Good regulatory design

Assessing the regulatory options for the Pharmacy Council and Medicines Control

NZIER report to Pharmacy Council

8 April 2019

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Authorship

This paper was prepared at NZIER by Mieke Welvaert.

It was quality approved by Derek Gill and Mike Hensen.

The assistance of Pam Duncan and Michael Pead at the Pharmacy Council is gratefully acknowledged.

L13 Willeston House, 22–28 Willeston St | PO Box 3479, Wellington 6140
Tel +64 4 472 1880 | econ@nzier.org.nz

Key points

Two regulators?

New Zealand currently separates the regulation of the delivery of pharmacy services between Medicines Control (in the Ministry of Health) who ensure pharmacy service delivery meets required standards and the Pharmacy Council who focus on pharmacist competence. Information sharing between the two regulators is limited and slow.

Or one regulator?

The Pharmacy Council asked NZIER to review the case for moving to one pharmacy regulator. This is a topical issue as the draft Therapeutics Bill and recent memorandum of understanding propose enhanced information sharing but stop short of recommending moving to a single regulator. Several other countries have single regulators.

We used Treasury's good design principles to assess the options

Using Treasury's good regulatory design principles, we assessed the three options:

- No information sharing (as was the case pre-memorandum).
- Information sharing as indicated in the memorandum.
- The singular regulator approach (as in the United Kingdom etc.).

We scored each of these options on the extent to which they are proportional, flexible, durable, predictable, transparent, capable regulators and growth supporting (low, medium and high).

Our scoring system depends on public safety improvements and cost

Our low, medium and high scoring system depends on the extent to which each option improves public safety and welfare or reduces costs.

No information sharing is low on good design...

No information sharing scores low to medium in all categories. The restriction on information flow limits regulators' scores across the board. The no information sharing option loses rank in reducing costs, adaptation, authority and consistency in giving guidance, transparency, capability and growth supporting – all because of the lack of information transfer.

...but the new memorandum should improve the status quo

The information sharing option is a big improvement on the pre-memorandum level of information sharing (no information sharing). Information sharing as described in the memorandum will help both regulators make efficiency gains (flexibility), learn about and improve their system (durability), be more certain and predictable with pharmacies and pharmacists (certainty and predictability), and make decisions that account for economic and non-economic objectives (growth supporting).

Information sharing also performs highest on several critical criteria

We graded each of Treasury's criteria in terms of their importance and relevance to social outcomes: essential, very important, somewhat important and not important.

Information sharing performed highest in several of the most important criteria: proportional, durable, certain and predictable, and growth supporting.

A single regulator also scores highly on several criteria

In contrast, a single regulator scored highest in terms of flexibility (least cost) and the combination of attributes that define a capable regulator (clarity of purpose and scope as well as the effective use of information).

No option dominates

The preferred option depends on the weightings. One option *dominates* when it scores higher than the other options in some criteria and no lower on any other criteria.

In this analysis we found that no information sharing is dominated by the two other options. However, the information sharing and single regulator options do not dominate each other. Neither option is equal or better than the other on all criteria. As a result, our qualitative analysis shows no clear best option.

Quantitative justification for a single regulator is limited

In our interim report, we scanned the literature on other countries' experience with pharmacy regulation and were unable to come up with a compelling quantitative case for the move to a single regulator (NZIER 2019).

Consider change management

As the memorandum was only signed in March 2019, neither regulator has yet had a chance to see the full effects of the potential from information sharing.

The move to information sharing does not preclude shifting to a single regulator regime if the potential from information sharing proves difficult to achieve. However, moving to a single regulator now means that the potential from information sharing remains untested and unknown.

- A short summary of our findings is available below in Table 1

Table 1 Comparison of pharmacy regulation options

Qualitative rating of low, medium or high fit with good regulatory principles

Criteria Definition Importance	No information sharing	Information sharing	Single regulator
Proportional Change fits the size of the problem **Essential**	NA	**High** The cost is small and the benefit is moderate	**Low** The cost is very high but the change still has a moderate benefit
Flexible Least cost approach to delivering the same service **Somewhat important**	**Low** Some duplication of effort leads to additional cost	**Medium** Less duplication of effort leads to less additional cost	**High** No duplication of effort means economies of scope and scale
Durable Enables opportunities for learning about and improving the system **Very important**	**Low** Limited opportunity for learning about and improving the system	**High** Allows for opportunity to learn about system issues	**Medium** Allows for opportunity to learn about system issues but path dependence could limit future adaptability
Certain and predictable Regulated entities are provided with clear, authoritative and consistent guidance that accounts for their long-term investment decisions **Very important**	**Medium** Guidance is less authoritative Decision-making criteria are clear Limits on consistency between Medicines Control and Pharmacy Council due to lack of information	**High** Guidance can be more authoritative Decision-making criteria are clear More consistency between Medicines Control and Pharmacy Council due to more information	**Medium** Guidance can be more authoritative Decision-making criteria are potentially less clear More consistency between Medicines Control and Pharmacy Council due to more information
Transparent and accountable Public has access to information about pharmacy and pharmacist quality of service **Somewhat important**	**Low** Proven limits on transparency due to aggregated reporting	**Low** Aggregated reporting will still curtail transparency Sharing will enable regulators to have a common view on some issues	**Medium** Aggregated reporting will still curtail transparency Could provide an *overview* of the sector that is accessible to and trusted by the public
Capable regulators Clarity of purpose/role; understands scope; uses information efficiently and effectively **Very important**	**Medium** Regulator is focused on either pharmacy or pharmacist business Potential for one regulator to leave tasks to other operators	**Medium** Regulator is focused on either pharmacy or pharmacist business Potential for one regulator to leave tasks to other operators	**High** Regulator is applying two different frameworks (process compliance and professional competence standards), and a lack of clarity at the

Criteria Definition Importance	No information sharing	Information sharing	Single regulator
	Minimal opportunity to analyse root cause of non-compliance	Opportunity to analyse root cause of non-compliance	management level can skew decisions about priority objectives All tasks covered by the regulator Opportunity to embed systems approach to pharmacy service risks minimisation
Growth supporting Decisions made adequately account for economic and non-economic objectives **Somewhat important**	**Medium** Regulators can still make well informed decisions, and each regulator ensures that they invest to meet their purpose	**High** More information means more informed decisions	**Medium** More information means more informed decisions, but one set of objectives could dominate

Source: NZIER

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1. Overview

The Pharmacy Council and the Ministry of Health have signed a memorandum of understanding to share information about pharmacist competency[1] (Ministry of Health and Pharmacy Council 2019). Information sharing between the Ministry of Health's Medicines Control (within Medsafe) and the Pharmacy Council can help both regulators better identify and address problems with the provision of pharmacy services by pharmacists. Other countries have an even more shared approach. The United Kingdom and Ireland as well as some Canadian and Australian states have only one organisation to perform the tasks of both the Pharmacy Council and Medicines Control. Should New Zealand take its information-sharing approach to the next level and combine both organisations? Or is the move to information sharing enough to achieve most of the benefits of co-ordinated regulation of pharmacists and pharmacies?

We assessed three pharmacy regulation options:

- No information sharing (as was the case pre-memorandum).
- Information sharing as indicated in the memorandum.
- The single regulator approach (as in the United Kingdom etc.).

We assessed these three options using Treasury's good regulatory design principles – a qualitative tool for assessing different regulatory options. Quantitative research shows no strong case for any regulatory option from a cost-benefit perspective (NZIER 2019). As a result, the Pharmacy Council has asked if we could evaluate the options from a qualitative perspective.

Good regulatory principles assess the extent to which regulatory regimes are:

- proportional
- flexible
- durable
- certain and predictable
- transparent and accountable
- capable regulators
- growth supporting.

However, our ratings system for these categories differ from those that Treasury uses. We will rate each option based on *how well* they meet each criterion (to a high medium or low degree or not at all). The Treasury scale works negatively and only identifies what could be wrong with an option (no significant concerns, possible areas of concern, strong indications of material concern). We have chosen a different ranking system because Treasury's system limits how we can score the different regulatory options.

We have determined the low, medium and high scores based on the extent to which an option maximises benefits (reduces harm) and minimises costs (see Table 2).

[1] conduct, professionalism, health and competence

Table 2 Ranking system

NZIER ranks extent to which criteria are met

NZIER scale		Definition
	Low	Low benefit/more costs
	Medium	Some benefit/some costs
	High	High benefit/few costs
	Not at all	No benefit

Source: NZIER

We note that maximum benefits are constrained. We found no compelling evidence that incidences of pharmacist or pharmacy errors will diminish by adopting different regulatory structures (NZIER 2019). The maximum benefit from a single regulator arises if the issues detected by the fitness practice and pharmacy regulators are unrelated[2].

For example, only 8.6 of 'concerns'[3] about fitness to practice came from pharmacy inspections in the United Kingdom in 2018. In Ireland in 2017, 5.7 percent of the total of 'complaints' plus 'concerns' (19.0 percent of 'complaints' only) came from pharmacy inspections in Ireland's single regulator systems (NZIER 2019). This suggests that better information flows from pharmacy regulators to fitness to practice regulators could at best address less than 9 percent of complaints and concerns *more quickly* than they do now. At the same time, the number of complaints and concerns about pharmacists in the United Kingdom was 4.2 percent of the number of pharmacist and in Ireland was about 2.5 percent of the number of pharmacists. This sum of these two rates is an extreme upper limit on the proportion of errors that could be identified more quickly through information sharing or moving to a single regulator model.

Furthermore, the total cost of delivering regulation is small. Medicines Control's budget for pharmacy regulation was $1.5 million in 2015/16, which is very small relative to the value of pharmaceuticals processed (NZIER 2019). In comparison, the Pharmacy Council's spending on complaints was between $300,000 and $400,000 for the 2017 financial year – also a very small regulatory cost. Overall, the pharmacy and pharmacist regulatory system is already highly effective and further possible cost savings are minimal. Please see Appendix A for further discussion of the different roles and approaches of the two regulators.

As a result, we have graded each good regulatory design principle in terms of its importance and how feasible maximum benefits at minimum costs can be achieved (see Table 3) on a scale from **essential** down to **not important**. Although we did not grade any of the principles as **not important**, we want the reader to know that **somewhat important** wasn't the bottom of our grade scale.

2 This assumption is unrealistic.

3 The United Kingdom regulator does not report formal complaints and informal concerns separately, but Ireland regualtor does make this distinction. We believe that the total of 'complaints' plus 'concerns' from the regulator in Ireland is the appropriate comparator for the 'concerns reported by the United Kingdom regulator.

Table 3 Principle grades and justification

Principle	Grade	Reason
Proportional	**Essential**	Proportionality tests for whether the changes made are worthwhile. If the change cost is large but the benefits small, the option has a low proportionality rating.
Flexible	**Somewhat important**	Flexibility is not especially important because the level of pharmacy and pharmacist errors is already very low relative to the number of pharmaceuticals processed, and the potential for further cost savings is minimal (NZIER 2019).
Durable	**Very important**	Durability is especially important in the pharmaceutical services field because the industry is changing. Pharmacists are increasingly relied upon as health service providers.
Certain and predictable	**Very important**	Certainty and predictability define a regulator's ability to perform its role effectively. If regulators are unable to communicate regulation to pharmacies and pharmacists well, these regulated entities will struggle to meet standards and provide up-to-standard services.
Transparent and accountable	**Somewhat important**	None of the options we are evaluating guarantees transparency.
Capable regulators	**Very important**	Regulated areas should be fully serviced by regulators. Without adequate and full coverage regulation, errors cannot be satisfactorily monitored and fixed.
Growth supporting	**Somewhat important**	Regulators need to be able to make good long-term decisions that consider economic and non-economic factors.

Source: NZIER

This report will assess each regulation option against each good regulatory design principle in section 4 *Qualitative findings*.

2. Context

Quality control is split between two regulators

Current regulation of pharmacy services is separated into:

- pharmacy regulation where Medicines Control issues a licence to operate a pharmacy (LtOP) and places conditions on, or cancels licences where expected standards are not upheld
- pharmacist competence where the Pharmacy Council issues practising certificates and places conditions or declines practising certificates where competence and fitness to practise do not meet the standards of practise required.

This separation has led to limited and slow information sharing between the two regulators because:

- Medicines Control and the Pharmacy Council are focused on different aspects of the delivery of pharmacy services (service delivery processes and adherence to good practice by a pharmacist, respectively)
- neither regulator has effective mechanisms for the full or timely sharing of information gathered from complaints, notifications or audits.

Both regulators have made a move to share information

In March 2019, the Pharmacy Council and the Ministry of Health signed a memorandum of understanding where they agreed to share information where either party identifies that there is reason to be concerned that the competence or fitness to practise of a pharmacist may pose a risk of harm to the public.

If the two regulators develop systems to quickly share information between them, both regulators could identify and address problems faster. We assume this level of quick and effective information sharing takes place in the information sharing regulation option we evaluate in this report.

We see room for improvement through information sharing

Examples from the Pharmacy Council show that Medicines Control audits detect problems with pharmacist competence that Pharmacy Council is better equipped to resolve.

Furthermore, both regulators could be more consistent in their guidance if they had the other's information as well. At present, the Pharmacy Council and Medicines Control sometimes have different views on pharmacy practice and safety.

A formal information-sharing agreement may not be enough

Even a formal information-sharing requirement would still leave the Pharmacy Council:

- dependent on the Medicines Control view of what pharmacy processes are lead indicators of unsafe practice and how they should be assessed

- with an information-gathering and complaints resolution process that is likely to be slower than Medicines Control's capacity to require corrective actions.

Other countries have single regulator systems

The United Kingdom, Ireland, parts of Canada and New South Wales in Australia have single regulator systems. Single regulator systems imply that all regulatory information about pharmacists and pharmacies is shared entirely and quickly to those that need it to regulate (NZIER 2019).

The Pharmacy Council has asked us to investigate whether a move to a single regulator system is better than the new information-sharing approach.

Both options can only mitigate up to 8–13 percent of errors

In the United Kingdom and Ireland – who have single regulator systems – only 5.7 to 8.6 percent of complaints and concerns about pharmacist fitness to practise are initiated from pharmacy inspections. Also the number of complaints and concerns about pharmacists in the United Kingdom was 4.2 percent of the number of pharmacist and in Ireland was about 2.5 percent of the number of pharmacists. This sum of these two rates is an extreme upper limit on the proportion of errors that could be identified more quickly through information sharing or moving to a single regulator model.

None of the options have much scope to reduce harms

Data on harm caused by community pharmacy errors is limited. However, the available data (Health and Disability Commissioner[4] reports and Medication Error Reporting Programme[5]) suggests that the harm from community pharmacy errors is already very low because of both a low incidence of errors and the low potential for serious harm potential for many of the errors reported.

Beware of path dependence

Moving to a single regulator system should be carefully considered because the change is difficult to reverse (path dependence).

Given the limited scope for reducing pharmacy or pharmacist error-related harms, you could wait until the effects of the recent memorandum of understanding become clear. Our qualitative analysis suggests that most of the potential benefits from changing the regulatory system could be achieved if an information-sharing approach is implemented as described in the memorandum.

As a result, consideration could be given to waiting until the effects of the memorandum are visible before considering a single regulator option.

[4] Costs of ACC claims for DHB mediation errors are published, but they are not a useful indicator of the potential cost of community pharmacy errors because of the difference in mix and volume of cases.

[5] This programme was a national system to collect and analyse near misses and errors in health (including pharmacy – medicine related errors). However, the programme is no longer in operation.

3. Three regulation options

We have chosen to look at three main regulatory options.

No information sharing, two regulators

The first regulatory option is a pre-memorandum status of information sharing, i.e. no information is shared between the Pharmacy Council and the Medicines Control business unit of the Ministry of Health. In this scenario**,** Medicines Control regulates pharmacies and the Pharmacy Council regulates pharmacists.

Information sharing, two regulators

The second option is information sharing as described in the memorandum of understanding for information sharing (Ministry of Health and Pharmacy Council 2019). The Pharmacy Council and Medsafe (within which sits Medicines Control) have agreed to share information relating to pharmacists including:

- *regulatory information (for example pharmacist registration and pharmacy licensing information);*
- *pharmacist and pharmacy practice information (including conduct and competence); and*
- *health information about identifiable individuals*[6]

(Ministry of Health and Pharmacy Council 2019, 2)

The Memorandum of Understanding was only signed in March this year, meaning that neither regulator has had a chance to see the full effects of information sharing on welfare outcomes.

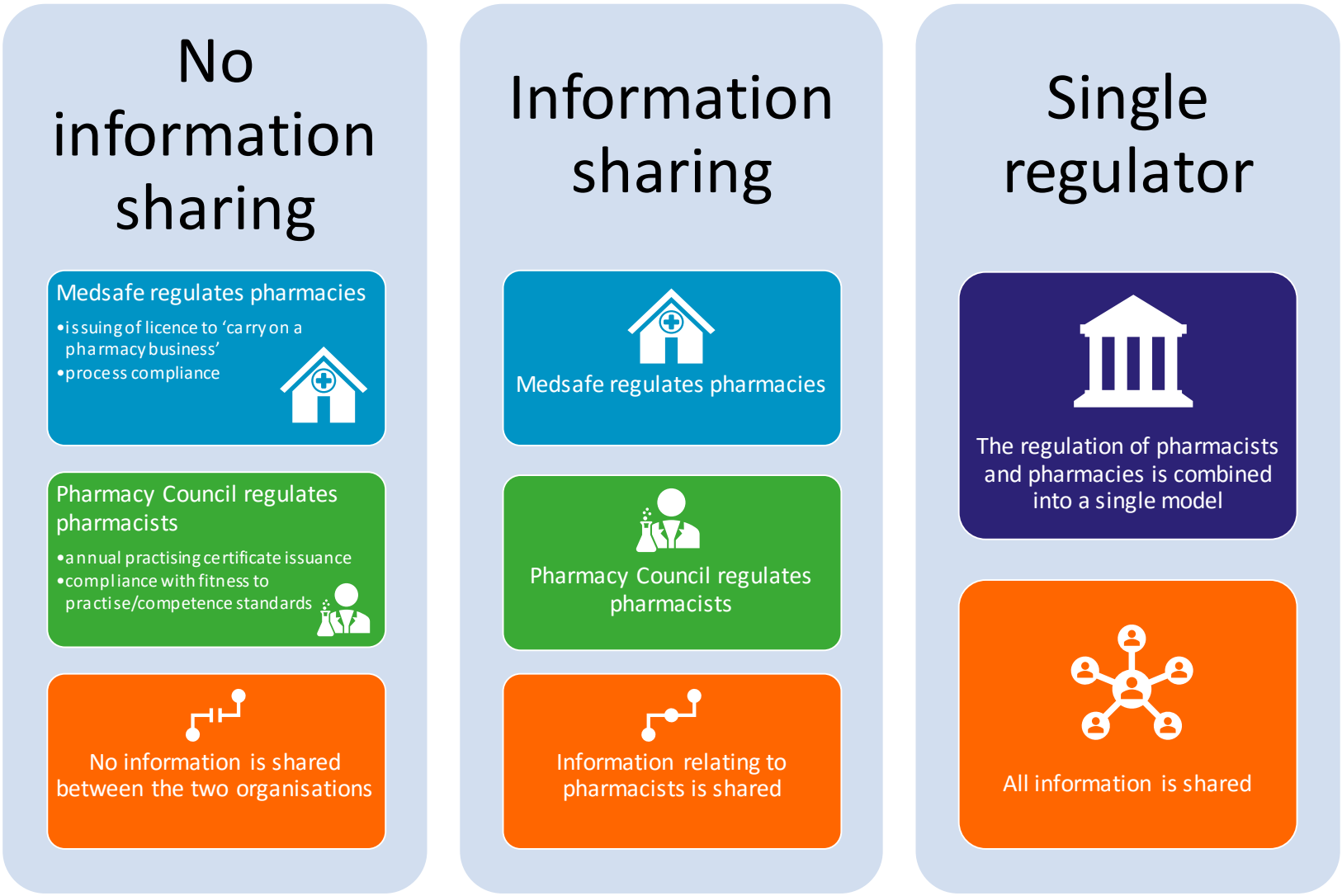
A single regulator

Under a single regulator, pharmacy and pharmacist regulation is combined under a single model and all information is shared within that organisation.

These three options are illustrated in Figure 1.Figure 1 Three regulation options

[6] Information sharing about this category has strict conditions under the memorandum of understanding. Health and identifiable information can only be shared if it relates to fitness to undertake role of effective control on pharmacy license. Medicines Control will not receive health information about pharmacists where it does not relate to Medicines Control's mandate.

Figure 1 Three regulation options



Source: NZIER

4. Qualitative findings

4.1. Proportional

Definition: The size of the change is proportionate to the size of the problem. We need a starting point from which to measure the size of the change. In this case, we used no information sharing as the starting point. As a result, no information sharing cannot be scored for proportionality.

How important: Essential

Why is it important?

Proportionality tests for whether the changes made are worthwhile. When we assess proportionality, we are asking the question: does the benefit of going ahead with this option justify the change? If the change cost is large but the benefits small, the option has a low proportionality rating.

Results

Information sharing

Information sharing meets the proportionality principle at a high level. Earlier detection of pharmacist contribution to process errors has a high value and enables more effective and efficient corrective action (for further information please see Appendix A). This outcome has a high value and relatively low cost from a good principles' perspective. As a result, the size of the benefit justifies the size of the change.

Single regulator

The single regulator option has a low proportionality ranking. Moving to a single regulator system requires a major organisational restructure, which has a high cost. The shift does not mean that systems and skills to assess pharmacy processes and pharmacist competence will immediately integrate.

However, moving to a single regulator system and complete information sharing could allow regulators to discover pharmacist error more quickly. Nevertheless, NZIER's interim report to the Pharmacy Council (NZIER 2019) shows that, given the types of errors, more information sharing between regulators may not reduce the number of pharmacist errors. From a proportionality principle perspective, we have tentatively scored the single regulator option as only partly meeting the criteria and erring on the side of not meeting the criteria at all.

Table 4 Proportionality

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Proportional	NA	**High** The cost is small and the benefit is moderate	**Low** The cost is very high but the change still has a moderate benefit

Source: NZIER

4.2. Flexible

Definition: The regulatory option has built in scope for organisations to "adopt least cost and innovative approaches to meeting legal obligations" (The Treasury 2014, 3).

How important: Somewhat important

Why is it important?

Flexibility is not especially important because the level of pharmacy and pharmacist errors is already very low relative to the amount of pharmaceuticals processed (NZIER 2019). As a result, the different regulation options cannot increase their flexibility score through an increase in wellbeing (NZIER 2019).

Options can increase in rank through cost savings. However, the cost savings from reduced overlap in regulator visits is a small part of Medsafe's overall budget and not large enough to warrant a high score in terms of our good regulatory principles.

Results

No information sharing

Even with no information sharing, pharmacist and pharmacy error is minimal relative to the volume of processing (NZIER 2019). However, having two regulators that collect and do not share cross-over information implies a duplication of effort. With their roles somewhat overlapping, the Pharmacy Council and Medicines Control are a higher-cost option for delivering pharmacy and pharmacist regulation.

Information sharing

Information sharing can enable both organisations to become more specialised in their roles of regulating pharmacies and pharmacists. Specialisation means that both regulators will become more efficient in their tasks. However, some degree of overlap in the regulators' tasks will remain, leading to less than optimal efficiency[7].

Single regulator

A single regulator will have the highest degree of information sharing.

Additionally, integrating the two regulators will generate cost savings and will be the least cost option for improving customer wellbeing (excluding the cost of converting to a single regulator system). For example, with a single regulator, you would no longer have two sets of regulators visiting any one pharmacy[8].

Table 5 Flexible

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Flexible	**Low** Some duplication of effort leads to additional cost	**Medium** Less duplication of effort leads to less additional cost	**High** No duplication of effort means economies of scope and scale

Source: NZIER

[7] Shared service could improve cost savings for the information sharing option in theory but is unlikely in practice (see 5. Other matters for more detail).

[8] Pharmacy Council rarely visit pharmacies, limiting the possible cost savings from reductions in duplicated effort

4.3. Durable

Definition: The ability to learn about and improve regulation, meaning that regulation can adapt and evolve when circumstances change.

How important: Very important

Why is it important?

This is especially important in the pharmaceutical services field because the industry is changing. Pharmacists are increasingly relied upon as health service providers. To be durable, regulatory systems must be "up-to-date with technological and market change, and evolving societal expectations" (The Treasury 2014, 4).

Results

No information sharing

No information sharing is low in durability. The lack of information sharing is an added hurdle to the ability of the Pharmacy Council and Medicines Control ability as regulators. Both the Pharmacy Council and Medicines Control are less able to monitor pharmacist performance and identify pharmacist problems quickly, hindering their ability to identify and adapt to problems as they arise. With siloed and restricted information, both organisations are limited in their ability to learn about and improve their systems.

Information sharing

Information sharing is highly durable. With the additional information, regulators will know more about who to target and how they can better assess their tasks and outcomes. For example, with the additional information, both Medicines Control and the Pharmacy Council can better track how the pharmacy profession is changing and understand how the other regulator is adapting to the change.

Single regulator

A single regulator will have the same, if not more, opportunity as the information sharing option to learn about system issues. However, a single regulator could become more rigid when responding to change and combining these regulatory roles will be difficult to reverse – an outcome known as path dependence.

Table 6 Durable

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Durable	**Low** Limited opportunity for learning about and improving the system	**High** Allows for opportunity to learn about system issues	**Medium** Allows for opportunity to learn about system issues but path dependence could limit future adaptability

Source: NZIER

4.4. Certain and predictable

Definition: Regulated entities are provided with clear, authoritative and consistent guidance. The Treasury has outlined the components relevant to this analysis in more detail:

- *Regulated entities have access to authoritative advice*
- *Decision-making criteria are clear and provide certainty of process…*
- *…There is consistency between multiple regulatory regimes that impact on a single regulated entity*

(The Treasury 2014, 5)

How important: Very important

Why is it important?

This principle is about the regulators' ability to perform their role effectively. If regulators are unable to communicate regulation to pharmacies and pharmacists well, these regulated entities will struggle to meet standards and provide up-to-standard services.

Results

No information sharing

In the case of no information sharing, regulated entities have access to less authoritative guidance because results from the Pharmacy Council and from Medicines Control can be conflicting. The Pharmacy Council and Medicines Control have different views of service quality[9]. January to March 2018 audits by Medicines Control found that 7 percent of pharmacies are putting consumers or service providers at risk (NZIER 2019). However, the Pharmacy Council found that only 2.7 percent of pharmacists had informal queries or complaints laid against them (NZIER 2019).

Both Medicines Control and the Pharmacy Council have clear decision-making criteria and processes as separate entities (i.e. in no information sharing and information sharing scenarios).

Information sharing

Information sharing meets a high rating in all aspects of certainty and predictability. The open access to information about pharmacists enables the two regulators to be consistent with one another and to support each other's authority in giving guidance. However, both regulators are still separate entities with separate roles, which means that they can maintain their clear decision-making processes.

Single regulator

Guidance is more authoritative and consistent as it comes from one organisation. However, due to the merging of regulator roles, decision-making criteria could become less clear for the pharmacies and pharmacists respectively. Furthermore, one regulatory role may ultimately become prioritised over the other, resulting in less clear decision-making criteria (Wilson 1991).

[9] More discussion on the comparison between pharmacy and pharmacist regulation in New Zealand is in Appendix A

Table 7 Certain and predictable

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Certain and predictable	**Medium**	**High**	**Medium**
	Guidance is less authoritative	Guidance can be more authoritative	Guidance can be more authoritative
	Decision-making criteria are clear (two entities, each with a single focus)	Decision-making criteria are clear (two entities, each with a single focus)	Decision-making criteria are less clear (one entity, dual focus)
	Limits on consistency between Medicines Control and Pharmacy Council due to lack of information	More consistency between Medicines Control and Pharmacy Council due to more information	More consistency between Medicines Control and Pharmacy Council due to more information

Source: NZIER

4.5. Transparent and accountable

Definition: Information about the quality of service that pharmacies and pharmacists deliver to public is accessible.

How important: Somewhat important

Why is it important?

The public needs to know that they can trust pharmacies and pharmacists and that service levels are being maintained/improved.

However, none of the options we are evaluating guarantees transparency. More information sharing implies a slightly higher potential that regulators will better understand the context and root cause of errors they report on but not that regulators will share additional information with the public. As a result, this category is only somewhat important for grading the different regulatory options.

If regulators wanted to become more transparent, they could provide more detailed reports to the public. The United Kingdom has chosen to make all reports "open and transparent about not only the outcome of an inspection, but also the evidence we have gathered to come to that decision" (General Pharmaceutical Council 2018, 20).

Results

No information sharing

Before the information sharing memorandum was put in place, reporting was separated into pharmacies and pharmacists. These reports have given the public conflicting views, with Medicines Control reporting a bigger share of pharmacies, and thus pharmacists, failing to meet expectations than the Pharmacy Council (for further discussion, please see Appendix A). Furthermore, reports are highly aggregated and do not show which pharmacies or pharmacists are performing at a sub-standard level. These results show that the no regulation option does not provide the public with accessible information about pharmacy and pharmacist service quality.

Information sharing

Information sharing allows aggregated reporting to note that regulators share information and have a common view on some issues. However, reporting will still be aggregated.

Single regulator

A single regulator can provide a more trusted and accessible overview of the sector to the public, but aggregated reporting still limits transparency with and accountability to the public. This is particularly the case if the single regulator was part of the wider Ministry of Health. An alternative organisational form would involve making the single regulator a Crown entity. Increased disclosure because of reporting requirements under Part 4 of the Crown Entities Act would raise the single regulator's transparency rank to high.

Table 8 Transparent and accountable

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Transparent and accountable	**Low** Proven limits on transparency due to aggregated reporting	**Low** Aggregated reporting will still curtail transparency Sharing will enable regulators to have a common view on some issues.	**Medium** Aggregated reporting will still curtail transparency Could provide an *overview* of the sector that is accessible to and trusted by the public

Source: NZIER

4.6. Capable regulators

Definition: "The regulator has the people and systems necessary to operate an efficient and effective regulatory regime" (Treasury 2014, 7).

Capable regulators:

- have clarity of purpose and role
- understand their scope in providing regulation
- use information effectively and efficiently.

How important: Very important

Why is it important?

Regulated areas should be fully serviced by regulators. Without adequate and full-coverage regulation, errors cannot be satisfactorily monitored and fixed.

Results

No information sharing

Regulators are moderately capable in the no information sharing option. Each regulator knows what their job is (clarity of purpose and role) as they are either regulating pharmacists or pharmacies. However, each regulator also could leave tasks for the other to cover if regulators don't understand their scope. Along with minimal opportunity to analyse the root cause of non-compliance (and being unable to use information effectively and efficiency across regulators), these factors combine to an overall medium rating.

Information sharing

Information sharing has the same score as no information sharing for clarity of purpose and understanding scope (high and medium), but information sharing allows for an opportunity to analyse the root cause of errors (medium) resulting in a medium score overall.

Single regulator

In a single regulator system, the regulator lacks some clarity in their role and purpose, with one regulator applying two different frameworks – process compliance and professional competence standards. Although single regulator models generally have different teams performing these tasks, a lack of clarity at the management level can skew decisions about priority objectives. Analysis by Wilson (1991) shows that, when roles are unclear, staff tend to prioritise the tasks and objectives that they prefer or find easy. As a result, in a single regulator, one framework could dominate.

However, a single regulator model also comes with benefits in scope as well as effective and efficient information use. With all tasks covered by one regulator, the risk is removed of one regulator leaving tasks for others to pick up.

The single regulator model also has the added advantage of being able to embed a systems approach to pharmacy service risk minimisation. With a full-picture view of the industry, the single regulator model can better pick up on risk factors that might otherwise be missed.

Table 9 Capable regulators

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Capable regulators	**Medium**	**Medium**	**High**
	Regulator is focused on either pharmacy or pharmacist business	Regulator is focused on either pharmacy or pharmacist business	Regulator is applying two different frameworks (process compliance and professional competence standards), a lack of clarity at the management level can skew decisions about priority objectives
	Potential for one regulator to leave tasks to other operators	Potential for one regulator to leave tasks to other operators	All tasks covered by the regulator
	Minimal opportunity to analyse root cause of non-compliance	Some opportunity to analyse root cause of non-compliance	Opportunity to embed systems approach to pharmacy service risk minimisation

Source: NZIER

4.7. Growth supporting

Definition: The regulatory option has an internal structure that supports long-term investment decision making, and trade-offs between economic and non-economic objectives are identified and justified.

How important: Somewhat important

Why is it important?

Regulators need to be able to make good long-term decisions that consider economic and non-economic factors.

Results

No information sharing

Even with no information sharing, regulators can still make well informed decisions. Keeping the two regulators separate also helps ensure that both roles (pharmacy regulation and pharmacist regulation) are adequately targeted.

Information sharing

Information sharing will enable the Pharmacy Council and Medicines Control to make better informed decisions about:

- how they choose to invest their time and resources (such as identifying which pharmacies to investigate)
- trade-offs between economic and non-economic objectives (i.e. to what extent they support pharmacists to improve their capability and service).

Single regulator

A singular regulator will have the opportunity to make the best-informed decisions about allocation of regulator resources. However, single regulators will run the risk that one profession or process perspective will dominate, meaning that trade-offs between objectives may not be identified or justified. Public management expert James Q. Wilson (1991) found that organisations with multiple roles (such as pharmacy regulation and pharmacist regulation) often find that one role dominates, leaving the other underserviced.

Table 10 Growth supporting

Qualitative fit with good regulatory principles of low, medium, high or not at all

Criteria	No information sharing	Information sharing	Single regulator
Growth supporting	**Medium** Regulators can still make well informed decisions, and each regulator ensures that they invest to meet their purpose	**High** More information means more informed decisions	**Medium** More information means more informed decisions, but one set of objectives could dominate

Source: NZIER

5. Other matters

Although it wasn't a primary focus of this review, we were asked to examine two secondary considerations; choice of legal for (e.g. Crown Entity) and use of shared services.

Legal form affects transparency

A single regulator could also operate using the Crown Entity legal form with an increase in transparency. The reporting requirements under Part 4 of the Crown Entities Act mean that a single pharmacy/pharmacist regulator will have to disclose more information about the operation of the regulatory regime. These requirements will mean that a single regulator will have an advantage over the other regulatory options regarding transparency (and a higher score for transparency and accountability).

Shared services

We briefly explored whether shared services between Pharmacy Council and Medicines Control could lead to back-office cost savings in processing functions.

Services can be shared for repeat routinised services, such as billing and call centres (Collis, Young, and Goold 2007). Although attractive in theory, in practise it is difficult to generate the savings promised by shared services. If realised, shared savings *could* marginally increase the flexibility of the information sharing option.

However, Medicines Control and Pharmacy Council have few services that could be shared in this way. As a result, we would not revise information sharing's score upwards even if we accounted for shared services.

6. Conclusion

Analysing the options against Treasury's good design principles shows a clear worse option: no information sharing. The single regulator and the information sharing options, where information is shared more, are much better designed.

No is low

No information sharing scores low to medium in all categories. These results clearly identify that the restriction on information flows limits regulators' ability to reduce costs and adapt and to be authoritative and consistent in giving guidance, transparent, capable and growth supporting.

High scores for the two information-sharing options

The information sharing and single regulator options both achieve high scores within the good design principles.

Information sharing ranks high in the principles of:

- proportionality (change fits the size of the problem)
- durability (can evolve)
- certainty and predictability (regulated entities understand the regulator)
- growth supporting (long-term decisions account for economic and non-economic factors).

A single regulator ranks high in flexibility (least cost) and capability as a regulator – both categories where information sharing only received a medium grade. A single regulator is also better than the information sharing option for transparency and accountability.

Key to weigh up the options

Whether one option is better than the other depends on how you weight each principle. We have attempted to apply a weighting to each principle of either **essential**, **very important**, **somewhat important** or **not important**.

Broadly, information sharing achieves higher scores in the more important principles compared to the single regulator option.

What drives the difference between weighted scores?

The main difference between these two good options is that single regulators run the risk of losing focus. Moving to a single regulator risks having an organisation that doesn't cover all aspects of regulation to the same level as two separate organisations that share information.

Path dependence can make a difference

Even though more information sharing through becoming a single regulator is likely, this change is difficult to reverse.

The newly signed memorandum has the potential to achieve most of the benefits of a single regulator, but without the potential costs. However, these benefits will depend on how the memorandum is implemented. Allowing key information to flow relatively

freely between the two regulators would enable both regulators to develop a shared operational picture, resulting in efficiency and efficacy gains.

As the memorandum was only signed in March 2019, neither regulator has yet had a chance to see the full effects of the potential from information sharing. The move to information sharing does not preclude shifting to a single regulator regime if the potential from information sharing proves difficult to achieve. However, moving to a single regulator now means that the potential from information sharing remains untested and unknown.

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Appendix A Comparison of New Zealand pharmacy and pharmacist regulation

Pharmacy and pharmacist regulation follow different models

Pharmacy regulation focuses on ensuring that process standards for the safe delivery of pharmacy services are in place and followed. The primary monitoring tool is an audit of pharmacy records and documentation for evidence that processes are followed. Most audits are initiated at the discretion of the regulator rather than in response to a third-party complaint. Typically, a pharmacy is not notified in advance of the audit, must supply all information requested and must agree to corrective action to rectify any non-compliance with process within a timeframe set by the regulator.

Pharmacist regulation generally focuses on ensuring fitness to practise primarily by vetting competence at the start of a pharmacist's career, checking that continuing professional development requirements are met and acting on complaints about fitness to practise. The actual assessment of fitness to practise is completed by an independent review panel, and the regulator implements the decision of the panel.

Pharmacist regulators have weaker powers to require delivery of information about and review pharmacist compliance with fitness to practise standards than pharmacy regulators have with respect to pharmacy compliance with process standards.

Medicines Control and Pharmacy Council have different views of service quality

Medicines Control audits and Pharmacy Council reports provide conflicting impressions of the quality of the delivery of pharmacy services:

- Medicines Control audits of pharmacy LtOP holders for January to March 2018 (Medsafe 2018) indicate that:
  - up to 7 percent of pharmacies are putting consumers or service providers at risk of harm through non-compliance with one of the 10 audit criteria[10]
  - pharmacies are fully attaining or exceeding practice standards for less than 30 percent of the 10 audit criteria.
- Pharmacy Council certification processes and response to complaints for the year ended 2017 indicate that:
  - 1.3 percent of pharmacists had conditions placed on their annual practising certificate (mainly to improve competence) and another 0.5 percent were monitored for health reasons
  - 2.7 percent of pharmacists were the subject of informal queries or complaints.

This difference in reporting comes about because each regulator is focused on different aspects of the delivery of pharmacy services. Medicines Control is focused on the service delivery processes used by licensed pharmacy operators while the

[10] Forty percent of the critical and high-risk non-compliance identified by Medicines Control in this report relate to criterion 5.07.04: Medicines requiring supply by an accredited pharmacist are recorded, sold and labelled in accordance with regulatory and professional requirements.

Pharmacy Council is focused on the competence and adherence to good practice of pharmacists and pharmacy technicians.

Furthermore, Medicines Control and the Pharmacy Council do not have effective mechanisms for sharing complaint or audit information effectively or quickly. In this report, we assume that the new memorandum of understanding will lead to more effective mechanisms for sharing information.

Different capacity to investigate compliance

Medicines Control can inspect pharmacies without notice and require the LtOP holder to provide information and agree to corrective action. In contrast, the Pharmacy Council can audit compliance with annual practising certificate requirements, make inquiries of pharmacists or activate investigation processes following a complaint. The Pharmacy Council's actions are more reliant on voluntary pharmacist co-operation and slower than the information-gathering tools available to Medicines Control.

These differences arise from the different legal rights and obligations associated with:

- Ensuring compliance with the conditions of a licence e to operate a business – in this case a pharmacy
- Assessing the fitness to practice of a professional or attaching conditions to the practice of a professional – in this case a pharmacist

A shift to either a single regulator or information sharing can ensure that pharmacist competence and pharmacy operating conditions are considered jointly in analysing the root cause of errors and achieving the regulatory goals of maintaining high safety standards. A shift to a single regulator will not automatically align regulator powers and process for the assessment of fitness to practice with the regulator powers and practice for assessing compliance with the conditions of a LtOP.