

Impact Summary: Therapeutic Products Bill – Personal Import of Medicine by mail/courier

Section 1: General information

| Purpose |
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| <p>The Ministry of Health is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. This analysis and advice has been produced to inform stakeholders to be consulted on an exposure draft of the proposed Therapeutic Product Bill.</p> <p>The already published <i>Therapeutic Products Regulation – Replacement of the Medicines Act 1981 and the Medicines Regulations 1984 with a new legislative scheme for therapeutic products – Analysis of specific issues and options Regulatory Impact Statement</i> developed for the March 2016 Cabinet paper did not include an analysis of the options regarding personal imports. This RIS has been developed to supplement that regulatory impact statement and should be considered within the context of the impacts outlined in it.</p> |

| Key Limitations or Constraints on Analysis |
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| <p>Data is not available on the amount of personally imported medicines as not all personally imported products are intercepted by Customs. However, even on the most pessimistic assumptions, personally imported medicines are about a quarter of one percent of the total prescription medicine use in New Zealand.</p> <p>Data is also not available on the proportion of intercepted personal imported medicines that are counterfeit or substandard, as these are not routinely tested. However, New Zealand and other countries have tested samples of imported unapproved medicines and found them to be substandard or contaminated.</p> |

| Responsible Manager (signature and date): |
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| <p>John Doyle Acting General Manager, Regulatory Policy Strategy and Policy Ministry of Health</p> |

To be completed by quality assurers:

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| Quality Assurance Reviewing Agency: |
| Ministry of Health and Treasury |
| Quality Assurance Assessment: |
| The Ministry of Health and the Regulatory Quality Team at the Treasury has reviewed the Regulatory Impact Assessment (RIA) "Therapeutic Products Bill – Personal import of Medicine by mail/courier" produced by the Ministry of Health and dated November 2018. The review team considers that it meets the Quality Assurance criteria. |
| Reviewer Comments and Recommendations: |
| The analysis is commensurate with the scale of the issue. While there are some uncertainties about the scale of the problem, as identified in the analysis, this proposal will form part of the consultation on the exposure draft of the wider Therapeutic Products Bill. We expect any insights gained from this consultation will inform revised analysis. |

Section 2: Problem definition and objectives

2.1 What is the policy problem or opportunity?

Prescription medicines are classified as such due to the risks associated with their use. For this reason, the prescribing and supply of prescription medicines is subject to a number of regulatory controls under the Medicines Act 1981. The Medicines Act is silent on the personal import of medicines. The practice has been that when a prescription medicine is personally imported, a New Zealand prescription is required before the medicine can be released to the importer/patient, because the general public needs a prescription to lawfully possess such medicines.

Most people are not likely to be able to identify a suitable and safe supplier or know how to check that a product has been subject to an appropriate regulatory review. If those products are substandard, counterfeit, or adulterated, they could pose a direct safety risk to the person receiving them.

Personal importation of medicines by consumers has increased with the advent of online sellers overseas. Between 9,000 - 14,000 parcels containing suspected prescription medicines are intercepted at the border each year. In 2017, there were 10,849 parcels referred to Medsafe that contained 15,802 medicines. 12,232 were confirmed to be prescription medicines and, of these, 25.6% (3,128) were released after the importer produced a valid prescription, and the remainder destroyed. For comparison approximately 45 million subsidised prescriptions are filled each year in New Zealand.

Internationally there are increasing concerns with the amount of substandard and falsified medicines available. Many of the medicines being personally imported through the post/courier by consumers are substandard or may be adulterated, or counterfeit. Deaths and serious harm have been reported internationally as a result of using counterfeit medicines. In April 2018 *The Lancet Oncology* reported that oncology drugs ranked fifth among the most commonly counterfeited drug categories in a 2016 survey. The trade in counterfeit non-prescription medicines is less prevalent than it is for prescription medicines because the profit is much lower.

The objective of policy in relation to the personal import of medicines by the post/courier is to balance personal freedom against protecting consumers from substandard, adulterated, or counterfeit medicines.

2.2 Who is affected and how?

A change in the policy for the personal importation of medicines by the post/courier would impact those individuals who currently source medicines this way. For instance:

- 1) individuals, or buying groups, who source medicines from overseas, as they are not funded in New Zealand and are cheaper if purchased overseas
- 2) visitors to New Zealand who require additional medicine, once the supply they brought with them has run out. While they could seek a prescription from a New Zealand prescriber, there may be significant additional costs for them if the medicine is not funded in New Zealand or they were not eligible for funding.

If the personal import policy was changed the impact on these consumers would depend on the avenues available to them to continue to access these medicines.

Some individuals may personally import medicines to avoid discussing a health issue with a New Zealand practitioner. However, they should not be self-prescribing in this manner.

Some consumers may be unaware of the personal importation requirements and order medicines via the post/courier anyway. Currently these consumers are able to seek a retrospective prescription to authorise the release of the medicine. If this was no longer possible, then it is likely that the amount of medicine intercepted by Customs that would be destroyed would increase.

2.3 Are there any constraints on the scope for decision making?

This matter is being considered as part of the development of the Therapeutic Products Bill that is being developed based on the policy decisions taken by Cabinet in 2015 and 2016 (accompanied by regulatory impact statements). The intention is to consult on the proposed approach as part of the public consultation of the draft Bill. The policy in this area could then be reconsidered, if desired, following consultation.

Section 3: Options identification

3.1 What options have been considered?

These options are ordered from lower to higher levels of regulation. As the regulation increases consumer safety increases, while personal choice decreases.

Option 1 (status quo) – Continuing to allow people to personally import medicines (by bringing the medicines lawfully supplied to them overseas with them when coming into the country or by post/courier), with the requirement that individuals have a prescription to import prescription medicines.

Pros: Consumer freedom and flexibility to order all types of medicines from whatever source they choose.

Cons: Continued risk of the medicines being substandard, counterfeit, adulterated or not meeting regulatory requirements. The impact of this is greater for prescription medicines.

Option 2 (proposed) – Continuing to allow people to personally import **non-prescription** medicines (by bringing the medicines with them into the country or by post/courier) and to bring prescription medicines into New Zealand with them (if lawfully prescribed), but curtailing the ability to personally import prescription medicines by the post/courier.

Pros: Consumer freedom to order lower-risk medicines from whatever source they choose. Reduces the risk of unsafe prescription medicines coming into New Zealand.

Cons: Some consumers may prefer to take the risk and source prescription medicines themselves, particularly if they are not funded in New Zealand.

Option 3 – Allowing people to bring all categories of medicines into New Zealand with them, but not allow them to order any category of medicine (ie both prescription and non-prescription) by the post/courier.

Pros: Reduces the risk of counterfeit, adulterated or inadequately regulated medicines being ordered from unregulated online suppliers, as they would only be available via more regulated channels.

Cons: Reduces peoples' ability to source all types of medicines from overseas, including preferred products not available in New Zealand or medicines that are cheaper overseas.

Note, all these options have enforcement costs, as a result of allowing some legitimate avenues for accessing unapproved medicines from overseas. Under all options the enforcement officer is required to determine whether there is an appropriate authorisation for the medicine (based on the requirements of that option).

3.2 Which of these options is the proposed approach?

The proposed approach is option 2. This option is intended to achieve the objective of striking a balance between personal freedoms and protecting consumers from unknowingly purchasing substandard or counterfeit prescription medicines.

Individuals would still be able to obtain medicines from overseas sources via other channels set up in the Therapeutic Products Bill. In particular, if a patient has a clinical need for an unapproved medicine (ie, one not approved in New Zealand) they can get it prescribed for them by a medical practitioner. A wholesaler with an (appropriate licence) could then source the medicine on their behalf. The individual would then receive the medicine from their doctor or pharmacist. These persons are better able to identify suitable accredited suppliers and are subject to regulatory oversight under the Therapeutic Products Bill.

There is also the potential to use permits to authorise the personal importation of prescription medicines via the post/courier in situations where it is in the best interest of the consumer and in line with the purpose of the Therapeutic Products Bill. This may be a suitable approach for visitors to New Zealand who require additional medicine or buying groups that have identified a suitable and safe supplier.

Section 4: Impact Analysis (Proposed approach)

4.1 Summary table of costs and benefits

| Affected parties | Comment: nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks. | Impact |
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Additional costs of proposed approach, compared to taking no action

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|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| Regulated parties | Some medical practitioners may not be comfortable with the increased emphasis on their responsibility when authorising the supply of an unapproved medicine. This is likely to add administrative costs to consumers sourcing medicines from overseas, due to the extra step of requiring the medicine to be imported on their behalf or obtaining a permit. There may be an additional cost for travellers if they could access funded medicine from their home country, but not in New Zealand (although the permit system could be used to avoid this). | Low |
| Regulators | Would need to develop new procedures and forms. | Low |
| Wider government | | |

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|-----------------------------|--|-----------|
| Other parties | | Low / Med |
| Total Monetised Cost | | |
| Non-monetised costs | | Low |

| Expected benefits of proposed approach, compared to taking no action | | |
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| Regulated parties | <p>Less risk of health harms from unknowingly importing and taking a counterfeit, adulterated or substandard prescription medicine.</p> <p>There is a lack of data on the amount of personally imported prescription medicine and the percentage that is counterfeit or substandard.</p> <p>In 2017, 12,232 prescription medicines of unknown quality were intercepted by Customs. This is likely to significantly under-represent the amount of prescription medicine being personally imported. Even if we only intercepted 10% of the amount of personally imported prescription medicines, this would still only be a tiny proportion of the subsidised prescriptions filled each year in New Zealand (45 million).</p> <p>New Zealand and other countries have tested samples of imported unapproved medicines and found them to be substandard or contaminated. The World Health Organisation estimates around 10% of medicine products in low and middle income countries are substandard or counterfeit. Anti-malarials and antibiotics are amongst the most commonly reported substandard and falsified medical products.</p> | Low / Med |
| Regulators | | |
| Wider government | Reduced health costs from harm caused by counterfeit, adulterated or substandard prescription medicines. | Low / Med |
| Other parties | | |
| Total Monetised Benefit | | |
| Non-monetised benefits | | Low / Med |

4.2 What other impacts is this approach likely to have?

The willingness of pharmacies and wholesalers to source and supply the medicines currently personally imported is unknown. The policy under the Therapeutic Products Regulatory Scheme is that unapproved products cannot be imported or supplied unless there are appropriate authorisations in place. Some wholesalers already specialise in the import of unapproved medicines. The difference under the proposed personal importation policy is that all unapproved prescription medicines would need to come through this channel (unless someone had a permit to personally import a medicine). Some of the medicines currently personally imported may come from questionable sources that regulated channels would not be willing to use.

The requirement for a sourcing exercise (rather than someone ordering the medicine themselves) could delay access to the medicine in these situations. For some unapproved medicines, it may be necessary for the wholesaler to maintain a small stockpile of the product so it was available for immediate release once a special clinical needs supply authority had been issued. If so, their wholesale licence would authorise such stockpiling. This might be used, for example, for medicines that must be available urgently.

Section 5: Stakeholder views

5.1 What do stakeholders think about the problem and the proposed solution?

This issue has arisen during the drafting of the Bill and has not been consulted on.

The Cabinet paper is seeking approval to include the proposed approach in the draft Bill that will be released for public consultation and seek feedback as part of that consultation.

Section 6: Implementation and operation

6.1 How will the new arrangements be given effect?

The proposed approach would be included in the draft Therapeutic Products Bill.

The Therapeutic Products Regulator would be responsible for the enforcement of these restrictions. The current regulator (Medsafe) already has an Investigation and Enforcement team that operates a border program alongside the New Zealand Customs Services. This would continue under the Therapeutic Products Regulatory Scheme.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

The regulator of the Therapeutic Products Regulatory Scheme would be responsible for ensuring compliance with the personal import requirements. There would continue to be an Investigation and Enforcement team operating a border program alongside the New Zealand Customs Services. This team would continue to collect data on the amount of prescription medicines intercepted at the border and the amount released or destroyed.

7.2 When and how will the new arrangements be reviewed?

The draft Therapeutic Products Bill contains a provision requiring it to be reviewed five years after commencement and then every five years after that.