

# Briefing for decision

## Use of standing orders, and off-label and unapproved medicines, under the Medical Products Bill

**Date due to MO:** 15 September 2025      **Action required by:** 29 September 2025

**Security level:** **IN CONFIDENCE**      **Reference:** H2025066825

**To:** Hon Casey Costello, Associate Minister of Health

**Consulted:** Health New Zealand:

**Proactive release:** This **title** is proposed by the Ministry of Health for proactive release:

### Contact for telephone discussion

Name	Position	Telephone
Tim Vines	Acting Director, Priority Projects Strategy and Policy	s 9(2)(a)
Helen Robinson	Principal Policy Analyst, Therapeutics, Strategy and Policy	

**Author:** Helen Robinson, Principal Policy Analyst, Strategy and Policy

### Minister's office to complete:

Approved       Decline       Overtaken by events

Needs change       Seen

See Minister's Notes       Withdrawn

Comment:

# Briefing for decision

## Use of standing orders, and off-label and unapproved medicines, under the Medical Products Bill

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**To:** Hon Casey Costello, Associate Minister of Health

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### Purpose of report

1. This report seeks your decisions on standing orders, and off-label and unapproved medicine use under the Medical Products Bill.

### Summary

2. Cabinet has agreed to a Medical Products Bill to replace the Medicines Act 1981, including high-level settings to enable access to medicines that do not have a Medsafe approval [SOU-24-MIN-0115]. To implement Cabinet's high level policy direction, we seek your decisions on detail of policy for activities with medicines, specifically:
  - a. authorisation of activities with medicines via standing orders issued by prescribers
  - b. use of medicines that do not have Medsafe approval (unapproved medicines)
  - c. off-label use: use of approved medicines differently to the Medsafe approval.
3. All of these activities are allowed under the Medicines Act and should continue under the Medical Products Bill. However, there are problems with how the Medicines Act regulates each activity. Current provisions create an administrative burden and unreasonable legal risk for individual practitioners, while sometimes hindering medicines access and failing to protect patient safety.
4. We recommend a suite of reforms and other changes through the Medical Products Bill to address these problems. In summary, these changes will:
  - a. better enable business-as-usual work by registered practitioners and other people, such as Defence Force medics and community vaccinators
  - b. introduce 'organisational standing orders' for medicines, to reflect team-based delivery of health services, better align accountability, and remove a significant administrative burden from individual prescribers
  - c. introduce basic safeguards such as expiry dates to medicines standing orders
  - d. enable off-label and unapproved medicine use in a wider range of situations
  - e. ensure that legal liability from substandard unapproved medicines sits with the person or entity that can best exercise effective control and oversight.
5. Cabinet has already agreed to high-level settings for medicines use under the Medical Products Bill. Once we receive feedback on the policies in this paper, we will develop drafting instructions on these matters.

## Recommendations

We recommend you:

- a) **Note** the Medicines Act 1981's regulation of standing orders, off-label medicine use, and use of unapproved medicines creates barriers and inefficiencies, while failing to adequately protect patients or prescribers **Noted**
- b) **Agree** to the following settings in the Medical Products Bill:
- i. reduce reliance on standing orders by enabling all practitioners registered under the Health Practitioners Competence Assurance Act 2003 to supply medicines classified as 'pharmacy medicines' when providing a health service **Yes / No**
  - ii. reduce reliance on standing orders by enabling tailored regulations for business-as-usual work by specific groups, such as Defence Force medics and community vaccinators **Yes / No**
  - iii. enable standing orders to be issued by specified types of organisation as well as by individual prescribers **Yes / No**
  - iv. enable audits and reviews of standing orders to be carried out by, or under the supervision of, one or more prescriber(s) who can issue a standing order **Yes / No**
  - v. introduce safeguards to standing orders, such as required expiry dates and the ability to revoke a standing order **Yes / No**
  - vi. carry over the intent of provisions from the current Medicines Amendment Bill, which would enable qualified practitioners to supply unapproved medicines in the event of supply disruption **Yes / No**
  - vii. enable off-label use of medicines via standing orders and secondary legislation, where appropriate, as well as via prescription **Yes / No**
  - viii. ensure that legal liability in relation to unapproved medicines sits with the person or entity that can best exercise effective control and oversight **Yes / No**
  - ix. specifically make supply of unapproved medicines a controlled activity, requiring a licence from Medsafe, and enabling the importation of unapproved medicines in anticipation of a prescription for an individual patient. **Yes / No**

Ruth Isaac  
Deputy Director-General  
**Strategy and Policy**  
Date: 15 September 2025

Hon Casey Costello  
**Associate Minister of Health**  
Date:

# Use of standing orders, and off-label and unapproved medicines, under the Medical Products Bill

6. This paper covers three key aspects of medicine use, and seeks your agreement on how they should be addressed in the Medical Products Bill:
  - a. authorisation of supply and administration of medicines via standing orders
  - b. use of unapproved medicines
  - c. use of approved medicines differently to the Medsafe approval (off-label use).

## Standing orders for medicines

### What are standing orders for medicines?

7. Under the Medicines Act, a standing order is a written instruction from a prescriber (or a veterinarian) authorising "any specified class of persons engaged in the delivery of health services" to supply and administer a medicine without a prescription.
8. The prescriber who issues the standing order is responsible for the work carried out under it. The issuer must countersign or audit medicine use under the order, but they are not required to supervise or directly oversee it. Without standing orders, or another mechanism, a prescription would be needed for each patient on a case-by-case basis.
9. The Medicines (Standing Order) Regulations 2002 (the Standing Order Regulations) set out administrative requirements for standing orders, such as what a standing order must include, and audit and review requirements.
10. The Medicines Act imposes very few restrictions on the use of standing orders. For example, they can be used to authorise supply and administration of controlled drug medicines such as opioids, and to authorise activities by people who are not registered under the Health Practitioners Competence Assurance Act.

### How are standing orders used?

11. Standing orders are widely used throughout the New Zealand health system, and in other contexts. Standing orders are currently used to enable virtually all supply and administration of prescription medicines by paramedics and other ambulance staff, and by New Zealand Defence Force medics. They also enable non-prescribing nurses to administer and supply medicines in hospitals, aged residential care, and the community. They are also sometimes used for non-medical purposes, such as administration of Botox (a prescription medicine) for cosmetic purposes.
12. Standing orders can enable innovative health services, including nurse-led clinics and services tailored for local communities. In many cases they are used because there is no other mechanism to enable necessary supply and administration of medicines. However some current uses of standing orders may not be safe or appropriate.

## What are the problems with standing orders under the Medicines Act?

*Standing orders create a significant burden on prescribers, without adequately protecting patients*

13. The current Standing Order Regulations require the issuer of a standing order to review the order at least once per year. They must also either countersign every supply and administration of medicine that occurs under the order, or at least once per month audit a sample of the activities carried out under the order.
14. Because the countersigning, audits and review must be carried out by the issuer, they do not provide any independent oversight of the suitability of the order or of the work being carried out under it. The audit requirement is also a significant burden for prescribers.
15. We are aware that some prescribers issue standing orders despite not having time to fulfil the audit requirement, because a standing order is needed to ensure patient access to medicines. Failure to conduct audits and reviews on medicine use under standing orders has been cited as a factor in adverse findings by the Health and Disability Commissioner, including some relating to patient deaths.
16. There is no ability for anyone (other than the issuer) to revoke a standing order, and orders are not required to have an expiry date. The lack of oversight and safeguards creates risk for patients, if a standing order authorises unsafe supply or administration of medicines.

*Standing orders fail to recognise the expertise of some people who work under them*

17. Standing orders enable a large amount of business-as-usual work, including core work by paramedics, Defence Force medics, and some nurses. In some cases, the people working under the standing order may be more familiar with the patients (and sometimes the medicine) than the person issuing the order.
18. In some instances, standing orders are needed to enable supply of relatively low-risk medicines, such as liquid paracetamol. This increases the workload of those issuing and working under standing orders, without any clear benefit to the patient. For example, it is an ongoing issue for community vaccinators who need to supply liquid paracetamol with some vaccines to minimise reactions.

## How can the Medical Products Bill better manage standing orders?

19. We propose several ways for the Medical Products Bill and its secondary legislation to address the above problems:
  - a. provide better mechanisms upfront in the Bill to enable business-as-usual activities, without needing to rely on standing orders
  - b. improve oversight and better reflect team-based models of care by creating a new 'organisational standing order' mechanism
  - c. modify existing requirements for standing orders to reduce the burden on individual prescribers and better protect patients.

*The Medical Products Bill will better enable business-as-usual work without relying on standing orders*

20. The Medical Products Bill is intended to improve safe access to medicines, including by better recognising the expertise of registered practitioners. Cabinet has already agreed that the Bill will make it easier to expand practitioners' prescribing rights [SOU-24-MIN-0115]. This will help reduce the need for standing orders in the first place.
21. We also propose that the Medical Products Bill enable all practitioners registered under the Health Practitioners Competence Assurance Act to supply medicines classified as 'pharmacy medicines' to patients as part of a health service (for example, a home visit by a community nurse). This would be distinct from any prescribing powers and would not enable retail sale by these practitioners. Practitioners would still have to act within their scope of practice and be subject to requirements such as recordkeeping. Any significant expansion of powers would need to be approved by the Minister of Health.
22. Other business-as-usual activities could be enabled via tailored regulations under the Medical Products Bill for specific groups, such as Defence Force medics and community vaccinators, where appropriate.

*Organisational standing orders can reflect modern models of care and improve oversight*

23. We recommend that the Medical Products Bill enable a form of standing order which would be issued by an organisation, rather than an individual prescriber. This would be in addition to the existing form of standing orders, issued by prescribers.
24. Organisational standing orders will reflect modern, team-based and multi-disciplinary models of healthcare. They will ensure appropriate oversight, avoid burdening individual prescribers, and ensure continuity through staff changes. The mechanism is based on Patient Group Directions in the United Kingdom's health system.
25. Responsibility for an organisational standing order would ultimately sit with the chief executive of the organisation. Practical responsibility for developing and monitoring an organisational standing order would usually be delegated to a clinical governance committee or other group of suitably qualified employees.
26. To ensure these orders are flexible and responsive to different organisational structures, we recommend that the Medical Products Bill enable regulations to be made which set criteria and requirements for making and reviewing the orders and monitoring medicine use. Regulations would specify the kinds of organisations eligible to issue these orders.
27. We expect that organisational standing orders will be used mostly by large organisations such as Health New Zealand and private hospitals to enable work by their own staff. They could also be used to authorise work (eg, community vaccination) by a contracted third-party organisation, if conditions set out in regulations are met.
28. Key stakeholders support the concept of organisational standing orders and consider that they would reflect best practice. We will continue to engage with stakeholders on what safeguards and accountability arrangements will be needed, and which types of organisations may be suitable to issue an organisational standing order.

*Improving standing orders*

29. The changes proposed above should significantly reduce reliance on standing orders issued by individual prescribers. However, it is likely that the current type of standing order will still be needed. As such, we recommend the following improvements:
- a. continue to require all standing orders to be reviewed annually, and to be audited or countersigned, but enable audits and reviews to be carried out by, or under the supervision of, one or more prescriber(s) with the authority to issue standing orders, rather than just the issuer
  - b. provide that an individual prescriber standing order expires a maximum of 90 calendar days after the issuer ceases practice.
30. We also recommend that the following safeguards apply both to individual prescriber standing orders, and to organisational standing orders:
- a. Require all standing orders to expire a maximum of two years after they are issued, with the ability to renew.
  - b. Enable the Director-General of Health, in consultation with the relevant responsible authority (eg the Medical Council), to modify or revoke a standing order if regulatory requirements are not adhered to, or if they believe on reasonable grounds that the activities enabled by the order would put patients at significant risk of harm, and issue a notice prohibiting the prescriber from making a similar standing order in the future.
  - c. Enable regulations that can limit which medicines can be included in a standing order, including by reference to classification level, type of medicine (eg, opioids, sedatives), issuer (ie, organisation or prescriber) or location (eg, health care facility, aged care facility).
  - d. Clarify whether standing orders can enable off-label medicines use, and/or use of unapproved medicines, as discussed below.
31. As part of secondary legislation work, we will also consult on the audit requirement with stakeholders to determine whether monthly audits are necessary and reasonable.

**Off-label and unapproved medicine use**

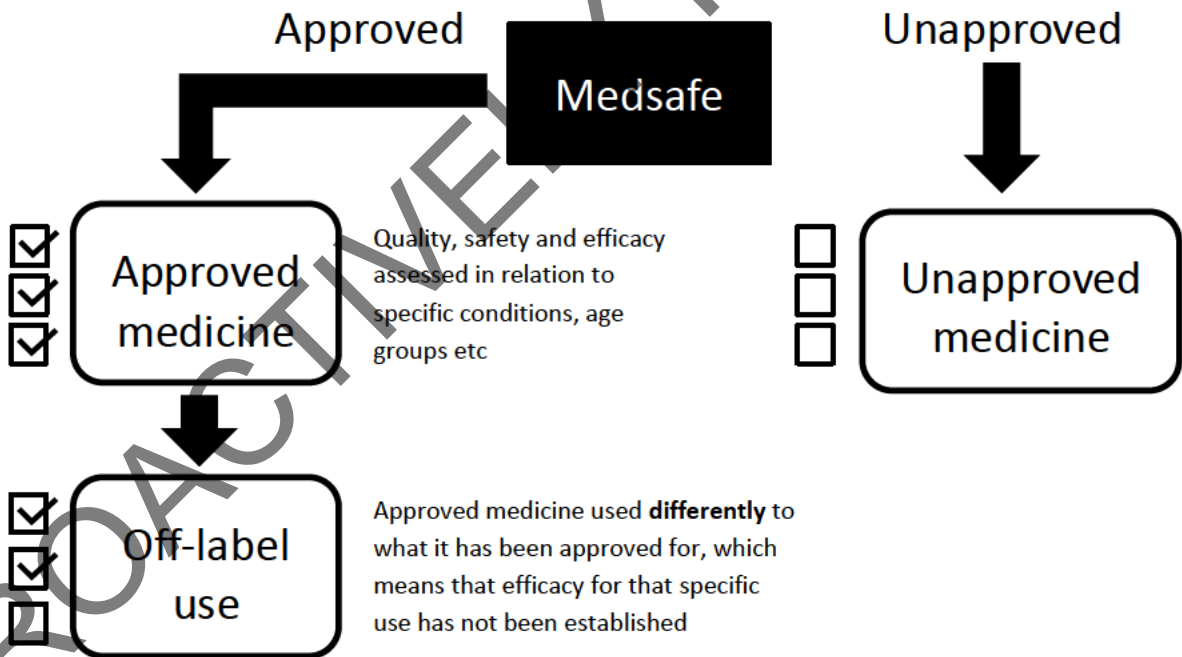
32. Medsafe assesses medicines for safety, quality, and efficacy in relation to one or more health conditions, and approves them for specific use(s) if they meet these criteria to an acceptable standard.
33. Currently, approved medicines have a data sheet provided by the manufacturer. The data sheet includes specifications such as the conditions the medicine has been shown to treat, the medicine's dosage, mode of administration, the population groups the medicine is approved for (for example adults), and when the medicine should not be used (for example if the patient is pregnant or is taking another medicine which will react badly).

**What is off-label medicine use and why does it happen?**

- 34. Off-label use is when an approved medicine is used differently from the specifications on the data sheet. For example, it may be used for a different condition; a different group of people, such as children; or in a different way, such as a higher or lower dose.
- 35. The contents of the data sheet depend on what the sponsor has sought approval for. Two medicines may be identical – including coming from the same production line in the same factory – but be approved for different uses under different brands. This means that use of one brand may be off-label and the other “on-label”, even though the medicines and their use are identical. If a practitioner prescribes a medicine using its generic name, whether or not the use is off-label may depend on which brand is dispensed. Under the Medicines Act, data sheets cannot be changed without the consent of the medicine’s sponsor.
- 36. Off-label use is common and part of routine care in some disciplines, especially in paediatric medicine due to the lack of clinical trial data on children. Practitioner bodies have published guidelines to support the ethical and clinically-appropriate off-label use of medicines.

**How and why are unapproved medicines used?**

- 37. This diagram illustrates the difference between off-label use of an approved medicine (covered above), and use of an unapproved medicine.



- 38. Use of medicines that do not have Medsafe approval (often called ‘section 29 medicines’) is common, but less so than off-label use. Unapproved medicines are most commonly used in one of three situations:

- a. when an approved medicine becomes unavailable, and the best available substitute has not been through the Medsafe approval process. The substitute may be identical to the unavailable, approved medicine; or different in some way, such as dosage, appearance, or non-active ingredients

- b. when the best treatment for a patient is a medicine which has not been brought to Medsafe for approval, most commonly because the New Zealand market for the medicine is very small
  - c. when a medicine is too new to have been through the Medsafe approval process, but initial evidence suggests it may be beneficial for a patient. This scenario also includes patients who initially accessed the medicine through their participation in a clinical trial and who now wish to continue to access the medicine as part of their ongoing clinical care.
39. The Medicines Act currently allows unapproved medicines to be supplied to patients on the request of a medical practitioner (a doctor). There are no further requirements in the Medicines Act for prescribing an unapproved medicine, although professional standards apply. Most suppliers are licensed wholesalers or manufacturers, but there is no specific requirements for suppliers of unapproved medicines to be licensed.

*Use of unapproved medicines will be expanded under the Medicines Amendment Bill and the Medical Products Bill*

40. The current Medicines Amendment Bill proposes to enable nurse practitioners and pharmacist prescribers to request supply of unapproved medicines in the same way as a medical practitioner. It will also enable supply of an unapproved medicine on the request of any prescriber, if the medicine has been funded by Pharmac as an alternative to an approved medicine which has become unavailable due to supply shortage. The Medical Products Bill will carry over the intent of these provisions.
41. The Medicines Amendment Bill will also make some Medsafe approvals faster and simpler, which should lead to more approvals and less need for unapproved medicines. However it is likely that unapproved medicines will continue to be widely used, especially while supply problems continue.
42. In September 2024, Cabinet agreed that the Medical Products Bill will enable supply of unapproved medicines, "if an appropriately qualified health practitioner considers this to be appropriate". Cabinet also agreed that responsible authorities would be able to modify prescribing powers, subject to the Minister of Health's agreement to any significant expansion [SOU-24-MIN-0115]. This will enable more health professions to gain prescribing rights for unapproved medicines, if the responsible authority and the Minister agree.

**What are the problems with off-label and unapproved medicine use under the Medicines Act?**

43. The Medicines Act does not specifically provide for off-label use. Medicines Act provisions for use of unapproved medicines are, likewise, unsuited to respond to supply shortages, and generally unfit for purpose. They also fail to protect patients from substandard medicines and inappropriately place all legal risk on practitioners.
44. Some of the above problems will be addressed through the Medicines Amendment Bill, and we recommend that the intent of these provisions be carried over. However more extensive reform is needed in the long term.

*Off-label and unapproved medicine use is unlawful in some situations, and this could create significant problems*

45. s 9(2)(h)

46. For example, community vaccinators cannot administer vaccines off-label (eg, giving a vaccine at a younger age, or a different number of doses). This creates barriers for immunisation programmes, and may be contributing to low immunisation rates in some communities. s 9(2)(f)(iv)

47. s 9(2)(h)

48. Most healthcare providers are aware that it is not lawful to use unapproved medicines under a standing order, and act accordingly. This has the potential to create serious problems if all approved versions of a medicine become unavailable, for example in emergency medicine use by ambulance services.

*Medicines Act provisions are not suited to respond to supply shortages*

49. The Medicines Amendment Bill's supply shortage provisions will improve access to unapproved medicines when they are needed to address a supply shortage. However, those provisions are still based on a prescription to a specific patient. They do not enable the replacement medicine to be supplied in the same way as the original medicine, for example under a standing order.

50. In addition, the Medicines Act does not allow pharmacies, wholesalers or hospitals to carry a stock of unapproved medicines before they are requested, even if they know a medicine will be needed. It is likely that this restriction is widely ignored, as compliance would mean delayed access to medicines which may be urgently needed.

*Liability under the current system does not align with responsibility or oversight*

51. Unapproved medicines are usually sourced by importers and wholesalers, and then supplied to patients via pharmacists. Prescribers usually have no oversight of where the medicine comes from. Despite this, they are legally responsible if they prescribe an unapproved medicine which turns out to be substandard and harms the patient. Similarly, a doctor who administers a replacement medicine is legally responsible for the replacement decision even if the decision is made by someone else, such as a hospital pharmacist.

**How can the Medical Products Bill better manage off-label and unapproved medicine use?**

52. We recommend that the Medical Products Bill make the following improvements to manage off-label and unapproved medicine use:

- a. enable off-label use under standing orders and via regulations, where appropriate
  - b. enable use of unapproved medicines under limited circumstances
  - c. ensure that legal risk sits with the person or entity best placed to exercise informed oversight and control of the relevant activity.
53. We also recommend that the intent of the supply shortage provisions in the Medicines Amendment Bill be carried over into the Medical Products Bill, subject to any lessons learnt from implementation of those provisions.

*Enabling off-label medicine use under standing orders and via regulations*

54. Off-label medicine use is very common, and essential to the healthcare system. For this reason, we recommend that the Medical Products Bill enable off-label use under standing orders (issued by specified organisations and/or individual prescribers) and via regulations, where appropriate. This would be in addition to the status quo provisions enabling off-label prescription by any prescriber.
55. Clearly enabling off-label medicine use will address most problems with off-label use, s 9(2)(f)(iv) We recommend that the specific issue of off-label vaccine use without a prescription be addressed in regulations. Off-label use would be based on clinical evidence and history of use, and legal responsibility would sit with the person or entity in charge of the vaccination programme.
56. Off-label use does carry an increased risk of adverse effects and ineffective treatment, compared to 'on-label' use. In regard to prescribing and similar individual practitioner decisions, we consider that these risks are best met through professional standards and guidance. This will ensure clinically supported decision-making without creating unnecessary regulatory barriers.
57. We intend that regulations will set criteria for off-label use via a standing order. For example, a standing order authorising a vaccine to be administered outside the authorised age range should specify a different specific age range. Standing orders should always specify which health conditions a medicine can be used for, regardless of whether that condition is off-label.

*Enable use of unapproved medicines only in limited circumstances*

58. Use of unapproved medicines is riskier than off-label use, as there has been no assessment of the medicine recognised in New Zealand. We recommend that the Medical Products Bill enable use of unapproved medicines only under specific circumstances, such as:
- a. under a prescription from a health practitioner who is allowed to prescribe unapproved medicines, as per the status quo and Cabinet agreements to date
  - b. where regulations specifically allow use of unapproved medicines, for example by Defence Force medics, who may need to treat conditions not normally present in New Zealand (eg radiation sickness or tropical diseases)
  - c. as part of a registered or notified clinical trial
  - d. under a supply shortage provision

- e. under an emergency arrangement notice, or other emergency provision
- f. under a standing order, but only in situations enabled by regulations, or if a supply shortage provision is in effect and the standing order specifically enables substitutions under supply shortage provisions.

*Legal risk from unapproved medicines should sit with the person who makes the relevant decision*

- 59. Under the Medicines Act, prescribers are legally responsible if they prescribe an unapproved medicine which turns out to be substandard, and which harms their patient. This is the case even though prescribers usually do not source the medicine or have any control or oversight of its source.
- 60. Prescribers should continue to be responsible for ensuring that a medicine is clinically appropriate for the patient and their condition. They should not be responsible for the safety and quality of the medicine unless they source and supply it themselves.
- 61. Where an unapproved medicine needs to be substituted for an approved one, responsibility should rest with the person who makes the substitution decision. This will often be the prescriber, but in hospital settings it is more likely to be a pharmacist.
- 62. Where Pharmac has funded an unapproved medicine, prescribers should be able to trust that this decision has included due diligence that the medicine meets appropriate standards. Pharmac should not be legally liable for funding decisions, but will need appropriate processes to ensure that funded medicines do not endanger patients. We will work with Pharmac on how best to ensure that patients are protected and appropriate accountability mechanisms are in place.
- 63. Importation and supply of unapproved medicines should be specified as a controlled activity under the Bill, requiring a licence from Medsafe. This is in keeping with Cabinet's decision in September 2024 that the Bill should provide for regulation of activities with medicines, including some types of supply, where regulation of the activity is necessary to protect consumer safety or public health [SOU-24-MIN-0115]. We consider that import and supply of unapproved medicines meets this threshold.
- 64. We understand that most importers and suppliers of unapproved medicines are licensed wholesalers, manufacturers, or pharmacies. Adding a licence to supply unapproved medicines would be a relatively simple process. A supplier could also be licensed solely to import and supply unapproved medicines. Licensed suppliers would be able to import and stockpile unapproved medicines in anticipation of need, which is not lawful under the Medicines Act.
- 65. Licensing the import and supply of unapproved medicines will help ensure that unapproved medicines are sourced from a reputable manufacturer or wholesaler. Prescribers would be able to prescribe an unapproved medicine with confidence that their patient will receive a medicine that meets acceptable quality and safety standards. If an unapproved medicine is poor quality, the supplier would be liable for any harm, rather than the prescriber.
- 66. The Therapeutic Products Act 2023 required a licence to supply unapproved medicines. This was controversial, but only because of a belief that a separate licence would be needed for each medicine. This was not the intention, and the Medical Products Bill will be clearer that a licence will cover supply of all unapproved medicines.

## Equity

67. Some groups may be more vulnerable to inappropriate off-label or unapproved medicine use. For example, people with intellectual impairments, or those with limited fluency in English, will be more reliant on a prescriber's judgement and less able to fully understand risks.
68. Off-label use is particularly common when prescribing to some groups, particularly children and pregnant women, as clinical trials rarely include these groups. These groups will therefore be more affected if regulation unduly restricts access of off-label medicine, or if off-label medicines are prescribed inappropriately.
69. Standing orders are a vital tool for delivering services to communities with specific or unusual needs, including rural and ethnic minority communities. In order to ensure these communities receive high quality services, regulation of standing orders needs to preserve flexibility, minimise administrative burden, and prevent unsafe medicine use.

## Next steps

70. Cabinet has already agreed to high-level policy for medicine use and the proposals in this briefing are consistent with Cabinet's decisions to date. If you agree to the recommendations in this paper, we will use them to inform drafting instructions to the Parliamentary Counsel Office.

ENDS.

PROACTIVELY RELEASED