Briefing for decision

Vaccine classification in New Zealand

Date due to MO:	12 December 2024	**Action required by:**	18 December 2024
Security level:	IN CONFIDENCE	**Reference:**	H2024055515
To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, 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
Alison Cossar	Manager, Strategy, Policy and Legislation	s 9(2)(a)
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Minister's office to complete:

☐ Noted

☐ Seen

☐ Needs change

☐ Withdrawn

☐ See Minister's Notes

☐ Overtaken by events

Comment:

Briefing for decision

Vaccine classification in New Zealand

Security level:	IN CONFIDENCE	**Date:**	12 December 2024
To:	Hon David Seymour, Associate Minister of Health		

Purpose of report

1. You have requested information on the vaccine classification process in New Zealand. Specifically, you asked for information on:
    a. why vaccines are automatically prescription by default
    b. reasons why default classifications could be changed
    c. clear reasoning for why you should not change the classification for vaccines
    d. if it is the case that you need to wait for a medicine to be approved by Medsafe before you can apply to the Medicines Classification Committee for a classification change, or whether this can be done in tandem, and
    e. how the recognised regulators of the abbreviated pathway default classify/treat applications for new vaccines.
2. This briefing also seeks your agreement to seek Cabinet approval to amend the Medicines Act 1981 by way of the verification pathway amendment to reflect modern membership and administration of the Medicines Classification Committee. This amendment is due to be considered by the Cabinet Legislation Committee in March 2025.

Summary

3. Medicine classification is enabled by the Medicines Act 1981, and is an important part of ensuring the safe use of medicines in New Zealand. Classifications impact on how a medicine can be accessed, stored, distributed, and the need for professional oversight.
4. New active ingredients in medicines are considered by the Medicines Classification Committee. The Committee carries out a robust and transparent process to classify medicines. The Committee may also reclassify medicines if new information suggests this would be appropriate, for example to increase accessibility or to better manage risks.
5. Some groups of medicines have an initial default classification to enable more efficient processing, particularly through the Medsafe approval process. New vaccines are part of the vaccine group entry, which has a prescription classification.
6. A new vaccine is automatically classed as a prescription medicine as part of the vaccine group entry. However, this does not preclude the Medicines Classifications Committee from considering and reclassifying a particular vaccine, if it has the evidence to do so.
7. The settings in the Medicines Act relating to Medicines Classification Committee membership and administration are outdated. In the long-term, the Government has

agreed to repeal and replace the Medicines Act with a new Medical Products Bill. However, interim improvements can be made to improve efficiency for the Committee, and we recommend you seek Cabinet approval in March 2025 to modernise these settings, through your Medicines Amendment Bill for the verification pathway.

Recommendations

We recommend you:

a)	**Note** the information provided on the classifications process for New Zealand.	**Yes/No**
b)	**Note** that the process carried out by the Medicines Classification Committee is robust and transparent, and is complementary to the Medsafe approval process.	**Yes/No**
c)	**Note** that the medicine classification system is able to change classifications when evidence is available to support that change.	**Yes/No**
d)	**Note** that the Medicines Classification Committee makes medicines more accessible where appropriate ("down scheduling").	**Yes/No**
e)	**Agree** to include the repeal of section 9(3) to 9(9) of the Medicines Act 1981 to enable improvements to the membership and functioning of the Medicines Classification Committee in the Cabinet Legislation Committee paper for the Medicines Amendment Bill for the verification pathway.	**Yes/No**
f)	**Note** that officials are available to discuss this process further.	**Yes/No**

Maree Roberts
Deputy Director General
Strategy, Policy and Legislation
Date: 11 December 2024

Hon David Seymour
Associate Minister of Health
Date:

Vaccine classification in New Zealand

Background

Classification of medicines

8. Medicine classification is an important part of ensuring the safe use of medicines in New Zealand. They determine how medicines are accessed and distributed based on their safety profile, potential for misuse, and the need for professional oversight. Classifications are enabled in the Medicines Act 1981 and listed in the Schedules in the Medicines Regulations 1984.

9. Medicines are classified based on their active ingredient. The Schedules of the Medicines Regulations set out lists of active ingredients and their classification. Medicines are grouped into four main categories:

    a. *Prescription medicines (Schedule 1)* – applies to medicines that require close monitoring, may have serious side effects, and require expert assessment of clinical appropriateness.

    b. *Pharmacist-only medicines (also known as Restricted medicines; Schedule 2)* – are available without a prescription but must be supplied by a pharmacist to ensure professional advice is provided.

    c. *Pharmacy medicines (Schedule 3)* – these medicines are considered to be of lower risk than pharmacist-only medicines but can only be sold in a pharmacy.

    d. *General sales medicines/Unclassified* – are medicines containing active ingredients that are not in the Schedules or are at levels that are not captured in the Schedules.

10. Pharmacist-only, Pharmacy and General Sale medicines are also referred to as "over-the-counter" or OTC medicines.

Why medicines are classified

11. Classification of medicines, and the associated controls, are important to ensure the safety of patients and to prevent misuse of medicines. For example:

    a. prescription medicines can only be dispensed on receipt of a prescription from an authorised prescriber, ensuring that the right medicine is given to the right recipient.

    b. to ensure appropriate processes for the supply chain of medicines. For example, prescription medicines can only be imported, stored and wholesaled by licensed entities. This ensures that there can be good storage and handling procedures, particularly with respect to cold chain management and record keeping for traceability, especially in the case of recalls and supply to authorised entities.

    c. prescription medicines can be seized at the border, whereas OTC medicines cannot. It is also an important import control on unapproved medicines as it prevents consumers from importing unapproved products into New Zealand without a prescription.

12. New active ingredients are usually classified as prescription medicines to ensure that medicines new to the New Zealand market undergo rigorous safety, quality and efficacy evaluation. It will usually require a period of use over 3 years in New Zealand or overseas to gather sufficient data, as most adverse events will have manifested themselves within this period.

Classification of vaccines

Vaccines are prescription by default

13. Most active ingredients in medicines would be classified individually. However, there are a small number of group entries which capture ingredients that are part of that group and have not yet been classified.

14. There is a group entry for vaccines. A group entry would normally reflect the most restricted classification of any medicine in the group. For vaccines, this is prescription medicine.

15. Having a group entry of prescription medicine means that New Zealand is implementing a framework that prioritises patient safety and ensuring administration by trained health professionals, until there is information to support a different classification.

16. Additionally, this group entry ensures that when a new medicine is applied for through the Medsafe approval process, the medicines can be assessed in the correct way (determined by its classification) and the process is not held up by first waiting for classification of the new active ingredient.

17. Having group entries also prevents importation of unapproved vaccines not yet classified, unless the person obtains a prescription. It also ensures that storage and supply are controlled for processes like cold chain, that are important for many vaccines, by licensed wholesalers.

Classification processes

18. Medsafe and the Medicines Classification Committee carry out complimentary roles for new medicines, which can be done concurrently. The processes are not completely independent of each other.

The process undertaken by Medsafe

19. Medsafe's role is to assess applications for approval of new medicines. Medsafe considers a range of factors to establish the quality, safety and efficacy of the product. Medsafe's assessment considers the whole product, and not just the active ingredient.

20. Medsafe and the medicine sponsor need to know the classification of the medicine to ensure the application has the correct information to meet its assessment approval pathway.

The process undertaken by the Medicines Classification Committee

21. The Medicines Classification Committee considers and makes recommendations to the Minister or their delegate (in this case the Group Manager of Medsafe) on any matter concerning the classification of medicines and access to medicines by health

professionals and the public. The Medicines Classification Committee is not the decision-maker.

22. The Medicines Classification Committee provides recommendations on the classification of active ingredients that:

    a. have not yet had a medicine application submitted in New Zealand

    b. have a classification but there is a submission to 'down schedule' the active ingredient to allow it to be more accessible

    c. have a classification but there is information that has highlighted a risk and the ingredient is being considered for up scheduling

    d. are classified by the Therapeutic Goods Administration (TGA) of Australia, in view of harmonisation. This is a standing item on the Medicines Classification Committee agenda.

23. One of the goals of the Medicines Classification Committee is increasing access to medicines (i.e. down scheduling). New Zealand has been recognised as being one of the most progressive medicines regulatory systems in enabling greater accessibility to medicines. For example, New Zealand was one of the first countries to allow for trimethoprim (an antibiotic for urinary tract infections) and sildenafil (e.g. Viagra) to be available through pharmacies, with conditions, without a prescription.

24. The Medicines Classification Committee works with the information provided to it by the submitter, and can also carry out its own research on an active ingredient. The Committee also has a consultation process for stakeholders (including the public) to comment on the proposal, as well as an objection process if a submitter or stakeholder is dissatisfied with the Medicines Classification Committee recommendation.

25. After the Medicines Classification Committee completes its review, it provides its advice to the Minister of Health or their delegate (i.e., the Group Manager, Medsafe) for a final decision and the decision is gazetted. The Schedules of the Medicines Regulations are regularly updated, to formalise the classifications in regulation.

Changing classifications

26. As noted above, the Medicines Classification Committee has a robust process to ensure that medicines are classified with the most appropriate classification for the best access balanced with the safe use.

27. Common reasons for not changing a classification are a lack of information on its safe use or factors that make it inappropriate for it to be more freely available, such as the severity of common adverse effects.

28. The Minister of Health (or delegate) can gazette a change in classification without going to the Committee. For example, during a measles outbreak in 2019 the Minister of Health temporarily changed the classification of a measles, mumps, rubella (MMR) vaccine so that it could be administered by pharmacist vaccinators to allow a short-term catch-up campaign.

Reclassification of vaccines happens where appropriate

29. It is expected that there will be individual medicines within a group entry that may be appropriate for a different classification. The classification process allows for the classification of any individual medicine to be considered for change when evidence is available. For example, the influenza vaccine is a prescription medicine, but has an exception that enables administration by trained vaccinators.

30. To change a classification, submitters are responsible for providing supporting information as to the benefits of the change and how any risks would be managed for the Medicines Classification Committee to consider. Factors such as the indication of medicine, the risks of misuse, the acute or chronic nature of the condition, the need for clinical oversight, etc are taken into account.

31. An example of this consideration is the recent submission to Medicines Classification Committee where the submitter wanted pharmacist vaccinators to be enabled to administer the yellow fever travel vaccine. The Committee recommended against this. These vaccines are given at travel vaccine clinics, where specialists also give advice as to how to manage risks of contracting the virus in the first place and how to identify symptoms. The yellow fever vaccine comes with significant risks of adverse events such as allergic reaction, and in some cases its more appropriate to manage the risks without vaccination.

How the recognised regulators classify new vaccines

32. New vaccinations in other jurisdictions are usually classified as prescription medicines, for the same reasons as New Zealand; safety, controlled access to appropriate people, control of the quality of the supply chain. Australia also "pre-empts" the classification of new active ingredients by having their classification committee classify them before an application is received, and can be individually assessed for a lower classification, in a similar way to New Zealand.

Removal of outdated requirements of the Medicines Classification Committee

33. While the processes for classifying medicines have generally worked well, overly prescriptive provisions in the Medicines Act create barriers. In September 2024, the Government agreed to repeal and replace the Medicines Act with a new Medical Products Bill.

34. In the interim, there is an opportunity to make minor amendments to the Medicines Act to address outdated requirements for the Medicines Classification Committee. We seek your agreement to include additional recommendations in the Cabinet Legislation Committee paper for the Medicines Amendment Bill for the verification pathway in March 2025 relating to the membership and terms of reference for the Medicines Classification Committee. While these matters have not previously been through Cabinet for approval, this proposal is relatively technical in nature.

35. Section 9 of the Medicines Act sets out requirements for the Medicines Classification Committee, including its general terms of reference. Section 9(3) is out-of-date because it requires that the Committee must consist of two people nominated by the New Zealand Medical Association, two people nominated by the Pharmaceutical Society of

New Zealand, and two by the Ministry of Health. However, the New Zealand Medical Association no longer exists and the mix of experts is too limited given that many more professions have interest in the classification of medicines.

36. To remedy this problem, we recommend repealing subsection (3) and relying on the general appointment power in the Medicines Act for the appointment of members. This change won't impact on current membership.

37. We also recommend repealing section 9(4) to 9(9). These provisions set out requirements for the operational management of the committee, such as appointment terms, quorum, and processes for reappointment and removal from office. We advise that these matters would best be managed by way of the Committee's procedures, similar to other committees. This will make administering the Committee more efficient and will reflect any wider membership.

38. If you agree, we will seek Cabinet agreement to this change at Cabinet Legislation Committee when it considers the Medicines Amendment Bill for the verification pathway. This is expected to be in March 2025.

Equity

39. Vaccines play a critical role in protecting public health, but not all individuals have the same access to information or services. Classification can play a role in ensuring that vaccines are safely supplied and administered equitably, particularly to underserved populations. This oversight helps to build trust and confidence in vaccination programmes.

Next steps

40. Officials are available to discuss the classifications process with you if you wish.

41. If you agree to the proposed amendments to the Medicines Act to remove outdated requirements for the Medicines Classification Committee and replace them with modernised requirements in the Committee's procedures, we will include these amendments in the draft Medicines Amendment Bill for the verification pathway. This Bill will be considered by Cabinet Legislation Committee in March 2025.

ENDS.

Briefing

Draft LEG paper: Medicines Amendment Bill 2025

Date due to MO:	3 March 2025	**Action required by:**	5 March 2025
Security level:	IN CONFIDENCE	**Health Report number:**	H202059381
To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Hon Simeon Brown, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		
Appendices:	1. Draft process for proposed verification pathway 2. Draft LEG paper 3. Medicines Amendment Bill version 1.6		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, Strategy Policy and Legislation	s 9(2)(a)
Allison Bennett	Group Manager, Health System Settings	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Draft LEG paper: Medicines Amendment Bill 2025

Security level:	IN CONFIDENCE	**Date:**	3 March 2025
To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Hon Simeon Brown, Minister of Health		

Purpose of report

1. This briefing provides you with a draft paper for consideration by Cabinet Legislation Committee which seeks approval to introduce the Medicines Amendment Bill to the House of Representatives.

Background

2. The attached Bill amends the Medicines Act 1981 to improve access to medicines.
3. The Government committed in its National-ACT and National-New Zealand First Coalition Agreements to introduce legislation to provide a streamlined medicines approval process to speed up the public's access to approved medicines.
4. The Bill introduces a new medicines verification pathway as an alternative, expedited option for pharmaceutical companies seeking consent to market medicines in New Zealand [SOU-24-MIN-0114].
5. The Bill also enables wider prescribing of unapproved medicines in certain circumstances. The Bill:
    a. enables nurse practitioners to prescribe unapproved medicines in the same way that medical practitioners currently can, and
    b. enables all authorised prescribers to prescribe alternative funded unapproved medicines in the case of a supply shortage of an approved medicine [SOU-24-MIN-0164].
6. The Bill also makes minor amendments to the settings for the Medicines Classification Committee by removing the details of the terms of the Committee from the Medicines Act so that these can be more appropriately set in the Committee's procedures. The attached Cabinet paper seeks Cabinet Legislation Committee agreement to this policy change.

Eligibility criteria and pathway rules

7. The Bill sets out the key requirements for medicines to be considered through the verification pathway (eligibility criteria) and creates a rule making power so that the detailed processes for the verification pathway can be set in secondary legislation.
8. In December 2024 we provided you with a draft of the proposed eligibility criteria and process requirements. We have reconsidered the draft eligibility criteria to ensure that

the right balance is struck between developing an enabling pathway to help speed up access to medicines, and ensuring that New Zealand specific circumstances can be considered where appropriate.

9. At this stage, only the Bill is being finalised for introduction to the House. However, we have provided an update on the draft rules to provide better visibility of the whole package.

Medicines Amendment Bill

10. The eligibility criteria in the Bill are those that are critical to the verification pathway. The majority of medicine applications are likely to meet these criteria and be able to use this pathway. The criteria ensure that there can be additional evaluation by Medsafe in the few circumstances where this is appropriate, such as where approval of a product has been refused or revoked in a recognised regulatory authority, or when local circumstances need to be taken into account. Any medicines that don't meet the criteria for the verification pathway can instead be considered through the current approval pathways.

11. For example, capecitabine is a medicine used to treat some types of cancer. This medicine requires genetic testing prior to use, because the absence of a certain enzyme in the body that breaks down the active ingredient in the medicine can result in toxic levels and cause death. The New Zealand health system is currently unable to carry out the genetic testing required, and therefore use of this medicine is highly risky in the New Zealand context. Medsafe assessment of the application would enable it to liaise with relevant organisations to determine risk and mitigations.

12. The Bill provides that for a medicine to be considered for the verification pathway, it must have full marketing authorisation granted by 2 or more recognised authorities, and the medicine to be supplied in New Zealand must be identical in all material aspects to the medicine authorised. It also provides that the Director-General of Health must be satisfied that the medicine:

    a. has not been rejected, withdrawn, or is pending deferral by a recognised regulatory authority for quality, safety or efficacy reasons,

    b. has not been subject to any regulatory action that may result, or has resulted in, a suspension or revocation of the market authorisation by any recognised regulatory authorities,

    c. does not need an independent assessment by Medsafe to contextualise the benefit-risk profile due to local disease epidemiology, public health considerations or New Zealand specific health risks.

13. Due to the technical nature of the details of the pathway, and the need to be able to refine these in a timely way, the Bill provides for the operational policies of the pathway to be set out in secondary legislation (rules) made by the Minister of Health. The rules can set out requirements for:

    a. applications for consent by verification, including lodging,

    b. the medicine for which consent by verification is sought,

    c. processing an application, including the timeframe.

Pathway rules

14. s 9(2)(f)(iv)

15.

16.

17.

18.

19.

Equity

20. The amendments made by the Bill will improve access to medicines for all New Zealanders. This would be particularly beneficial for vulnerable and high needs communities, including older people, Māori and Pacific people (due to higher rates of poor health), disabled people, and people with chronic or rare health conditions. These groups will benefit from more efficient access to medicines.

Next steps

21. We recommend you consult with your colleagues on the draft Bill.

22. In order to have the Bill enacted and the rules in place by the end of 2025, we recommend that the Bill be introduced by April 2025.

23. The final version of the attached Cabinet paper will need to be lodged by **10am on 20 March 2025** to be considered by the Cabinet Legislation Committee on 27 March 2025.

24. In order to meet these dates, we recommend the timeframe below:

Date	Step
5 March – 18 March	Ministerial consultation on the draft Bill and LEG paper
19 March	Final paper is provided to you
20 March	Paper lodged with Cabinet Office
27 March	Cabinet Legislation Committee consideration of the paper and draft Bill
31 March	Cabinet consideration
31 March	Introduction of the Bill to the House

Recommendations

We recommend you:

a) **Agree** to send the Cabinet paper and draft Bill for Ministerial consultation between 5 March and 18 March 2025 **Yes/No**

b) **Agree** to lodge the Cabinet paper with the Cabinet Office by 10am, 20 March 2025 **Yes/No**

c) **Note** that we will keep your office informed as we develop the draft rules **Noted**

Maree Roberts
Deputy Director-General
Strategy, Policy and Legislation
Date:

Hon David Seymour
Associate Minister of Health
Date:

ENDS.

Talking points: LEG paper Medicines Amendment Bill

- The paper seeks Cabinet's approval to introduce the Medicines Amendment Bill
- You will be aware that enabling faster access to medicines is an objective in the Government Policy Statement on Health 2024-2027. The Bill is a step towards this.
- The Bill also meets one of the agreements in the both National-Act and National-NZ First coalition agreements, to introduce legislation to provide a streamlined medicines approval process

Verification pathway

- The new verification pathway will provide a shorter, more efficient way for medicines to be approved and distributed in New Zealand when they have already been approved by 2 recognised overseas regulators.
- The UK and Singapore have similar pathways for medicines approval, where they have been approved by overseas regulators. The WHO is encouraging use of reliance pathways like this and they are increasingly being used by other regulators.
- This pathway will reduce a regulatory barrier, helping to enable faster access to medicines for patients
- The Bill sets out the key requirements and powers for the pathway, so that the details of the pathway can be set in secondary legislation which will be approved by the Minister of Health. This means that we can ensure that the system is adaptable but is still robust and provides certainty to industry.

Unapproved medicines

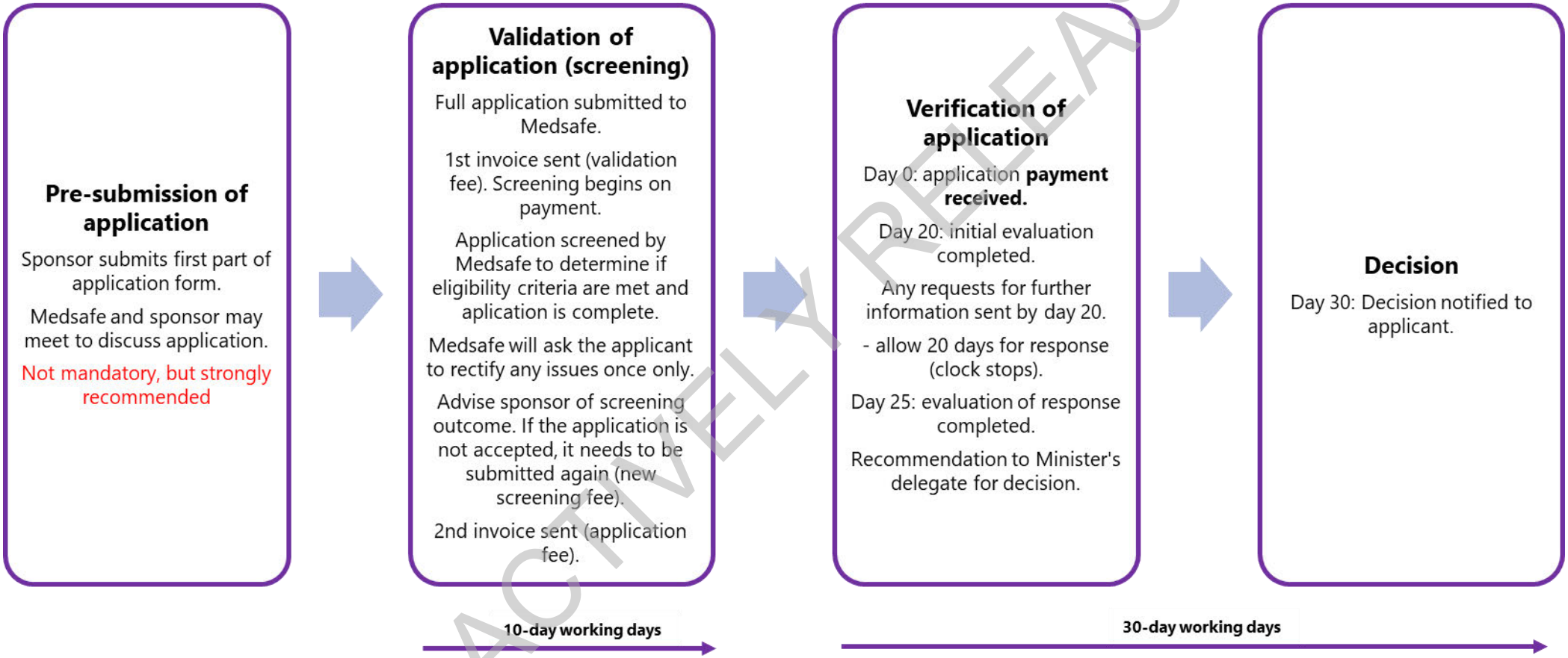
- The Bill also enables wider prescribing of unapproved medicines where these are necessary for a patient's care.
- New Zealand, along with many other countries, frequently experiences supply chain issues for medicines, including some critical medicines.
- Unapproved medicines are generally a last resort, but sometimes they are necessary for a patient's care when an approved medicine is in short supply.
- The Bill enables nurse practitioners to prescribe unapproved medicines where these are required for their patient, just as medical practitioners currently can.
- The Bill also enables other prescribers to prescribe unapproved medicines during supply shortages when the unapproved medicine is funded by Pharmac as an alternative to an approved medicine in short supply.
- This will allow the efficient prescribing of an alternative funded medicines, ensure continuity of care for patients, and reduce the burden on medical practitioners.

Medicines Classification Committee

- The Bill also takes the opportunity to remove outdated requirements for the Medicines Classification Committee, so that the detailed terms can instead be set in the Committee's procedures, which is more appropriate for that level of detail.

Minister's Notes

Appendix 1: Draft process for proposed verification pathway



Appendix 2: Draft LEG paper for Medicines Amendment Bill

Appendix 3: Medicines Amendment Bill version 1.6