a risk if the ingredient is contained within an imported therapeutic product.

93 Accordingly I propose that the legislation give the new therapeutics regulator the power to prohibit the importation and distribution of medicines that contain an environmentally hazardous substance and to prescribe disposal requirements on the advice of the EPA. The regulator could request an assessment of the environmental risks or this advice could be provided on the initiative of the EPA. The new regime will establish regulation around the disposal of therapeutic products. These changes should assist in managing their potential impacts on the environment from finished dose form medication.

Placement of provisions

94 In November 2015 Cabinet agreed to a flexible legislative framework and was advised that to achieve this end as much detail as possible would be contained in regulator-made instruments. Cabinet also agreed that placement of key provisions – particularly the categorisation of products as medicines, medical devices, cell and tissue therapeutic products, or hybrids – should be discussed with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and that the Minister should report back if any changes were proposed as a result.

95 Discussions with these bodies conclude that changes will be needed to the proposal that these categorisations be placed in regulator-made instruments. The Ministry was advised that the desire for flexibility to change these categorisations in response to changing technology did not outweigh the need for certainty in these core settings and that they should not be included in third tier legislation. I propose that officials continue this engagement and settle

placement matters with a view to the legislation being as flexible as possible while also providing certainty as to the scope of the regulatory regime and its requirements.

Consultation

96 The following agencies were consulted on this paper: Parliamentary Counsel Office, Treasury; State Services Commission; Ministries of Business, Innovation and Employment, Justice, Primary Industries, Environment, Women, Social Development, Foreign Affairs and Trade; Te Puni Kokiri; PHARMAC; ACC; Environmental Protection Authority; and New Zealand Customs. Agency views are reflected in this paper.

97 The following agencies were informed about this paper: Department of Prime Minister and Cabinet.

98 The Ministry has had targeted engagement on the issues in this paper with a range of industry and sector stakeholders and further consultation is planned before the release of the exposure draft and as part of that process.

99 Agency comment:

99.1 The Parliamentary Counsel Office notes that the timeframe to develop, consult on, and introduce the Bill is tight.

99.2 Treasury and the Ministry of Business, Innovation and Employment continue their support for the removal of ownership restrictions on pharmacies.

Financial Implications

100 Cabinet has agreed that the new regulatory regime will be able to be funded through both cost recovery and Crown revenue. An indication of how these costs should fall will be contained in the policy proposals that accompany the exposure draft.

101 The costs of developing the new regime are currently met from within the Ministry of Health's baseline funding (including some funding from the Ministry's third party revenue baseline funding). Consideration will be given to whether implementation costs that cannot be reasonably met from these sources will be managed within usual budget processes or factored into fee-setting for the new regulatory regime. It is expected that any bids would be part of the 2017 Budget process.

Human Rights

102 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.

Legislative Implications

103 This paper proposes that further drafting instructions for the Therapeutic Products Bill be issued. The Therapeutic Products Bill will repeal and replace the

Medicines Act 1981 and it has priority 5 on the legislation programme (to be introduced in 2016).

Regulatory Impact Analysis

104 [final comment to come from Treasury following assessment of the final RIS].

Gender Implications and Disability Perspective

105 There are no particular matters with respect to gender implications or disability perspectives.

Publicity

106 The Ministry continues to engage with sector stakeholders on the design of the regulatory regime and there is considerable interest in it.

Release of Cabinet papers and regulatory impact statements

107 The Ministry has undertaken targeted consultation with industry and sector stakeholders as the proposals for the new regime have been developed. To facilitate further engagement now and later in the year with the exposure draft, I propose that this Cabinet paper, the two considered by Cabinet in November 2015, and the associated regulatory impact statements be proactively released by the Ministry of Health before May 2016. Before release the Ministry will assess whether redactions, consistent with the grounds for withholding information under the Official Information Act, should be made.

Exposure draft

108 Cabinet has agreed that I will release an exposure draft of the Bill for consultation along with a statement of the policy to be contained in subordinate legislative instruments (SOC-15-MIN-0049 refers). In order that the maximum possible time is allowed for developing and consulting on the draft Bill I propose that Cabinet agree that I approve the release of this package of material (the draft Bill and consultation document) and report back the key outcomes from the consultation at the time that I seek approval to introduce the Bill (unless there are matters of particular significance that should be addressed by Cabinet before introduction).

109 I intend to make a media statement at the time the exposure draft and consultation material are released.

Recommendations

110 The Minister of Health recommends that the Committee:

Previous consideration

1. note that, as recorded in SOC-15-MIN-0050 and SOC-15-MIN-0049, in November 2015 Cabinet:

   a. agreed the objectives for a new regulatory regime for therapeutic products in New Zealand

b. agreed the means to achieve those objectives

c. agreed that drafting instructions be provided to the Parliamentary Counsel Office for the key elements of a Therapeutic Products Bill to repeal and replace the Medicines Act 1981

d. noted that the Minister of Health would report to the Social Policy committee during March 2016 on further policy issues with a view to further drafting instructions being authorised; these include prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework and the form of the regulator

e. noted that the Minister of Health will report to Cabinet and seek agreement on the most appropriate [pharmacy] licensing arrangements for the Bill following sector consultation on the Draft Pharmacy Action Plan

f. noted that the Ministry of Health will discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments further with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and that the Minister of Health will report back on the outcome if any changes are proposed

Clinical trials

2. note that clinical trials that are conducted with a robust safety and ethical framework can offer a number of social and economic benefits to New Zealand

3. note that the ethical processes are out of scope for the therapeutic products regulatory regime as they are covered by the New Zealand Public Health and Disability Act 2000 and that officials are working to streamline and improve coordination and cooperation between the regulatory and ethical approval processes

4. agree that the therapeutic products regulatory regime cover trials of all therapeutic products (all medicines, medical devices, cell and tissue therapies, and hybrid products) with requirements commensurate with the risk an individual trial presents

5. agree that the regulator have the necessary powers to enable it to set requirements, approve trials, change conditions, access information, inspect, audit and take action to ensure safety (including revoking approval)

6. agree that, under the overall committee structure previously agreed by Cabinet, the regulator be required to establish a committee to consider applications for clinical trials

7. agree that the current timeframe for considering applications remain at 45 working days and that this be contained in a subordinate instrument

Cell and tissue therapeutic product regulation

8. note that, since Cabinet agreed in November 2015 that cell and tissue therapeutic products would be included within the scope of the therapeutic products regulatory regime, the key elements of the regime have been tested with the sector

9. note that this work supports inclusion of all cell and tissue therapeutic products within the regime (including minimally-manipulated tissue for immediate transplantation and xenotransplantation) with requirements calibrated to the risk of the products and the way they are used in clinical practice

10. agree that the regime include a mechanism to enable minimally-manipulated tissue (both for immediate transplantation and banked for later transplantation) to not be subject to the requirement for pre-market approval

11. agree that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to the requirement for activities licences

12. agree that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to import and export requirements

13. agree that items 10 – 12 be drafted so as to allow these settings to be changed in the future should issues arise that warrant it

14. note that both legislative placement and the accountability arrangements agreed by Cabinet for the regulatory regime will ensure that there is appropriate oversight by Government, and sector engagement with, any proposal to put additional regulatory requirements in place for minimally-manipulated tissue for immediate transplantation

Prescribing and dispensing

15. agree that prescribing therapeutic products, while closely associated with the therapeutic products regulatory regime, is essentially part of a health practitioner's practice

16. agree that controls over who is authorised to prescribe prescription therapeutic products and any conditions on that practice should sit under the Health Practitioners Competence Assurance Act 2003

17. agree that the Health Practitioners Competence Assurance Act 2003 be amended to include mechanisms for prescribing authority to be part of a health practitioner's Scope of Practice (including amendments to prescribing authority)

18. agree that those mechanisms include the Minister of Health deciding whether to approve the parameters of prescribing proposed for inclusion in a Scope of Practice

Pharmacy licensing

19. note that pharmacy licensing is aimed at ensuring the integrity of the supply chain of therapeutic products and Cabinet has previously agreed to continue the international norm of licensing pharmacies

20. agree that the therapeutic products regulatory regime provide for the regulator to:

    a. issue licences, for up to three years

    b. require information

31. agree that the current exemption permitting the Crown to parallel import medicines be replaced with a credible alternative that will enable the Crown to source alternative supplies of therapeutic products in appropriate circumstances

Offences and penalties framework

32. agree that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings, and infringement notices

Regulator form

33. agree that the regulator not be established as a Crown Entity

34. agree that the powers of the regulatory regime (and associated administrative powers) be vested in the chief executive as defined in the State Sector Act

Interface with the Hazardous Substances and New Organisms Act 1996

35. note that therapeutic products may contain new organisms, including genetically modified organisms, or a hazardous substances which are regulated under the Hazardous Substances and New Organisms Act by the Environmental Protection Authority

36. agree that the new therapeutics regulator and the Environmental Protection Authority will work together to ensure the application process for therapeutic products containing new organisms is efficient and effective

37. note that there is no legislated mandate under Hazardous Substances and New Organisms Act or the Medicines Act to prohibit the importation and distribution of medicines that contain an environmentally hazardous substance

38. agree that the Therapeutic Products Bill provide the ability to prohibit the importation and distribution of medicines that contain an environmentally hazardous substance and to prescribe disposal requirements on the recommendation of the Environmental Protection Authority

Drafting instructions

39. authorise drafting instructions being provided to the Parliamentary Counsel Office to give effect to the decisions in items 2 – 38

40. agree that the Minister of Health has the ability to make further policy decisions for the purposes of preparing the exposure draft of the Bill where the matter is consistent with the decisions made by Cabinet to date on the content of the Therapeutic Products Bill

41. agree that the Ministry of Health issue drafting instructions in respect of other matters that are currently contained in the Medicines Act 1981 and that are uncontentious with appropriate adjustments made to reflect decisions made by Cabinet on the design of the new regulatory regime

Placement of provisions

42. note that discussions with the Parliamentary Counsel Office and the Legislation Design Advisory Committee about the placement of key provisions in the legislative hierarchy indicate that generally core definitions should not be included in third tier legislation (as was initially proposed)

43. agree that officials continue to work with the Parliamentary Counsel Office and the Legislation Design Advisory Committee on placement matters with a view to the legislation being as enabling as possible while also providing certainty as to the scope of the regulatory regime and its requirements

Report backs

44. agree that the Minister of Health report to the Social Policy Committee on institutional arrangements for the regulator, including whether the regulator should be the Department or a Departmental Agency, no later than October 2016

45. agree that the Minister of Health report to the Social Policy Committee by June 2016 on extending Part 7A of the Medicines Act that controls specified biotechnical procedures (including xenotransplantation) and who should approve clinical trials of this technology in the new regulatory regime

Process matters

46. agree that the Minister of Health approve the release of an exposure draft and supporting consultation material later in 2016 and that the Minister report back to Cabinet on the outcomes of consultation at the time approval is sought to introduce the Therapeutic Products Bill (unless there are matters of particular significance that should be addressed by Cabinet earlier)

47. agree that, to facilitate stakeholder engagement, the Ministry of Health release this paper, SOC-15-SUB-0049, SOC-15-SUB-0050, and associated regulatory impact statements before May 2016 (noting that there may be deletions to the papers consistent with the Official Information Act 1982).

[Authorised for lodgement

Hon Dr Jonathan Coleman

Minister of Health]

MINISTRY OF HEALTH
MANATŪ HAUORA

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Action required by: comment before 10 November 2015

Draft Therapeutic Products Regulation Cabinet papers for your review

To: Hon Dr Jonathan Coleman, Minister of Health

Copy to: Hon Peter Dunne, Associate Minister of Health

Purpose

To provide you with drafts of the Therapeutic Products Regulation Cabinet Papers, prior to final papers being prepared for you to lodge with the Cabinet Office on 12 November 2015.

Key points

- The new Therapeutic Products Bill will replace the Medicines Act 1981 and its regulations with a clearer, more flexible, more comprehensive and cost efficient regulatory regime. These objectives will be best met by:
  - regulatory requirements that are consistent with international approaches and effectively administered
  - a regulator that can exercise regulatory powers independent of the Minister of Health, is accountable, and that can engage internationally
  - an enabling legislative framework that can be readily maintained and updated.
- The new regime is being designed to meet the needs of the health and disability support sector now and into the future, to give effect to Government's expectations for regulatory systems and mindful of the global settings for therapeutic products.
- We seek your comments on the draft Cabinet Papers so that final papers can be prepared for you to lodge with the Cabinet Office on 12 November, so that they can be discussed at Social Policy Committee (SOC) on 18 November 2015.
- Cabinet agreement to these papers, and issuing of drafting instructions to the Parliamentary Counsel Office is important in order to meet your preferred timetable of introduction to the House in late 2016.
- You are to provide further advice to SOC in March 2016 that will enable further drafting instructions to be issued. It is proposed that an exposure draft of the Bill be released for consultation during 2016, followed by introduction to the House in late 2016 and passage in 2017.
- Officials have consulted stakeholders and agencies on the proposed approach to the Bill, and will continue to do so as drafting progresses, and through exposure drafts of the Bill that will be accompanied by policy documents on the context of the regulations and subordinate instruments.
- A Regulatory Impact Statement (RIS) has not been provided with this draft, but will be provided with the final version you receive. We are currently working through RIS feedback with The Treasury.

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Draft Therapeutic Products Regulation Cabinet papers for your review

Recommendations

The Ministry recommends that you:

a) **Agree** to provide comment on the attached draft Cabinet Papers by 10 November 2015 so that final papers can be prepared for you to lodge with the Cabinet Office on 12 November 2015. **Yes / No**

b) **Note** Cabinet agreement to these papers, and issuing of drafting instructions to Parliamentary Counsel Office this year is important in order to meet your preferred timetable of introduction to the House in late 2016.

c) **Note** that the Ministry for Business Innovation and Employment advises that Ministers' Joyce and Goldsmith will have interests in aspects of this regime.

d) **Note** Minister Adams is likely to be interested in the interface between this Bill and the Natural Health Products Bill.

e) **Forward** a copy of this Health Report and Draft Cabinet Papers to your Ministerial colleagues Hons Joyce, Adams and Goldsmith for their information. **Yes / No**

Kathy Brightwell
Acting Deputy Director-General
Policy Business Unit

Minister's signature

Date:

Database number: 20151871

Draft Therapeutic Products Regulation Cabinet papers for your review

Context

1. As discussed with you on 21 September 2015 these papers set out the context and key elements of the new regulatory regime for therapeutic products. Cabinet agreement to these papers will enable drafting instructions to be prepared for the Parliamentary Counsel Office before Christmas, which is important in order to meet your preferred timetable of introduction to the House in late 2016. Approval to issue further drafting instructions on discrete elements of the regime will be sought in March 2016.

Content of drafts

2. Due to the volume of information dealt with in the Therapeutic Regulations proposal, the advice to Cabinet has been split into two papers:
   - Paper 1: seeks agreement on the objectives of the regime
   - Paper 2: seeks agreement to drafting instructions for key elements of the legislation including; purpose and principles, definitions, regulatory approvals (products) and licensing (manufacturing and sales), cost recovery, compliance, monitoring, enforcement and vigilance.
3. Compared to the status quo, the new regime will have:
   a. **greater scope**. It will cover all therapeutic products (medicines, medical devices, cell and tissue therapies, hybrids, and new products) across their lifespan with controls pre- and post-market.
   b. **clearer roles, responsibilities and accountabilities.** The regulator will be responsible for technical matters (both the design of detailed regulatory requirements and technical decision-making) and the Minister of Health would be responsible for oversight and effective performance by the regulator. Accountability arrangements would be provided that balance regulator independence.
   c. **a more flexible legislative framework.** There will be a better balance between what is contained in the primary act and what is in regulations and subordinate instruments. The regulator will be able to manage approvals and licensing more flexibly (within clear boundaries and accountability settings) and the regime will be able to be kept up to date more readily.
   d. **simpler and clearer regulatory requirements.** The regulatory requirements for product approval and licensed activities will be based around a set of clearly stated principles set around consumer safety and delivery of health outcomes. Therapeutic product classifications and license conditions for supply will be based on risk. Provisions will also be made for advertising controls, compliance, audit, post-market vigilance, and enforcement. Exceptions may be approved by the regulator consistent with the principles.
   e. **a greater range of approval pathways.** The regulator will be able to set out different pathways to regulatory approval. The choice of approach (full assessment, partial assessment, unilateral recognition) would depend on the nature of the product and its risk profile. For the majority of products the international standards for risk classification will guide the choice of process. The accountability arrangements proposed for the regulator would provide the ability to ensure that the regulator is using the most efficient approach at any point in time. Paper 1 provides a description of why a regime that is heavily or completely weighted in favour of unilateral recognition will not be in New Zealand's long-term interests.

Consultation

4. In consulting with other agencies on drafts of these papers key issues that agencies have sought to clarify include:

   a. **legislative placement**. In seeking a flexible regime that is able to be kept up to date (which argues for placing key provisions in subordinate instruments), care needs to be taken to ensure that government and industry are also provided with certainty about legislative settings (which argues for placement in primary legislation). The papers propose that key defining provisions and principles are contained in the primary legislation, matters of accountability and further detail on key settings are contained in regulations, and detailed regulatory requirements and further definition of key concepts are contained in regulator-made subordinate instruments. Regulator-made instruments are proposed to be made disallowable instruments and subject to review by the Regulations Review Committee.

   b. **interface with the Natural Health Products Bill**. The Natural Health Products (NHP) Bill will put in place a separate regulatory regime and regulatory authority for low-risk natural health products. The NHP scheme will be based on a notification system which permits a list of low-risk ingredients and low-level claims to be made for natural health products for a relatively small fee. It may be possible for some products to be regulated under the Therapeutics regime if a product can meet the higher regulatory threshold. A product sponsor may wish to have the product regulated under one regime or the other, or both simultaneously, where they see a market advantage in doing so.

   c. **pharmacy ownership**. We are not seeking Cabinet decisions on proposals relating to pharmacy ownership in these papers. This is due in part to the consultation underway with pharmacy stakeholders on their Action Plan 2015-2020. The draft paper does state that current restrictions on pharmacy ownership are not necessary to achieve the objectives of the regulatory scheme. To date agencies have supported removal of restrictions on the ownership of pharmacies.

5. The Ministry's industry working groups for medicines and medical devices have been consulted on the high-level framework contained in these papers and they are generally comfortable with it. Discussions are ongoing as the proposals are developed.

Issues not covered in these drafts

6. The further advice to be provided in March 2016 will cover the following topics:

   a. proposed institutional form of the regulator
   b. regulatory approach to cell and tissue therapies
   c. clinical trial arrangements
   d. detail of the proposed offence and penalty framework
   e. pharmacy ownership
   f. import and export (including parallel importation)
   g. prescribing, dispensing and administration
   h. interface with the Hazardous Substances and New Organisms Act
   i. privileged statements (statements about therapeutic products during periods of data protection)
   j. further advice on legislative placement of provisions if required.

END.