Response to questions from a webinar on the Medical Products Bill

On 7 November 2024, the Ministry of Health | Manatū Hauora delivered a webinar on the Medical Products Bill. This document responds to questions raised during and following the webinar.

Please note: Answers reflect decisions made to 14 November 2024 and may be subject to change as the Bill is developed.

Questions about the presentation

Q: Will the slides and video from the presentation be made available?

A: Yes, the video of the presentation can be viewed here (Link) and the slides from the presentation are available at: (link).

Unapproved medicines / section 29

Q: Will the Bill address the issue of section 29 (of the Medicines Act 1981)? Will something be done in the interim to address the current issues associated with section 29 of the Medicines Act? Will it extend to nurse practitioner prescribers.

A: The new Bill will include pathways for health practitioners (as defined in the Health Practitioners Competence and Assurance Act – 'HPCA Act') to supply unapproved medicines to patients, where there is a clinical need. Cabinet noted that Parliament and the public spent a lot of time on these provisions in the Therapeutic Products Bill and the new Bill will not waste that effort.

There will be safeguards built into the new Bill to mitigate the risks associated with the use of unapproved medicines, such as counterfeit, contaminated or substandard products.

The new Bill will repeal the Medicines Act rather than amending it. Any changes to the Medicines Act in the interim would be part of a separate work programme.

Q: Will the replacement for section 29 of the Medicines Act enable veterinarians to prescribe?

A: Subject to further decisions by the Government, the Medical Products Bill will likely include provisions enabling veterinarians to prescribe *human* medicines for their animal patients. Veterinarians are regulated under other legislation, as are veterinary medicines.

Q: Will there more monitoring of unapproved OTC [over-the-counter] and prescription medicines imported into NZ Pharmacies? Will the new act give Medsafe ability to fine importers or pharmacies?

A: The new Bill will enable the regulator to monitor and respond to adverse events involving medicines and medical products. The Bill will put in place post-market surveillance obligations for product sponsors, or people importing products into New Zealand under a licence or permit. As part of our work we are looking at ways to improve oversight of imported medicines generally.

Subject to further decisions by the Government, the Bill will likely include a full suite of compliance and enforcement powers, including the ability to impose fines.

Practitioners (other than s29 issues)

Q: What will be the definition of a 'health practitioner' - cover only professions under HPCA Act [Health Practitioners Competence Assurance Act] or a wider scope?

A: There is no plan for the new Bill to alter the definition of 'health practitioner' used in the HPCA Act. References in the Medical Products Bill to 'health practitioner' will likely only extend to those practitioners who are regulated under the HPCA Act.

However, the Bill will enable other individuals to engage in regulated activities, either under a licence or permit, or as permitted via regulations.

Q: Will this mean nurse practitioners will be able to prescribe medicines like hormonal therapy?

A: The Bill will include consequential amendments to the HPCA Act to establish new and more straightforward pathways for health practitioners to gain additional prescribing

rights, via scopes of practice. It is not possible at this stage to provide a definitive answer on specific medicines.

Q: How will it be easier for professions to gain prescribing powers under the Medical Products Bill? How will the Bill tie in with the HPCA act?

A: The Bill will include consequential amendments to the HPCA Act to establish new and more straightforward pathways for health practitioners to gain additional prescribing rights, via scopes of practice.

The Government notes that health professions are best placed to say what their members can do with medicines and medical devices. Nonetheless, where a profession would gain significant new or expanded powers, a safeguard is needed. As such, part of the consequential amendments to the HPCA Act will be a requirement for the Minister of Health's approval when a profession is gaining powers which currently require legislative change, such as a profession gaining the right to prescribe medicines.

This work will be coordinated with work to review and potentially update the HPCA Act.

What will and won't be regulated as a medical device

Q: Would equipment that benefits health be regulated as a medical device? What about physiotherapy exercise equipment in medical setting, eg spinal units, passive motion machines? Would therapy equipment be included as a medical product?

A: The Bill will cover products intended for use in or on a human for a medical/therapeutic purpose. The definition of 'medical/therapeutic purpose' will align with international practice. While it is too early to provide a definitive answer for individual products, the Bill will include provisions enabling products to be excluded from the scope of the Bill should they be appropriately regulated under another regime (eg, consumer protection laws).

Q: Will IVDs be in scope? Will the Bill cover point-of-care tests [POCTs]?

A: Yes, *in vitro* diagnostic medical devices will be regulated as medical devices. POCTs will be regulated as a subset of *in vitro* diagnostic medical devices.

Q: What about pathology diagnostics? i.e. in vitro devices including test kits, analysers (and their software), and would this also cover tests developed in-house? Are in-house/laboratory developed IVDs likely to be regulated under the bill - will this require registration of these tests, as is the case in Europe and Australia?

A: In-house/laboratory developed IVDs require different regulatory treatment to other medical devices and IVDs. These diagnostics will be within the scope of the Medical Products Bill, but the specific regulatory settings (including registration requirements) will be detailed in secondary legislation and the options will be publicly consulted on.

Related questions:

Will infusion pumps/ syringes with medication safety software be regulated? As medical device?

Will incontinence products like underwear, bed pads and other waterproof medical products be exempt?

Will electro acupuncture machines, heat lamps be regulated/not regulated?

What about hearings aids and the software used in them. there are some over the counter hearing aids available in the market and iPhone apps claiming to be hearing aids for mild to moderate hearing loss.

Is it likely that menstrual cups and discs will be classed as medical devices under the new legislation?

A: The Bill will cover products intended for use in or on a human for a medical/therapeutic purpose. The definition of 'medical/therapeutic purpose' will align with international practice. While it is too early to provide a definitive answer for individual products, the Bill will include provisions enabling products to be excluded from the scope of the Bill should they be appropriately regulated under another regime (eg, consumer protection laws).

If a device is regulated under the Bill, regulation will be risk-proportionate and different approval pathways will be available for medical devices depending on their risk.

As noted in the 30 September 2024 Cabinet paper, the Government is still to make final decisions about the regulation of software-as-a-medical device.

Q: How has disability related equipment been considered? Some of this is highly specialised and prescribed by specialists for an individual's need, whilst a lot is readily available commercially.

A: We are considering how the new Bill could/would apply to disability-related equipment. The definition of 'medical/therapeutic purpose' will align with international practice. While it is too early to provide a definitive answer for individual products, the Bill will include provisions enabling products to be excluded from the scope of the Bill should they be appropriately regulated under another regime.

Software as a Medical Device

Q: Would SaMD include AI programmes (for example) to support record keeping?

A: As noted in the 30 September 2024 Cabinet paper, the Government is still to make final decisions about the regulation of software-as-a-medical device. Based on international definitions of software-as-a-medical device, recording keeping, whether AI-assisted or not, is unlikely to fall within the definition of software as a medical device.

Q: Would remote monitoring software ie software that provides access to the data / information from implantable devices such as pacemakers, be regulated as a medical device/SaMD?

A: The Government has not made a final decision about the regulation of software-as-a-medical device (SaMD). In any case, it is too early to provide a definitive answer for individual products. If SaMD is included in the Bill, the definition will be harmonised with international definitions, and provisions in the Bill will allow the regulator to make it clear how a given product is to be regulated.

Q: Would software like a nurse call system be included as a medical device?

A: As noted in the 30 September 2024 Cabinet paper, the Government is still to make final decisions about the regulation of software-as-a-medical device. However, based on international definitions of software-as-a-medical device, a nurse call system is unlikely to fall within the definition of software-as-a-medical device.

Q: Will smart watches be considered medical devices?

A: The Bill will cover products intended for use in or on a human for a medical/therapeutic purpose. The definition of 'medical/therapeutic purpose' will align with international practice. While it is too early to provide a definitive answer for individual products, the Bill will include provisions enabling products to be excluded from the scope of the Bill should they be appropriately regulated under another regime (eg, consumer protection laws).

We note that while many smart watches are not regulated as medical devices *per se* some software that can run of those watches is regulated as software-as-a-medical device. As noted in the 30 September 2024 Cabinet paper, the Government is still to make final decisions about the regulation of software-as-a-medical device.

Gene therapies

Q: Will/how will CAR-T cell therapies be regulated?

A: The Government has agreed that the Medical Products Bill will enable pathways for approval for gene therapies, including CAR-T cell. The development lifecycle for these technologies and therapies will likely be regulated under the Medical Products Bill and the Government's planned Gene Technology Bill.

Q: Is there ongoing dialogue with the MBIE as they own the development of a framework for regulation of GMOs [genetically-modified organisms] in new Zealand? Given that therapeutics of the future will be gene therapies, is there thought being given as to how two regulatory schemes will interact as they are developed in parallel?

A: Yes, our team has been involved throughout the development of the Gene Technology Bill. This work is ongoing, but cohesion between the two regulators is a priority.

The Medical Products Bill will likely be enacted after the Gene Technology Bill and we will therefore have the opportunity to establish clear and efficient approval pathways early.

Q: Will human cells type of products (stem cells etc) be categorized under "substances of human origin"?

A: Yes, if they are intended for a medical purpose. The approval pathway for products including or derived from stem cells will depend on the nature of the product and the risks associated with it.

Other questions about how things will be regulated or defined

Q: When will there be an indication of whether radiopharmaceuticals will be included or not? Is MOH engaging with industry experts to understand these products?

A: No specific timeframe has been set for deciding about radiopharmaceuticals. The Ministry of Health is keen to hear from practitioners and experts who work with these products (please reach out to us at therapeuticproducts@health.govt.nz).

The Bill will include provisions enabling products that would otherwise be medical products to be excluded from the regime (in full or conditionally). These provisions could be used for radiopharmaceuticals should it be considered appropriate.

Q: When the term "medicines" is used does that include vaccines by default?

A: Yes, vaccines are included under medicines as they are intended for use in humans for a medical purpose (ie, the prevention of disease).

Q: Will the [Bill] now only cover human use, excluding animal use?

A: Subject to further decisions by the Government, the Medical Products Bill will likely include provisions enabling veterinarians to prescribe *human* medicines for their animal patients. Veterinarians are regulated under other legislation, as are veterinary medicines.

Q: Will melatonin be considered a natural health product in future?

A: Access to melatonin is currently via a prescription for most New Zealanders. This ensures consumers can discuss the medicine with a prescriber to confirm it is appropriate for them.

The Ministry is currently working on the framework for a standalone bill for natural health products (NHPs). It will broadly determine what products and ingredients will be part of that regime. Following the passing of the bill, secondary legislation will then be developed with more specific details around the scope. It is therefore too early to say whether melatonin will be considered a NHP, noting that melatonin is currently a medicine based on an assessment of the evidence, which is consistent with many other countries.

Q: My understanding of the TPA was that it would give the regulator the ultimate say on any products that border between legislation to determine whether a product was a medicine, cosmetic or NHP. Essentially giving them much more power to decide without the burden of testing in a court of law. Will the intention be the same for this act to provide more discretion to the regulator?

A: In common with other pieces of legislation, the Medical Products Bill will include a power to make regulations that bring products into the regime or to exclude them. These regulations would be made by Cabinet (ie, the Government) and would follow a period of consultation. These regulations would be subject to judicial oversight.

As part of its compliance programme, the regulator might determine that a product being supplied in New Zealand is a medicine or medical device. A decision by the regulator that a product is a medicine or medical device would ultimately be subject to judicial oversight.

Q: Would the new Act accommodate products like Ivermectin and Hydroxychloroquine? Under what conditions may they be made available?

A: Ivermectin and hydroxychloroquine are currently scheduled as prescription medicines under the Medicines Regulations 1984. The Medical Products Bill will enable medicines to continue to be classified based on risk. While no decisions have been taken on specific products, it is likely that existing medicines classification will be carried over into the new regime.

Q: I understand Sunscreen is currently under TBC. Will NZ use similar sunscreen guidance as TGA AUST L? Treated as medicine as in AU, EU and FDA.

Sunscreens are currently regulated under the Sunscreen (Product Safety Standard) Act 2022, which sets a standard for sunscreens that requires products to go through

consistent and internationally recognised testing. The Fair Trading Act 1986 enforces this product standard.

The Therapeutic Products Act 2023 would have replaced the Sunscreen Act on commencement in 2026. The government has not yet made any decisions on whether the Medical Products Bill will replace the Sunscreen Act. If it does, it is likely that a risk proportionate approach will be taken for the regulation of sunscreens. Lessons from other jurisdictions will be considered regarding the risks and benefits of regulating sunscreens as a medicine, and whether a different approach is appropriate.

Q: Will the Bill include regulations around surface disinfectants?

While it is too early to provide a definitive answer for individual products, the Bill will include provisions enabling products to be excluded from the scope of the Bill should they be appropriately regulated under another regime (eg, consumer protection laws). We note that surface disinfectants are considered to be medical devices in some jurisdictions but not in others.

If a device is regulated under the Bill, regulation will be risk-proportionate and different approval pathways will be available for products depending on their risk.

Product approvals and standards (including harmonization)

Q: Who would determine which approval process is appropriate for a given product?

Any decisions regarding the appropriate approval pathway for a given medical product will be taken by the Medical Products regulator on a case-by-case basis.

Q: Would there be a list of pre-approved ingredients (Actives and Excipients) that can be used in Medicines similar to TGA's Permissible Ingredient Determination? How would it affect importers of 'Ingredients' for medicines?

There will not be a list of pre-approved ingredients for medicines in the Bill. The Permissible Ingredient Determination under the Therapeutic Goods Act in Australia principally applies to lower risk products called complementary medicines. Complementary medicines are similar to 'natural health products', which are not within the scope of the Medical Products Bill.

On 30 September the Government agreed to develop a standalone bill for natural health products. Consideration of whether to include a similar sort of list of pre-approved ingredients will be considered as part of that regime.

Q: Will implementation of the proposed 'reliance pathway' for product approval linked to the new Bill, or will the current [Medicines Act] be amended to allow this ahead of this timeline?

There is a Government commitment to enable Medsafe to approve medicines based on approval by two trusted overseas regulators. We expect that this will be implemented on a faster timeline than the new Bill, likely via an amendment to the Medicines Act 1981.

Q: Are you considering regulatory tools such as UDI for medical devices or labelling requirements for medicines that leverage global standards?

Cabinet have made decisions on the overarching principles of the Medical Products Bill, including the principle that regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators. This would include harmonising with global standards where possible and practical.

Q: With the verification pathway - would an approval based on ACCESS or Project ORBIS be considered?

Verification pathways will enable the medical products regulator to rely on decisions designated entities. This will not be limited to overseas regulatory authorities. The criteria for designating entities will be detailed in secondary legislation and the ultimate decision on designating entities will lie with the medical products regulator.

Q: If a product that has already met the FDA and/or TGA regulatory requirements, why does it have to go through an additional regulatory process in tiny NZ? Is this not a costly and time-consuming exercise of trying to recreate the wheel? Surely, if a product is approved for the US then why not NZ?

Cabinet has agreed to overarching principles of the Medical Products Bill, including the principle that regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators.

Specific decisions have been made for enabling:

- an abbreviated assessment pathway, where a medicine has been approved by one trusted overseas regulator; and
- verification pathways for medical devices already approved by trusted overseas regulators

Reliance on decisions made by designated entities, such as trusted overseas regulators, will enable regulatory approval processes to be optimised, and duplication of efforts to be minimised.

Q: What space/section would medical devices that already have approval, like nasal sprays or intestinal adsorbents (binders), be placed?

Currently medical devices in New Zealand are able to be supplied without an approval. Under the new regulatory regime, medical devices that are currently supplied in New Zealand will be appropriately transitioned into the new regime to ensure they meet acceptable standards of quality, safety and efficacy/performance.

The Government is yet to make decisions on these transitional provisions and relevant time periods for transitioning devices to be compliant.

Q: How closely aligned with TGA do you expect the regime to be?

The Government has decided that one of the overarching principles of the Medical Products Bill is that regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators.

No decisions have been made on whether there would be a preference towards harmonising with a particular overseas regime, but we do recognise the supply chain relationship for companies supplying to Australia and New Zealand.

Q: Will there be additional consultation regarding grandfathering provisions for Medical Devices and Medicines to support continued access of currently available therapies to NZ patients while transitioning to the new legislation?

There will be opportunity for the public to comment on provisions of the Medical Products Bill during Select Committee.

In developing proposals for transiting existing products, the Ministry of Health is utilising the extensive feedback received on the Therapeutic Products Act, and undertaking targeted engagement with key stakeholders, to inform the settings for transitions medical products into a future regulatory regime.

Q: Will medical devices currently on the market be grandfathered or will new registrations/notifications be required in order to supply currently available devices? How will the new legislation impact therapeutic products that are currently included in WAND? Will new registrations be required for these products?

Currently medical devices in New Zealand are able to be supplied without an approval. Not all medical devices are required to be notified to the WAND database at present so we cannot rely entirely on the WAND database to inform which medical devices are currently supplied in New Zealand and whether those devices on the database meet acceptable standards of quality, safety and efficacy/performance.

Under the new regulatory regime, medical devices that are currently supplied in New Zealand will be appropriately transitioned into the new regime to ensure they meet acceptable standards of quality, safety and efficacy/performance.

The Government is yet to make decisions on these transitional provisions. However, particular attention will be placed on minimising disruption to supply of safe and effective medical devices and learning from experiences in overseas jurisdictions.

Q: Will there be legislated timeframes for Medsafe decisions for prescription medicines via full assessment pathway and abbreviated pathway?

The Government is yet to make decisions on statutory timeframes for the assessment of medicines and medical devices under the Medical Products Bill.

Q: Will there be guidelines for product approvals pathway? When will the documents be released, considering that public submission is planned to open for late 2025/early 2026.

Regulatory guidance is an important component of any regulatory regime and will be developed prior to the commencement of the new regime.

There is no timetable for the development of guidance yet and this work will be dependent on the timing for the introduction and passage of the Medical Products Bill.

Q: Can you please comment if the regulation will introduce a renewal process for medical device approvals, like other overseas markets?

The Government is yet to make decisions on whether medical device approvals (ie, market authorisations) will undergo a renewal process.

Advertising

Q: Is the direct-to-consumer advertising of medicines (DTCA) being considered (banned or regulated) for inclusion in the new Bill?

A: The Government has not made any decisions yet on DTCA in the Medical Products Bill.

Q: Is there any way the current Medicines Act, specifically Sections 57 - 59, can be amended or clarified ahead of the timeline to enable Trade Shows to occur in conjunction with Conferences, even if they are exhibiting products (medicines or devices) available oversees and not yet approved in New Zealand

A: Ministers have been advised on enabling trade shows in conjunction with conferences; however, the Government has not made any decisions yet on the advertising provisions in the Medical Products Bill.

Q: What other rules around advertising might change?

A: The Government has not made any decisions yet on the advertising provisions in the Medical Products Bill.

Imports

Q: Will importation of unapproved medical devices be allowed?

A: Yes. The Government has agreed that the Bill will include mechanisms for the importation of unapproved medical devices.

Q: Will there be requirements for GMP [Good Manufacturing Process] inspections on manufacturers importing low risk medicines from MRA [Mutual Recognition Agreement] and non-MRA countries?

The particular requirements for GMP inspections have not been determined and will likely be consulted on as part of implementing the Medical Products Bill and developing necessary secondary legislation and guidance.

Natural health products (including medicinal cannabis)

Q: What if any steps are being taken to make the new 'medicines act' less about medicines, and more about health outcomes? How will it apply to medicinal cannabis and CBD products?

A: No decisions have been made about the approach to regulating medicinal cannabis or CBD products under the Medical Products Bill. We note that medicinal cannabis products are currently regulated under the Medicines Act 1981 and the Misuse of Drugs Act 1975.

In September 2024, the Government agreed that the purpose of the new Bill will be to:

> *support improved health outcomes for all New Zealanders by enabling timely access to safe, high quality, and effective medical products; and to do this by providing cost-effective assurance that medical products meet acceptable standards of safety, quality, and efficacy or performance*.

Cabinet also agreed to high-level principles for the new regime:

- *regulation should be proportionate to benefits and risks, and support timely access to medical products;*
- *the likely benefits of medical products should outweigh their likely risks;*
- *regulation should recognise differences between product types, including the differences between medicines and medical devices;*
- *regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators;*
- *the regulatory system should support innovation, competition, economic growth, and exports in a way that maintains New Zealand's reputation as a producer of high-quality products*.

Q: Will something like section 32 of current medicines act in relation to Natural health practitioners prescribing over and above usual levels in vitamins, herbs and minerals which is currently available and allowed under a consultation at present?

A: The Government has agreed to a standalone bill for natural health products. It is likely that a standalone natural health products law will not commence until after the commencement of the Medical Products Bill. No decisions have been made on whether the Medical Products Bill should include an equivalent provision to section 32 of the Medicines Act 1981.

Regulated activities

Q: Please comment on regulation of controlled activities such as manufacturing.

Cabinet agreed that that the Medical Products Bill should provide for the regulation of some activities with medicines and medical devices, including manufacture, distribution, prescribing, and some types of supply, where regulation of the activity is necessary to protect consumer safety or public health.

Post market surveillance

Q: When adverse event occur, would post market surveillance initiative include regulators undertaking independent investigation?

The Government is yet to take formal decisions about post-market surveillance (PMS) settings.

The regulator

Q: Will the Medical Products Act create a new regulator, or will it be Medsafe?

A: The Government is yet to take formal decisions about the form of the regulator. The Medical Products Bill will broaden the scope of products/services that are regulated, such as the regulation of medical devices.

Fees / cost recovery

Q: Will there be an increase in prescription evaluation fees - will Ministry operate on full cost recovery?

A: We assume this question refers to funding for the medical products regulator. The Government is yet to take formal decisions about the funding settings for the regulator. Medsafe is currently cost-recovered, as are most comparable regulators internationally.

Timeframes

Q: What is the expected timeframe for issuing draft regulation, supporting the Bill, for industry review and comment?

The Government intends that the Medical Products Bill will be passed in 2026 and come into effect in late 2028. It is anticipated that the drafting of secondary legislation, rules and regulations could begin in late 2025 and continue through to around 2029. There will be opportunities for input and comment during this process.

Q: Will the Natural Health Products regime be developed concurrently with the medical products and devices regime all be it over a longer time frame and will the same team be overseeing both?

A: A standalone natural health products bill will be developed following engagement with the natural health products sector. The medical products and natural health products regimes are currently overseen by the same team within the Ministry of Health.

The Ministry of Health is working with Ministers and the Ministry for Primary Industries to agree the timing and manner of stakeholder engagement. Work on a new natural health products bill will not commence until after we have engaged with stakeholders.

Q: What is the contemplated consultation period for the Bill? Will it follow the TPA process?

A: The Government intends that the Medical Products Bill will be passed in 2026 and come into effect around 2028. Due to this tight timeframe, there will not be an exposure draft for the Medical Products Bill like there was for the TPA. Insights gained during the development of the TPA and from submissions on the TPA Repeal Bill will be considered in the development of the Medical Products Bill. We will continue to use targeted consultation to develop the Bill.

Miscellaneous questions

Q: Will prescriptions be increased to 6 and 12 months?

A: No decision has been made regarding prescription length. Details will likely be set out in secondary legislation.

Labelling questions:

Will there be requirement for medicine labels to include Medsafe Number like TGA AUSTR

Is a requirement to place Braille on medicine labels being considered as part of the legislation? This is a requirement that exists throughout the European Union.

Rules relating to labelling requirements, such as registration number, are better suited to secondary legislation. Secondary legislation will be subject to public consultation so there will be opportunity to provide feedback at a later date.

Q: Would there be stricter regulations around Fluoride? Administering fluoride by municipalities, and products containing fluoride?

A: There are no plans to change the current approach around fluoride regulation.

Q: Will Pharmac rules be aligned to the new Act?

We will work with Pharmac to ensure alignment between different systems.