THE BIG PICTURE: HEALTH

A prescription for change

June 2022

Contents

Preparing for change

Major reforms mean the second half of 2022 promises to be a busy period for the health sector. Implementation of significant structural reforms will begin amid the challenges posed by the ongoing COVID-19 pandemic, while long-awaited efforts to modernise regulation around therapeutic products also look set to proceed. With such significant change expected, those in the sector will want to be prepared.

Health has been firmly centre stage over the past two years, with a focus on the sector's response to the pandemic. In addition to upending life as we know it, COVID-19 has re-emphasised existing issues with the health system, including the inequities experienced between different regions and patient groups. Meanwhile, ongoing review/reform in related areas, including the disability sector, has implications for the health system as well.

The focus on health is only going to continue with the implementation of major new reforms. As part of its response to the 2020 Health and Disability System Review, the Government has now passed the Pae Ora (Healthy Futures) Act 2022. As well as disestablishing all 20 district health boards in favour of a more centralised approach, the Act establishes a new Māori Health Authority and new governance documents for the sector. This legislation enters into force on 1 July 2022, following which these far-reaching changes will be implemented.

Meanwhile, regulatory changes are also overdue elsewhere in the sector. After consultation on a draft Therapeutic Products Bill in 2018-2019 to replace the 40-year-old Medicines Act 1981, indications were that revised legislation would enter the House in late 2021. With that deadline now passed, progress is expected in 2022, with the latest comments from the Ministry of Health suggesting a new Bill will reach Select Committee stage in late 2022 or early 2023. Not only would such legislation update existing provisions around medicines, it is also expected to introduce a new regime for regulating medical devices and novel products, while revisiting contentious issues such as advertising of therapeutic products, ownership of pharmacies and regulation of natural health products.

In *The Big Picture: Health*, we take a close look at the Pae Ora (Healthy Futures) Act which seeks to implement the Government's proposed health sector reform, as well as the possible content of new therapeutic products regulation.

Change so significant will have implications for many. Those entities operating in the sector will wish to ensure that they are across the details of any changes which may impact their operations and to consider getting involved with the relevant reform and implementation processes to ensure their voices are heard.

BELL GULLY

Part 1: a centralised, but local approach?

The Pae Ora Act

The Pae Ora Act's aims include to achieve equity by striving to eliminate health disparities among population groups, in particular for Māori, and to build towards pae ora (healthy futures) for all New Zealanders.

The Act then provides for development of 'localities' and corresponding 'locality plans' to set priority services and outcomes for local areas.

The Act will disestablish the 20 existing DHBs and transfer their resources to two new entities:

- **Health New Zealand** will take over planning and commissioning of services, as well as the functions of DHBs.
- **The Māori Health Authority** will drive improvement in hauora Māori, including through commissioning kaupapa Māori services, co-commissioning and planning services with Health NZ and monitoring the performance of the system for Māori.

The Act provides for a series of policy statements, strategies and plans to be developed by the Minister of Health, Health NZ and the Māori Health Authority which will set and give effect to the priorities for the health system, along with a New Zealand Health Charter, which will set out common values and behaviours.

The Pae Ora (Healthy Futures) Act seeks to implement the Government's policy of centralising healthcare in New Zealand, with the aim of achieving greater equity across the healthcare system.

The Act, which will restructure New Zealand's healthcare system, was passed in June 2022, and will come into effect on 1 July 2022, although full implementation of the complex approach is expected to take several years.

Pathway to Pae Ora

The stated purpose of the Act is to provide for the public funding and provision of services in order to:

- protect, promote and improve the health of all New Zealanders
- achieve equity in health outcomes among New Zealand's population groups, including by striving to eliminate health disparities, in particular for Māori
- build towards pae ora (healthy futures) for all New Zealanders

The overall purpose of the Act aligns with the Government's earlier indication that addressing inequity of health outcomes, particularly for Māori, is a key priority. The Act further includes new "health sector principles", which echo the call for equity, and which are to guide the various health entities covered by the Act and the Ministry of Health in the performance of their functions. The principles include that the health sector should:[1]

- be equitable (including ensuring Māori and other population groups have access to services in proportion to their health needs, receive equitable levels of service and achieve equitable health outcomes)
- engage with Māori, other population groups and other people to deliver services and programmes that reflect their needs and aspirations
- provide opportunities for Māori to exercise decision-making authority on matters of importance to Māori, as well as choice between quality services for Māori and other population groups

Following the Select Committee process, the Act was amended to also provide that:

- the health sector should resource services meeting the needs/ aspirations of iwi, hapū, whanau and Māori
- health workforces should be representative of the communities they serve
- the health system should be informed by lived experience

The Act also places positive obligations on health sector entities in respect of Te Tiriti o Waitangi. Specifically:

- the Minister, Ministry and all health entities are to be guided by the health sector principles which, amongst other things, are aimed at improving the health sector for Māori and improving hauora Māori outcomes
- a Hauora Māori Strategy will be jointly prepared by the Māori Health Authority and the Ministry of Health
- Health NZ and the Māori Health Authority must jointly develop a New Zealand Health Plan, and work together in performance of Health NZ's functions
- Health NZ will be required to engage with iwi-Māori partnership boards (IMPBs) – the first time they have been formally recognised as part of the health system. The Māori Health Authority will also be required to support and engage with IMPBs
- IMPBs will have functions to:
  - engage with whanau and hapū around local health needs, and share those insights with Health NZ and the Māori Health Authority
  - assess the current state of hauora Māori in their localities for the purposes of determining priorities for improving it
  - work with Health NZ and the Māori Health Authority in agreeing to locality plans
  - monitor performance in their locality and engage with the Māori Health Authority to support its stewardship of hauora Māori
- the boards of Health NZ and the Māori Health Authority must have knowledge of and experience and expertise in relation to Te Tiriti o Waitangi and tikanga Māori
- the Minister must also establish a Hauora Māori Advisory Committee to advise on certain matters. For example, the Minister must seek and consider the committee's advice before exercising any power to issue letters of expectation or directions to the Māori Health Authority. The Minister will also be required to clearly state where they have not followed the advisory committee's advice and members of the committee will be appointed on the nomination of IMPBs (six members) and health-specific Māori organisations (two members)

It is hoped that these changes will lead to more equitable outcomes for all New Zealanders.

Establishment of the new entities

The Act makes significant changes to structure of the sector, disestablishing key agencies and introducing new ones.

CURRENT MODEL

MINISTER OF HEALTH

MINISTRY OF HEALTH

Responsible for:

- Policy and regulation
- Arranging for national services
- DHB funding and performance management
- Strategy and planning

HEALTH PROMOTION AGENCY

Responsible for:

- Programmes promoting promoting health and well-being

INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH

- Crown entity contracted to the Ministry
- Provides surveillance, applied epidemiology and laboratory services

20 DISTRICT HEALTH BOARDS

- Comprised of elected representatives
- Provide and contract for local services
- Responsible for their geographic area
- 12 public health units operate within DHBs but contracted by the Ministry

DHB PROVIDER

PRIVATE AND NGO PROVIDERS

- Provide various health services
- Includes PHOs, GPs, pharmacists, private hospitals etc

SHARED SERVICES AGENCIES

- Subsidiaries contracts on behalf of DHBs
- Manage contracts on behalf of DHBs

NEW MODEL

MINISTER OF HEALTH

DHBS DISESTABLISHED

MINISTRY OF HEALTH

Chief Steward responsible for:

- Policy
- Strategic direction
- Monitoring overall performance

MAORI HEALTH AUTHORITY

Responsible for:

- Advising on hauora Māori
- Leading development on Māori health workforce
- Directly funding kaupapa Māori services and commissioning services in partnership with Health NZ
- Monitoring system performance in relation to Māori

PUBLIC HEALTH AGENCY

Responsible for:

- Public health policy, strategy, monitoring and intelligence

HEALTH NZ

Responsible for:

- Day-to-day running of whole health system
- Includes a unified public health service
- Four regional divisions

Commissioning and provision of health and disability services

Health New Zealand

The first new entity the Act will establish is Health NZ. Health NZ will be established as a new Crown agent under the Crown Entities Act 2004. Its objectives will include:

- designing and delivering services in accordance with the health sector principles
- encouraging community participation in health improvement and service planning
- otherwise promoting health in collaboration with other social sector agencies

Its functions include jointly developing and implementing a New Zealand Health Plan with the Māori Health Authority, owning and operating services, and developing and implementing 'locality plans', which set the priority outcomes and services for a locality.[2] Further to the Select Committee's amendments, it would also have an explicit role in workforce planning and a role relating to health research. Health NZ will have responsibility for designing and commissioning most healthcare services, working in conjunction with the Māori Health Authority. As a Crown agent, Health NZ will be subject to directions from the Minister to give effect to Government policy relating to its functions and objectives.

For most providers (other than of kaupapa Māori services), Health NZ will likely become the primary point of contact, as both customer and contract manager. Existing DHB/shared services staff will be subsumed into Health NZ, while transitional provisions in the Act will mean Health NZ will automatically replace DHBs as a party to existing contracts.

The Ministry of Health will remain chief steward of the health system, focusing on strategy, regulation, policy and monitoring.

It will work with the Māori Health Authority to monitor performance of the health system in relation to hauora Māori, and with both Health NZ and the Māori Health Authority in respect of those entities preparing the New Zealand Health Plan. Those organisations currently governed by the soon-to-be repealed New Zealand Public Health and Disability Act 2000 (such as Pharmac and the New Zealand Blood Organ Service) will also continue.

The Māori Health Authority

The Act also establishes the Māori Health Authority as an independent statutory entity. That means that it will be independent of the Minister, but must give effect to any Government Policy Statement (GPS), issued under the Act.[3] The Māori Health Authority has an extensive list of functions, including improving service delivery and outcomes for Māori at all levels of the health system, and monitoring the delivery of hauora Māori services by Health NZ. In addition to designing and arranging services, the Pae Ora Legislation Committee further considered the Māori Health Authority should be responsible for delivering services, just as Health NZ is. In addition, the Select Committee felt the Māori Health Authority should receive additional functions to align with Health NZ's, including undertaking/promoting public health initiatives, undertaking research and evaluating the delivery/performance of services it itself provides. The Māori Health Authority also has obligations around engaging with and reporting to Māori, for example in jointly developing the New Zealand Health Plan with Health NZ.

The long-term future of a separate Māori Health Authority may be in doubt.

At the time the Pae Ora Act was being debated, the National Party suggested that it would potentially scrap the Māori Health Authority as a separate entity should it form the next government.[4] National's position has previously been that a Māori Health Authority would not reduce inequities and that the commissioning arm of the authority would inherently conflict with its role as a monitor of the health system.

New governing documents

The Act provides for the development of strategic documents to guide the health sector.

GOVERNMENT POLICY STATEMENT on Health

The Minister must issue a GPS at intervals of no more than three years. This will set priorities for the publicly funded health sector, including priorities in relation to Māori, for improving health outcomes for disabled people, rural communities and other populations, and clear parameters for the New Zealand Health Plan. In preparing the GPS, the Minister must consult with Health NZ and the Māori Health Authority, and engage with any organisations and individuals the Minister considers appropriate.

HEALTH STRATEGIES

The Minister must also prepare a New Zealand Health Strategy. This will assess the current state of health sector performance and medium and long-term risks/trends, as well as providing a framework to guide the health sector in protecting and improving people's health. In addition, the Minister must prepare a Hauora Māori Strategy, a Pacific Health Strategy, a Health of Disabled People Strategy and, following further amendments to the Act, a Women's Health Strategy and a Rural Health Strategy. Health entities must have regard to these strategies when exercising their powers. While further health strategies for different populations, including rainbow and refugee communities, were considered, these proposals were rejected on grounds that specifying further strategies could result in certain populations receiving too much or too little focus, with mechanisms such as locality planning and the GPS thought capable of addressing these concerns.

HEALTH PLAN

Health NZ and the Māori Health Authority are to jointly develop a New Zealand Health Plan to give effect to the GPS. This plan will set the operational direction of the health system in New Zealand and how Health NZ and the Māori Health Authority will provide and commission services to achieve the desired improvements. Annual performance reports must also be prepared against specific outcomes in the Health Plan and the Health Plan will need to take into account the preferences/priorities expressed in locality plans. The Health Plan will also be independently audited before presentation to the Minister.

HEALTH CHARTER

The Minister must prepare a New Zealand Health Charter, to set out common values and behaviours that health entities and workers are expected to demonstrate. Officials are looking to progress an interim NZ Health Plan and NZ Health Charter, with engagement on these expected in 2022.[5]

LOCALITY PLANS

Health NZ must, in agreement with the Māori Health Authority, determine geographically defined localities for planning and commissioning primary and community health services. It must then develop a locality plan for each locality, in agreement with the Māori Health Authority and IMPBs and after consultation with local consumers and communities, social sector agencies.

Localities and locality plans

Localities are a key component of the new regime and will be important for entities operating in the sector to understand and engage with. An obvious challenge for any centralised health system is to ensure that the distinct needs of local communities are understood and accounted for. The current system attempts to do this through 20 democratically-elected DHBs. The new model will attempt to do so through locality plans.

Localities would be geographically defined areas, to be established by Health NZ in agreement with the Māori Health Authority, for the purpose of commissioning primary and community health services. Having established a locality, Health NZ must then develop a locality plan, in agreement with the Māori Health Authority and IMPBs and after consultation with local consumers and communities, local authorities, and social sector agencies. That plan must:

- set out the locality's priority outcomes and services
- provide for its duration (which must be a minimum of 3 years)
- give effect to the NZ Health Plan

Health NZ and the Māori Health Authority will also be required to report annually on progress against the priority outcomes set out in each locality plan.

By setting a locality's priorities and priority services, locality plans have the potential to significantly impact Health NZ's commissioning in the area covered by the plan.

Recent announcements give the first insights into how big localities may be and where might constitute a locality. Health NZ has been working to develop 'locality prototypes' to assist with developing this element of the new system. A long list of potential prototypes was released in December 2021,[6] with prototypes in particular considering areas with high Māori and Pacific populations, high levels of deprivation and rural areas.[7] Selection, contracting and 'go live' were then expected in January-February 2022. In April 2022, the Minister of Health announced the first nine 'locality networks' as:[8]

- Ōtara/Papatoetoe
- Hauraki
- Taupō/Tūrangi
- Wairoa
- Whanganui
- Porirua
- West Coast
- Eastern Bay of Plenty
- Horowhenua

The exact boundaries of these localities were to be "decided by the community"; however, the areas listed have the capacity to vary quite significantly in size. The Minister further indicated that there would be between 60 and 80 localities in total, meaning defining precise geographic scopes, consulting with local communities and developing plans will represent a significant undertaking over the coming years.

From here, work is expected to continue on establishing 'prototype localities' and locality plans, with remaining localities to be identified by July 2024 and locality plans established by July 2025. Entities will wish to keep track of progress in areas relevant to them and carefully review any locality plans published.

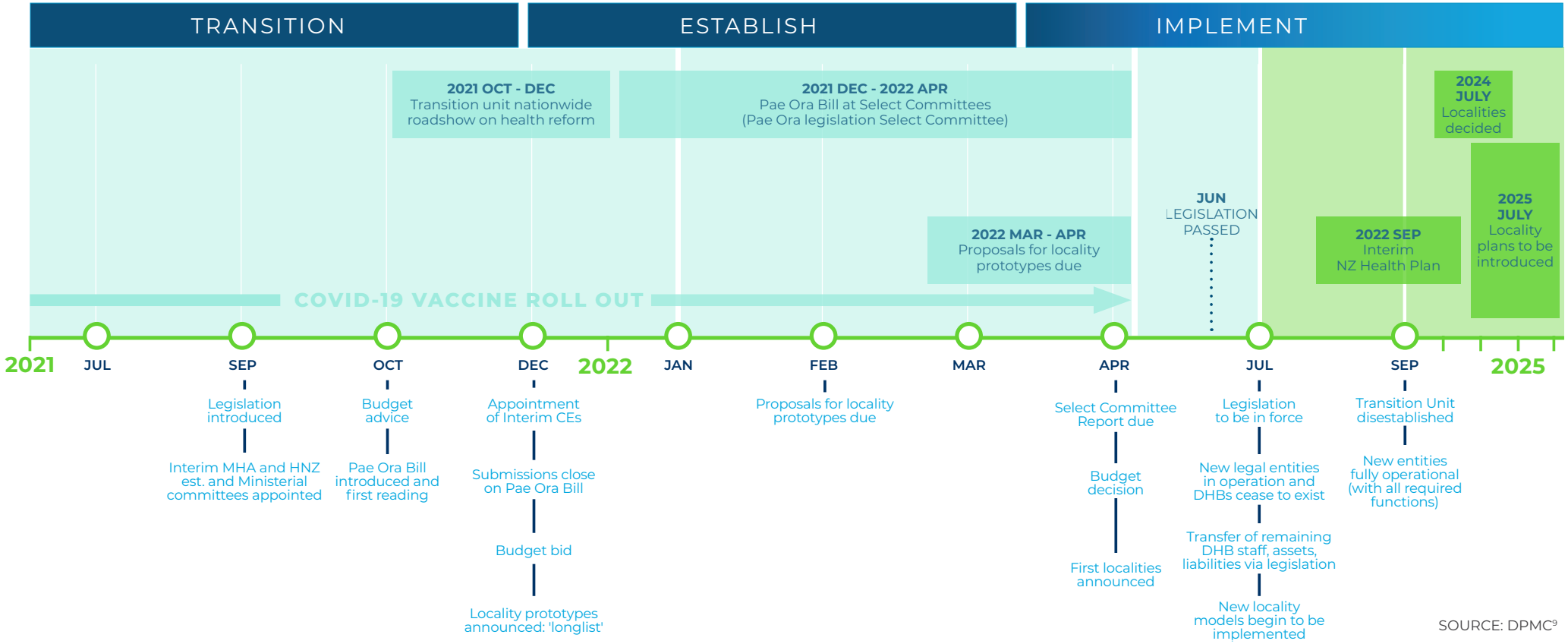
The future

The Act enters into force on 1 July 2022, at which point the DHBs will be disestablished and all existing staff transferred to Health NZ. From there, work will be undertaken to build the capacity and staffing of the new entities as they assume their full functions. The next phases in the new regime's development will be key for many stakeholders. In particular, we consider that there are likely to be two key work streams (for both stakeholders and officials):

- engaging with the implementation of the new regime, including the development of fundamental documents (such as the NZ Health Plan) and localities/locality plans
- managing contracts and relationships during the move from DHBs/shared services to Health NZ as the primary customer/contract manager

We discuss these elements on the following pages.

Engaging with the reforms



SOURCE: DPMC[9]

The new regime will involve the development of a number of key documents. The NZ Health Plan will be important in setting priorities for national services, while locality plans will set priorities for commissioning at the local level. The Health Charter will be important for consumers and their advocates. It will be important for stakeholders to keep abreast of when these documents are to be consulted on and introduced, to both ensure their voices are heard and that they are ready for any change in focus relevant to their activities.

Managing change

The Act provides for any existing contracts or other documents which refer to DHBs to be read as referring to Health NZ. Health NZ will also acquire all rights, liabilities and contracts of DHBs upon the Act's commencement (on 1 July 2022). As such, the Act effectively provides for an automatic novation, with Health NZ automatically becoming the counterparty to any contract involving DHBs. Any reference to a DHB's geographical area or resident population would, however, be preserved.

Thus, in theory, suppliers should not need to do anything upon Health NZ's replacing DHBs on 1 July 2022. However, to the extent that they have not already done so, suppliers may nevertheless wish to consider:

- If their contract also involves a shared services agency as contract manager, how this will be affected. The Transition Unit's indication is that staff from shared services agencies, as with staff of DHBs, will be transferred to Health NZ upon its establishment, so personnel suppliers are dealing with may not change. However, depending on the particular situation and contract, there may be notices to be given/action to be taken to transfer the contract manager's role to Health NZ.
- What term remains on their contracts and what termination rights those contracts contain. While it will likely take some time for the new arrangements to bed in and locality plans setting new priorities to be issued, the pace of change may not necessarily be consistent nationwide and suppliers may wish to be prepared.
- If suppliers are aware of any existing problems with their contracts and their preferred options for resolving them.

Again, as with any significant change, the reforms are likely to produce their own share of challenges as staff work through the migration to the new Health NZ. Given that change will be occurring across the country at the same time, if suppliers have particular issues with key contracts, they may wish to consider raising them with staff as soon as possible to ensure that they are properly addressed. Presenting Health NZ staff with possible solutions, during this busy period, should also be preferred.

Part 2: a new regime for therapeutic products

A novel treatment or a repeat prescription?

Therapeutic products, including medicines and medical devices, have been essential to New Zealand's pandemic response. However, the legislation regulating such products is now over 40 years old, has significant gaps and has been the subject of criticism for decades. Attempts to adopt a joint approach with Australia in the 2000s failed. Subsequent efforts to develop New Zealand-specific legislation have been slow. Despite Cabinet decisions in 2015-2016, a draft Bill being consulted on in 2018-2019 and indications legislation would be advanced by the end of 2021,[10] a new therapeutic products Bill is yet to enter the House. Indications are now that this may occur towards the end of 2022/early 2023.

While there is significant work to be done, with the final legislation yet to be released and key details likely to follow in regulations and rules, movement in this important area is encouraging.

We do not yet know what a new therapeutic products Bill will contain. However, consultation materials released in late 2018 provide a strong indication. These suggest that key issues which may be addressed include:

- a new regulatory regime for medical devices
- regulation of new products which may not be medicines or medical devices
- import and export of therapeutic products
- pharmacy licensing requirements
- whether or not direct-to-consumer advertising should continue to be permitted

New legislation would also likely reform the existing regulator (Medsafe) while also reforming the relevant penalties provisions, with current penalties under the Medicines Act extremely low.

Regulation of medical devices

Medical devices are any articles which achieve a therapeutic purpose other than through immunological, pharmacological or metabolic means – that is, which are not medicines. They range from relatively low-risk products such as bandages and plasters to complex medical machinery and implantable products, including pacemakers, artificial joints and surgical mesh. Such devices also include in-vitro diagnostic testing devices (such as used to detect COVID-19) and software which has a therapeutic purpose.

At present, pre-market requirements for medical devices are very limited, with suppliers generally just needing to ensure the device's information is entered into Medsafe's Web-Assisted Notification of Devices database.[11] There is no requirement for pre-market approval, as there is with medicines, although in practice some buyers may request evidence of overseas approvals. Medical device clinical trials are also unregulated.

Post-market, the Minister and Director-General of Health have some limited powers to restrict supply of devices, but again these have limitations.[12] As a result, specific provisions allowing for regulation of COVID-19 testing devices have had to be included in bespoke pandemic response legislation.[13]

This would likely change under any new legislation, with the earlier consultation materials suggesting a new Bill would likely require that medical devices be approved before they can be supplied, with processes dependent on the risk classification of the particular device. This would be a major change from the status quo. In addition, medical device clinical trials would require a licence,[14] while a more comprehensive post-market regime would be introduced.

BELL GULLY

Regulation of medical devices

What would be covered?

A key issue any new legislation will need to address is how far regulation of medical devices should extend. In particular, there are various products which act similarly to medical devices and have similar risks associated with them, but which are technically used for a cosmetic, not a therapeutic, purpose and so may not be captured by existing definitions of medical devices. Examples might include fashion contact lenses (which do not correct a person's vision), dermal fillers and IPL machines for laser hair removal, all of which can cause harm. One issue canvassed during the 2018-2019 consultation was whether regulation should extend to such products — there is currently some regulation of particular beauty treatments by some local councils but no central regulation. Various submissions, particularly from consumer groups and similar, supported regulation of such devices for safety reasons, while beauty providers were generally opposed. The Government will need to consider how it balances these valid safety considerations with avoiding unnecessary regulation where products are genuinely low risk.

A principles-based approach

As to the detail of any new regime, it is difficult to know exactly what this would look like. The 2018 draft Bill sought to take a 'principles-based' approach, with much of the detail left for regulations and regulator-made rules. For example, beyond requiring that the regulator be satisfied that a product's quality, safety and efficacy/performance have been established and that its likely benefits outweigh its likely risks, the criteria for a product's approval would otherwise be provided for in regulator-made rules. While this may have some expediency benefits, these will need to be balanced with providing certainty for the industry.

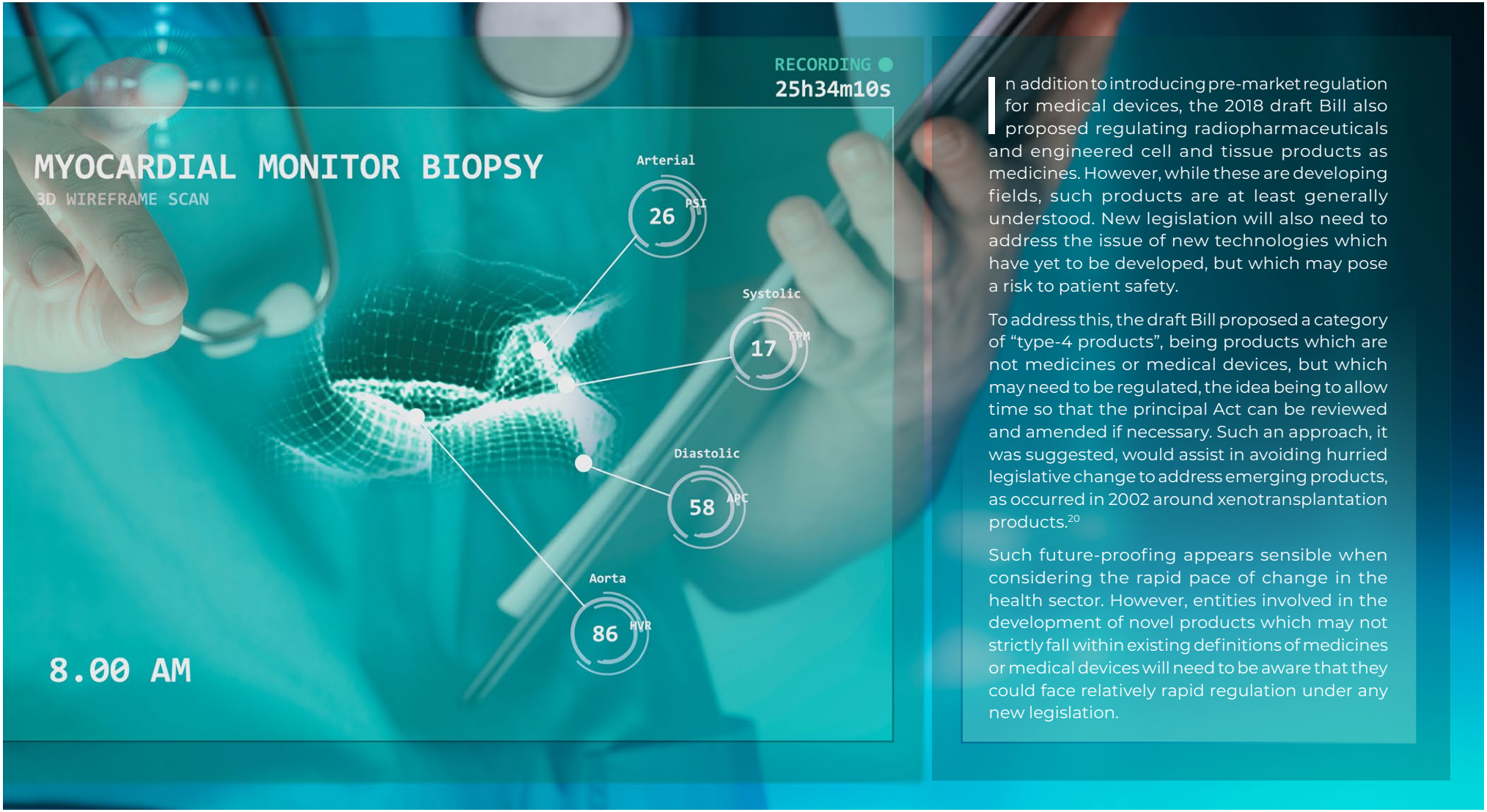
Relying on overseas regulators?

There has been some suggestion in consultation materials that New Zealand would adopt an approach based on that put forward by the International Medical Device Regulators Forum.[15] However, while there are many commonalities in approaches taken overseas and increasing efforts to harmonise, there remain differences, some significant, between jurisdictions. It is therefore not clear exactly what approach is proposed.

The consultation document also suggests that a New Zealand regulator would take a relatively hands-off approach, not directly assessing products' conformity with key principles/standards, but instead relying on assessments undertaken overseas, with its principal responsibilities being to check that products have been properly classified and that overseas assessment certificates are in date.[16] While this may assist in ensuring that products (at least products which already have overseas approvals) get to market relatively quickly and reduce the burden on the regulator, there may be questions as to whether such a role will allow the regulator to maintain sufficient capacity to assess the safety of new products,[17] or the flexibility to deal with particular devices where there is a need for more active regulatory intervention (as was the case with COVID-19 point-of-care tests). In addition, this approach would make the recognition of overseas regulators crucial to the regime's performance – the 2018 draft Bill provided for regulations to set criteria for recognition, while regulator-made rules would identify the regulators to be recognised.[18] This would require the regulator to have a good understanding of the various approaches taken overseas.

More generally, we note that other aspects of the devices industry may also become regulated with the 2018 consultation materials suggesting that wholesalers (except of the lowest-risk devices), including importers and exporters, would need to be licensed under a new regime.[19]

Regulation of novel devices



In addition to introducing pre-market regulation for medical devices, the 2018 draft Bill also proposed regulating radiopharmaceuticals and engineered cell and tissue products as medicines. However, while these are developing fields, such products are at least generally understood. New legislation will also need to address the issue of new technologies which have yet to be developed, but which may pose a risk to patient safety.

To address this, the draft Bill proposed a category of "type-4 products", being products which are not medicines or medical devices, but which may need to be regulated, the idea being to allow time so that the principal Act can be reviewed and amended if necessary. Such an approach, it was suggested, would assist in avoiding hurried legislative change to address emerging products, as occurred in 2002 around xenotransplantation products.[20]

Such future-proofing appears sensible when considering the rapid pace of change in the health sector. However, entities involved in the development of novel products which may not strictly fall within existing definitions of medicines or medical devices will need to be aware that they could face relatively rapid regulation under any new legislation.

Importation of products

The draft Bill released in 2018 also suggests that new legislation would introduce import regulation for therapeutic products, with products required to be approved or otherwise authorised before they enter New Zealand.

While medicines in particular are already likely to be approved before they enter New Zealand, suppliers will need to be aware of consequences for their processes if new importation regulation is introduced.

The 2018 draft Bill also proposed changes to personal importation of prescription medicines. Under the Medicines Act, individuals can currently import prescription medicines via the post providing they have a "reasonable excuse", which Medsafe interprets to be a prescription or letter from their prescriber.[21] If a new therapeutics Bill follows the same approach, this would no longer be permitted – instead, a medical practitioner would need to issue a special clinical needs supply authority, with importation of the product then done by the practitioner, a pharmacist or a wholesaler licensed to import the product.[22]

Alternatively, the regulator could allow personal importation in appropriate circumstances. Personal importation of particular medical devices could also be subject to special restrictions. The idea behind this change is to ensure prescription medicines are only imported by those best able to identify suitable suppliers and to reduce the risk of poor quality or counterfeit products being imported.[23]

Pharmacy licensing

The criteria for pharmacy licensing was identified as a potentially contentious topic and specifically consulted on as part of the 2018-2019 consultation. Currently, the Medicines Act requires that pharmacies be majority owned by a pharmacist, with the pharmacist having "effective control" of the pharmacy. Individual pharmacists may have the majority shareholding in up to five pharmacies.[24] However, documents noted that there was confusion around how some of this may work in practice and whether the provisions were in fact achieving their intended purpose.[25] The 2018 consultation documents therefore canvassed options of: [26]

OPTIONS FROM 2018 CONSULTATION DOCUMENTS

1 Retaining and strengthening provisions requiring pharmacist ownership. This could be done by clarifying that majority pharmacist ownership meant that a pharmacist or pharmacists receive the majority of the profit and hold the majority of the governance rights, while effective control requires that pharmacists be responsible for how the pharmacy operates, with "management and operational control" over its systems/practices. The Government also sought feedback on whether the five-pharmacy limit (or a similar limit) should be retained.

2 Moving to a system of open ownership but with targeted licensing requirements to ensure a pharmacist was responsible for quality systems/practices relating to supplying medicines. Thus, a "supervisory pharmacist" would need to be responsible for quality management systems and a pharmacist would need to be in charge of day to day operations.

Officials' reports on the consultation suggest that a majority of submitters, particularly members of the pharmacy sector, preferred strengthening accountability, with concerns raised that removing it would impact on quality and safety.[27] Others agreed with that approach, but recommended that requirements that pharmacists receive the majority of the profit be removed. It remains to be seen which way the Government goes, although Cabinet papers suggest a preference for retaining pharmacist-ownership requirements.[28]

Direct-to-consumer advertising

While the 2018 draft Bill was drafted on the basis that direct-to-consumer advertising of medicines and other therapeutic products would continue, the issue was specifically raised in the 2018-2019 consultation. Currently, New Zealand and the US are the only high-income countries which allow such advertising of prescription medicines and direct-to-consumer advertising has been criticised by health professionals.[29]

Officials' reports on the consultation noted that this issue attracted significant comment, with strong views both ways. The advertising sector, industry and some elements of the pharmacy sector supported continued direct-to-consumer advertising, including on the basis that such advertising is informative and informs treatment decisions, while health practitioners were opposed on grounds that such advertising provides an unbalanced view and potentially leads to increased costs. Again, it is not yet clear what approach the Government may take; however, given the level of interest and opposition, even if such advertising is retained, it may be subject to greater restrictions in future.

Expansion into natural health products?

One area which was specifically excluded from the draft Bill consulted on in 2018 was natural health products, which include vitamins, herbal remedies, animal extracts and probiotics. Instead, the intention at the time seemed to be that these would be addressed as part of a new regime. However, Cabinet papers released in March 2022 show that Cabinet has since agreed that such products should be regulated under the any new Therapeutic Products Bill.

Specifically, officials advised that the current arrangements for regulating natural health products are not fit for purpose, and that new regulation would enhance consumer safety while promoting the industry's development and growth.[30] In particular, officials considered that such products generally pose a higher risk than foods, although a lower risk than medicines, yet at present enforcement action relies principally on the Fair Trading Act 1986 and Consumer Guarantees Act 1993, which provide a limited range of options for dealing with issues.[31] Further, because New Zealand cannot certify that natural health products meet product safety/ quality standards, New Zealand-made products are not being accepted for sale in some jurisdictions.[32]

From here, officials intend to undertake further policy work on aspects of the proposed scheme. They also advised that they intend to undertake targeted engagement with consumer/ industry representatives and other stakeholders to inform the proposed Bill's practice. This will include engaging with practitioners of rongoā Māori. Participants in this sector will likely want to engage with these processes to the extent possible.

Next steps

Once officials have settled on the reach of the new Bill, the next step will be for any new legislation to enter Parliament, with the first reading to be followed by a Select Committee review process. Any parties with interests in the reforms will wish to consider making submissions to the Select Committee at the appropriate time.

Once passed, any new Act is expected to come into force a maximum of two years after royal assent. The 2018 consultation materials suggest that those requiring product or activity licences would then have six months to make an application for approval, at which point they would receive a temporary licence. Practically, change is still some time away. However, suppliers, particularly those with large numbers of products, will want to keep track of the reform, including the proposed transitional period, as progress is made.

What else in 2022?

COVID-19

While the spread of the Omicron variant has seen restrictions largely rolled back, isolation and certain vaccine requirements remain in place. There have also been sporadic calls for inquiries into New Zealand's handling of the pandemic.

Mental health reform

The Ministry of Health has now consulted on reform to the Mental Health (Compulsory Assessment and Treatment) Act 1992 as part of responding to He Ara Oranga: Report of the Government Inquiry into Mental Health and Addiction. Further work in this space is expected in 2022.

Disability sector reform

The Government announced in October 2021 an intention to introduce new Accessibility for New Zealanders legislation alongside creation of a Ministry for Disabled People. The new Ministry will ensure that disability is not merely treated as a health issue and instead adopt a 'whole of life' approach to disability.[33] We expect to see consultation with relevant groups and potentially introduction of the new legislation in the near future.

Health kaupapa inquiry

The Waitangi Tribunal issued its final recommendations from stage 1 of its Wai 2575 inquiry in October 2021, with some of those recommendations already being incorporated into the Pae Ora Bill. The rest of 2022 is likely to see further progress on stage 2 of the inquiry, focusing on specific topics, including Māori mental health and the experiences of Māori with disabilities. We expect the Tribunal's ultimate recommendations may influence the various plans and strategies required as part of the health system reform.

Bell Gully's health practice

As new issues continue to face the health sector in New Zealand, understanding the changing regulatory and legal environment is essential. We provide advice on many issues impacting the health sector with particular strengths in procurement, as well as the statutory and regulatory framework.

Our team have worked on a wide variety of matters across the health sector and we advise a range of clients from PHARMAC to a number of DHBs, as well as those in the medical industry looking to enter New Zealand.

We have significant experience advising on a range of work for fundamental New Zealand health providers including purchasing strategies and tender processes and contracting. We assisted with the drafting of a record-breaking agreement for the highest number of new medicines funded from one single agreement, advising officials from MBIE, the Ministry of Health, PHARMAC, MFAT and The Treasury on securing a portfolio of COVID-19 vaccines.

We also advise Crown entities on their contracting with health providers and private sector clients on how medicines and medical devices regulation applies to them. We have been involved with key regulatory aspects of New Zealand's health system including advising on the development of the New Zealand Public Health and Disability Act and the Human Rights Act implications of decision criteria for rationing health funding. We are now closely monitoring and working with clients in relation to the health sector reform.

Our specialists have a wide range of expertise in public law and regulation, litigation and dispute resolution, corporate law, employment law and privacy and data protection and are able to assist with health-sector specific expertise on:

- service provision contracts
- pharmaceutical concerns
- medicine and medical device approvals
- medicine advertising requirements
- privacy obligations under the Health Information Privacy Code
- financing
- taxation
- reorganisation
- asset transactions
- joint ventures
- judicial reviews
- employment
- licensing
- clinical trials

Bell Gully's health team

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Endnotes

1 The explanatory note to the Bill indicates that these principles are derived from the principles for the health system discussed by the Waitangi Tribunal in the WAI 2575 Inquiry: Explanatory note to the Pae Ora (Healthy Futures) Bill.

2 This will be a geographically defined area set in accordance with section 48.

3 Crown Entities Act 2004, s 105; Pae Ora Act, s 39. The Māori Health Authority is a health entity for the purposes of s 39 of the Act.

4 https://thespinoff.co.nz/live-updates/05-04-2022/national-would-scrap-the-maori-health-authority-focus-on-fixing-single-system

5 https://www.futureofhealth.govt.nz/publications/stakeholder-updates/update-from-the-transition-unit-wednesday-17-november-2021/

6 https://www.futureofhealth.govt.nz/publications/stakeholder-updates/update-from-the-transition-unit-thursday-9-december-2021/

7 https://www.futureofhealth.govt.nz/publications/stakeholder-updates/update-from-the-transition-unit-wednesday-17-november-2021/

8 https://www.stuff.co.nz/national/politics/128415367/health-minister-andrew-little-announces-nine-new-localities-for-health-reforms.

9 https://dpmc.govt.nz/sites/default/files/2021-04/htu-factsheet-implementation-roadmap-en-apr21.pdf
https://www.futureofhealth.govt.nz/about-the-reforms/timeline

10 https://www.stuff.co.nz/national/politics/300310925/government-to-introduce-new-law-for-vaccine-after-legal-challenge

11 Medicines (Database of Medical Devices) Regulations 2003.

12 Medicines Act, ss 37 and 38.

13 COVID-19 Public Health Response (Point-of-care Tests) Order 2021.

14 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [414]. The proposed Bill would also add licensing requirements for trials involving approved medicines being used for an unapproved purpose.

15 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [353].

16 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [373] – [375].

17 Office of the Minister of Health "Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft" Cabinet paper 2018 at [22].

18 Draft Bill at cl 207.

19 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [408].

20 Office of the Minister of Health "Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft" Cabinet paper 2018 at [28].

21 https://www.medsafe.govt.nz/consumers/miet/importmedicines.asp

22 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [81]-[82].

23 Office of the Minister of Health "Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft" Cabinet paper 2018 at [37].

24 Medicines Act, ss 55D to 55F.

25 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [467]-[469].

26 Therapeutic Products Regulatory Scheme – Consultation Document (2018) at [464] onwards.

27 Key themes from submissions on the Therapeutic Products Bill. Available at: https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation

28 Office of the Minister of Health "Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft" Cabinet paper 2018 at [52].

29 Office of the Minister of Health "Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft" Cabinet paper 2018 at [45].

30 https://www.health.govt.nz/system/files/documents/pages/regulating_natural_health_products_cab_paper_redacted_redacted.pdf at [3].

31 At [14]. Some products are also regulated under the Dietary Supplements Regulations 1985.

32 At [17].

33 https://www.beehive.govt.nz/release/government-delivers-transformative-changes-disabled-people

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