

In vitro diagnostic devices need a robust regulatory framework

Geoffrey CE Herd, Samarina MA MUSAAD

ABSTRACT

AIMS: To discuss the regulatory scope of *Medicines Act 1981* related to point-of-care testing (POCT) *in vitro* diagnostic (IVD) devices, the implications of the now repealed *Therapeutic Products Act 2023* and the regulatory requirements which will be needed in the proposed *Medical Products Bill*.

METHODS: This review includes the relevant sections on regulation of IVD devices under the *Medicines Act 1981*, the role of Medsafe, the relevant sections of the *Therapeutic Products Act 2023*, the cabinet papers on the proposed *Medical Products Bill* and published literature on regulation for POCT devices in New Zealand and overseas.

RESULTS: IVD devices are not regulated under the *Medicines Act 1981*. Faulty devices have been supplied to health services and direct to the public. New Zealand is currently behind international regulatory standards. Cabinet papers and the proposed *Medical Products Bill* state that IVD devices should be regulated and subject to a risk classification system.

CONCLUSION: A comprehensive regulatory framework for POCT IVD devices is required to ensure the supply of high-quality devices to health services and consumers. The proposed *Medical Products Bill* must include a regulatory framework for POCT IVD devices in the interests of patient safety. Implemented wisely, the advantages of regulation outweigh disadvantages.

Point-of-care testing (POCT) devices are *in vitro* diagnostic (IVD) devices that produce medical laboratory test results near to a patient, or at the point-of-care (POC).^{1,2} POCT can help improve clinical decision making by providing test results faster than conventional laboratory-based testing. Examples of POCT IVD devices include urine pregnancy test kits, rapid antigen test (RAT) kits, capillary blood glucose meters, nucleic acid amplification testing and portable or bench top multi-analyte blood analysers.

The scope and scale of POCT in New Zealand is extensive. POCT is performed in many settings including public and private hospitals, pharmacies, general practice, rural and remote settings, ambulance services, marae and schools. POCT devices are used by patients at home and in the community for many reasons, including managing glycaemia using simple glucose meters or wearable devices with result trending, alarm systems, remote monitoring and automated insulin dosing or warfarin anticoagulation. POCT is very important for decision making in rural and remote settings;³ it can improve outcomes⁴ and improve access to testing.⁵

Medical laboratory testing is essential but tests, whether laboratory-based or POCT, are associated with risk. Inaccurate or clinically unreliable test results can occur due to pre-analytical errors, e.g., incorrect specimen collection; analytical errors,

e.g., the device or analyser is not properly calibrated and quality controlled; or post-analytical errors, e.g., incorrect reporting or interpretation of results. Clinical risks are amplified at the POC where testing is usually performed by non-laboratory trained individuals or health professionals, outside of the controlled medical laboratory environment, with results that are actioned swiftly. This is most relevant for results of high clinical risk, e.g., troponin or neonatal lactate results.

Conventional medical laboratory testing is governed by registered pathologists, medical scientists and technicians, using diligently selected IVD devices and tests that are, for the most part, accredited in New Zealand by International Accreditation New Zealand (IANZ). The choice of devices, platforms and tests in the laboratory is based on thorough established processes. POCT in accredited public hospital laboratories is also subject to clinical governance and oversight and is performed by trained and certified staff using verified IVD devices to minimise clinical risk.

POCT devices used outside accredited laboratory settings or supplied to the public are accessible without appropriate clinical governance, oversight or local laboratory verification. This is compounded by the fact that currently, there is no pre-market assessment or regulation even though POC tests carry no less a risk, if not more, than laboratory-based tests. It is in the public interest that these

IVD devices are subject to a national regulatory and clinical governance framework.^{6,7}

This viewpoint article outlines the lack of regulation for POCT IVD devices under the *Medicines Act 1981 (MA 1981)*⁸ and the limitations of the current state, with real world examples. Now that the *Therapeutic Products Act 2023 (TPA 2023)*⁹ has been repealed, the Ministry of Health – Manatū Hauora proposed a *Medical Products Bill* to Cabinet.¹⁰ The article calls for an effective regulatory framework for publicly funded POCT and, where relevant, direct-to-consumer (DTC) or over-the-counter (OTC) IVD devices. The regulatory implications for conventional laboratory testing, medicines, medical devices and natural health products are not discussed.

Methods

The limitations of the role of Medsafe and relevant sections on the regulation of IVD devices under the *MA 1981*⁸ are discussed, with examples of faulty IVD devices in the public domain. The article also reviews relevant sections of the *TPA 2023*,⁹ the cabinet papers on the proposed *Medical Products Bill*¹⁰ and discusses literature on POCT regulation in New Zealand and overseas.

Results

The regulatory status of POCT devices in New Zealand

At the time the *MA 1981*⁸ was enacted, POCT IVD devices were limited to urine glucose and ketone tests and urine pregnancy test kits. Hand-held glucose meters for personal use became available internationally from the mid-1980s. The *MA 1981* includes legal definitions for the terms “therapeutic purpose” and “medical devices”.⁸ In terms of POCT, the interpretation of the Act is difficult. However, the definition of “therapeutic purpose” in the *MA 1981* includes some functions of POCT,⁸ such as:

“(a) ... *diagnosing* [and]
monitoring [e.g., COVID-19] ...

“(c) *testing the susceptibility of persons to a disease or ailment* [e.g., pre-diabetes] ...

“(e) *testing for pregnancy*.”⁸

This legal definition of a therapeutic purpose does not imply that Medsafe regulates IVD devices.

In its Regulatory Guidance, Medsafe states that IVD devices are medical devices under the *MA 1981* and must comply with requirements of the Act and its regulations.¹¹ It lists a range of medical devices for diagnosing or monitoring a disease, such as thermometers, heart rate monitors, medical imaging systems and urine pregnancy test kits. Medsafe also has a mechanism to report adverse events.¹¹

Urine pregnancy test kits being the only POCT IVD devices listed may still not be subject to approval by Medsafe.¹² Also, Medsafe notes on its website that: “*As the pre-market legislative/regulatory requirements are minimal, this places even more responsibility on the manufacturer/importer to ensure the medical devices supplied are safe and effective.*”¹²

Medsafe has a risk classification system for medical devices such as drug eluting stents or cardiac pacemakers, but as of July 2014 it states that it has no risk classification system for IVD devices,¹¹ which is not clinically effective. Medsafe operates the Web Assisted Notification of Devices Database (WAND). Suppliers are encouraged, but not obligated, to notify WAND of their IVDs.¹³

COVID-19 public health response point-of-care tests order 2021

On 22 April 2021 an order—“COVID-19 Public Health Response (Point-of-care Tests) Order restricting import, manufacture, supply, sale, packing and use”—was created in response to the SARS-CoV-2 pandemic.¹⁴ The New Zealand Point of Care Testing Advisory Group (NZPOCTAG) provided advice on this order, which stated that the director-general may exempt POC tests from prohibitions provided that the “*point-of-care test or class of point-of-care tests is sufficiently accurate and reliable so as not to pose a material risk to the public health response to COVID-19*”.¹⁴ This was an exemplar of regulation limiting the use of potentially unsafe POCT hence mitigating clinical risk and supporting public health measures. The order was revoked on 28 April 2023.¹⁴

Adverse events management for POCT

The director-general of health has power to investigate unsafe devices under Section 38 of the *MA 1981*.¹¹ Examples of problematic IVD POCT devices recorded on the Medsafe website include:

1. 24 July 2020; the Yes! urine pregnancy test kit showed a high rate of false positive and inconclusive results; this test kit was

withdrawn on 2 March 2021.

2. 26 May 2016; the Easy Check pregnancy test kits, for professional use, showed an unacceptable rate of invalid (inconclusive) and false negative results.
3. 5 September 2022; recall of a batch of the KetoSens Test Strips owing to a high rate of clinically unsafe falsely elevated ketone test results.¹⁵

POCT devices evaluated in New Zealand and found not to be fit-for-purpose include a device for the detection of Group A *Streptococcus* in throat swabs¹⁶ and a handheld device for testing capillary blood glycated haemoglobin (HbA1c).¹⁷ In April 2024, at-home OTC RAT kits for chlamydia, gonorrhoea and herpes-2 were vigorously advertised and sold in New Zealand. In response, a multidisciplinary position paper was published cautioning against their use, indicating that these devices have not been verified and that overseas evidence on similar kits showed unacceptable clinical performance.¹⁸ These examples of faulty devices demonstrate the need for regulation in New Zealand.

POCT pathologists and scientists recognise the technical and analytical limitations, and therapeutic implications associated with IVD devices. A national adverse events management system specifically for POCT devices was proposed in 2015¹⁹ to address the need for a robust, easily accessible system to monitor trends in performance, record near-misses or clinical incidents and develop alerts where devices are found to be faulty or produce clinically misleading results. Such a system would be bolstered by connectivity to improve operator and device management, reduce transcription errors, improve safety and assist with adverse events management.²⁰

IVD device regulation in other jurisdictions

Lack of a regulatory system for IVD devices in New Zealand is not consistent with other jurisdictions. Therapeutic products including IVD devices are regulated in Canada,²¹ and in Australia they are regulated by the Therapeutic Goods Administration (TGA).²²

The TGA provides guidance for manufacturers on meeting clinical evidence requirements for IVD devices and states in Essential Principle 15 that an IVD medical device must meet the “analytical and clinical requirements to support its intended use, based on appropriate scientific and

technical methods”.²³

The TGA provides comprehensive information on the regulation of medical and IVD devices which ensures that the level of regulation is appropriate and consistent with clinical risk.²⁴ The risk classification system is based on the intended use and clinical risk, to person or public, associated with inaccurate results. The TGA lists classes one to four for IVD devices; the higher the clinical risk, the higher the risk classification. A pregnancy test kit is classified as class two, with a low personal health risk or associated risk level. Class three includes tests used to detect sexually transmitted disease, with a moderate public health or high personal risk, and a kit with analyser and test strips for international normalised ratio testing.²⁵

The Therapeutic Products Bill 204-1 (2022) and the Therapeutic Products Act 2023

The *Therapeutic Products Bill 204-1* was introduced to parliament on 30 November 2022.²⁶ The NZPOCTAG, in its 2023 submission on this bill, advised that POCT IVD devices should be regulated along with appropriate verification, quality assurance, adverse events management and recall systems.²⁷ The *TPA 2023* received royal assent in July 2023 and was due to be enacted by September 2026.⁹

The *TPA 2023*⁹ had its limitations but was a step in the right direction. Section three stated that the purpose of the Act “is to protect, promote and improve the health of all New Zealanders” and in this context, provides for the “acceptable safety, quality, and performance of medical devices across their lifecycle”.⁹ Section eight stated that medical devices are therapeutic products covered by the regulatory scheme and these ranged from tongue depressors to robotic surgery machines.⁹

Section 15, of the *TPA 2023*, lists up to 11 therapeutic purposes. The following stated therapeutic purposes are relevant to this topic:

“(a) preventing, diagnosing, monitoring ... for a disease, ailment [e.g., COVID-19] ...

“(c) testing the susceptibility of humans to a disease or an ailment [e.g., human papilloma virus] ...

“(e) testing for human pregnancy ...

“(g) investigating a human physiological process ... [e.g., diabetic ketoacidosis].”²⁹

The *TPA 2023* requires the regulator to evaluate a medical device to determine its safety and fitness-for-purpose and its likely benefits and risks.⁹ It includes provisions for recall orders for faulty devices and states that the regulator can designate a testing entity to carry out tests on therapeutic devices.⁹ These sections are consistent with the advice provided in the NZPOCTAG submission on this bill.²⁷

The new coalition government revoked the Act within the first 100 days of government. The cabinet paper CAB-24-MIN-0154 presented on 23 May 2024 states that reasons for repeal were to improve timely approval for medicines, avoid over regulation of natural health products and low-risk medical devices and that the regulatory framework would be cost-prohibitive for exporters.²⁸

Ministry of Health – Manatū Hauora Social Outcomes Committee proposed *Medical Products Bill*

On 24 September 2024, a Cabinet Social Outcomes Committee paper titled “Modernising the Regulation of Medicines and Medical Devices”¹⁰ authorised the associate minister of health to issue drafting instructions for a *Medical Products Bill* to replace the *TPA 2023*.¹⁰ The proposed Bill covers medicines and medical devices and recognises the regulatory differences between them. The purpose of the Bill is to improve health outcomes by enabling access to effective medical products, which must meet acceptable standards of safety, quality and clinical efficacy or performance.¹⁰ An example of a regulatory and authorisation schema for IVD POCT devices in New Zealand was proposed in 2019.⁶

The proposed *Medical Products Bill* includes a risk proportionate regulatory framework and is harmonised with international good practice.¹⁰ The framework included the use of assessments and decisions from trusted overseas regulators. Medical devices range in complexity and risk; devices which expose staff or patients to minimal risk would have minimal regulation.¹⁰

The cabinet paper notes that “*clinically worthless tests are being sold to patients at chemists including tests for sexually transmitted diseases*”.²⁸ These test kits are not publicly funded, but in the interest of public health, government should assume a role in regulating them.

The proposed Bill would regulate advanced technology, such as artificial intelligence or software as a medical device (SaMD), as medical

products.¹⁰ An example of a SaMD was the QUiPP App, a cell phone-based application. This application is used in conjunction with clinical parameters and POCT results for the prediction of preterm labour. In this context, the QUiPP App is recognised as a medical device. However, it is essential that POC IVD devices used to produce quantitative results (e.g., in ng/L), are also subject to appropriate regulation, together with clinical governance and quality assurance, to ensure the actual test results are clinically reliable for use with the QUiPP App.

Discussion

The *MA 1981* does not provide a regulatory framework for POCT IVD devices. The scope, scale and complexity of POCT has increased dramatically since the 1980s; the regulatory framework needs to reflect these advancements. Public hospitals and health services may not be aware that publicly funded health IVD devices have not been subject to pre-market assessment, are not required to be notified to the WAND database and have no risk classification. Since the repeal of *TPA 2023*,⁹ New Zealand has been left with a regulatory void for POCT devices.

There are currently significant limitations to the extent of oversight for medical devices. Relying on manufacturers to ensure safety of devices and tests is not satisfactory due to commercial conflict of interest, lack of transparency of information supplied, and known and unknown limitations in clinical performance data supplied by the manufacturer.

Clinically reliable POC test information relies on carefully selected devices and tests that are fit for purpose in the intended clinical setting. From a best practice perspective, regulation is inextricably linked with risk management. It is the first tier of risk mitigation that supports clinical governance performed at the healthcare provider level. This assumes higher importance considering the pressures and limited resources in the health sector. By reducing the availability and use of unreliable and potentially unsafe devices and tests, regulation can reduce the risk of misdiagnosis or inappropriate management, the risk of serious harm, and healthcare costs.

Previous experience with faulty IVD devices suggests that the regulator must have the legislated power to initiate recalls and request additional verification and reassessment of device performance. To that end, a user-friendly accessible

adverse events management system needs to be implemented.¹⁹

Like any decree, while regulation has advantages, it would have disadvantages. Table 1 lists pros and cons of regulating POCT IVDs and proposes risk mitigating measures. The list is not exhaustive.

The regulatory process should be transparent to allow policymakers to review and improve the process. Regulation should be accompanied by regular clinical audits and research to facilitate continuous improvement.²⁹

Harmonisation and alignment with international regulatory frameworks could avoid inadvertent over regulation of IVD devices. New Zealand can learn from these countries, and we

in turn can share our expertise with IVD devices and POCT.

Right four of the Code of Health and Disability Consumers' Rights 1996³⁰ states that consumers/patients have the right to reasonable standards of care, in this case accurate POCT results. Clinical staff must be able to rely on the accuracy of POCT information for decision making and in turn inform and communicate this test information to the patient in accordance with right five and right six of the code.³⁰

Where possible, the regulator should ensure that more than one brand or model of an IVD device with reliable analytical performance are selected so that in the event of a recall, manufacturing problem or global logistical supply

Table 1: Pros and cons of regulating POCT IVDs and risk mitigating measures.

Advantages	Disadvantages, risks and mitigation measures
Improved safety of devices, particularly high-risk devices, and tests.	Risk of overregulation inhibiting competition and innovation, reducing consumer choice, and potentially falling behind international standard of care.
Supports better health outcomes.	Mitigation: risk-appropriate regulation.
Aligns with international regulatory frameworks.	Need to resource the regulatory machinery, which if under resourced can create an inefficient system with no true benefits.
Supports clinical governance of POCT in the community and in hospitals.	Mitigation: risk-appropriate regulation, scoping, building on existing systems.
Supports funding bodies fund devices (and tests) that are fit for purpose, using tax-payer money judiciously.	Potentially increased cost to manufacturers and suppliers.
Complements pro-equity measures.	Potential delays in availability and access to the New Zealand consumer/s.
Aligns with Code of Health and Disability Services Consumers' Rights, in particular right four: "Right to services of an appropriate standard".	Mitigation: an agile and responsive regulatory system.
Informs commercial entities, such as pharmacies, deciding on choice of devices and tests.	Potentially disproportionate delays in availability and access of devices/tests for rare disorders.
Gives the clinicians and consumers a measure of confidence.	Mitigation: an agile and responsive regulatory system.
Improved traceability and supply chain management.	Research and development leaving New Zealand.
Maximises efficiencies in the healthcare sector, which has broader societal benefits.	Mitigation: support innovation within an accountable and transparent regulatory system.
Patient-centric focus, which is responsive to unmet needs of New Zealanders	

problem, an alternative device is available. In the past year there have been two disruptions to the supply of the foetal fibronectin (fFN) test kits, used in the prediction of preterm labour, due to manufacturing issues. Obstetric units replaced fFN with one of two alternative tests in New Zealand. Addressing disruption to supply chains for medical devices was particularly relevant during the COVID-19 pandemic.

A regulator must have overall responsibility for the regulation of publicly funded IVD devices and, where appropriate, DTC and OTC IVD devices, with advice from POCT experts.⁶ Purchasing and on-going funding of POCT devices is not a simple monetary decision. In the absence of regulation, health providers and users of POCT devices are encouraged to be vigilant and critical and consult

with their local accredited laboratory for advice. The NZPOCTAG New Zealand Best Practice Guidelines for Point-of-Care Testing is also a valuable resource to ensure safety, quality and clinical and operational effectiveness.²

In conclusion, the current regulatory state for IVD devices is unsafe, does not serve our clinicians and consumers, is not aligned with international standards and fosters a reactive approach. Structured risk-based regulation would be a huge milestone for New Zealand, and with a considered approach its risks can be mitigated, if not avoided. This viewpoint articulates measures that would help establish an effective regulatory framework for POCT IVD devices that is tailored to the population's needs.

COMPETING INTERESTS

Nil.

AUTHOR INFORMATION

Geoffrey CE Herd: Point of Care Testing Coordinator, Pathology Services Te Tai Tokerau Northern Region; Lead Scientist, Northern Region Point of Care Testing Network, Whangārei Hospital, Whangārei.
 Dr Samarina MA Musaad: Chemical Pathologist and Point of Care Testing Pathologist, Waitemata, LabPlus Te Toka Tumai and Northland Te Tai Tokerau; Clinical Lead Chemical Pathology LabPlus, Auckland Hospital, Auckland; Clinical Lead Northern Region Point of Care Testing Network; Chair New Zealand Point of Care Testing Advisory Group.

CORRESPONDING AUTHOR

Geoffrey CE Herd: Point of Care Testing Coordinator, Pathology Services Te Tai Tokerau Northern Region, Whangārei Hospital, PO Box 9742, Whangārei. E: geoff.herd@northlanddhhb.org.nz

URL

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