MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Pharmacy Quality Audit Update

Reporting Period 2017/2018 Quarter 3

Version 1.0

August 2018

MINISTRY OF HEALTH
MANATU HAUORA

Contents

Section 1: Background

1.1. Medicines Control

Medicines Control is a branch of Medsafe responsible for administering a range of operational functions regulating the supply chain of medicines and controlled drugs. Audits are conducted of individuals and organisations holding a regulatory instrument (licence) to assess compliance with regulatory requirements, aligning with the public safety intent of the legislative framework.

1.2. Pharmacy Quality Audit Updates

The purpose of these updates is to support continuous quality improvement in the pharmacy sector by providing an overview of current audit trends and findings in the pharmacy quality audit framework. The 2017/2018 Q3 reporting period relates to audits conducted during January, February and March 2018.

This is the first update to be published by Medsafe, and forms an integral part of implementing the risk based audit framework. Feedback from the pharmacy sector is very welcomed (please provide feedback to the Manager, Medicines Control by email to medicinescontrol@moh.govt.nz).

Section 2: Pharmacy Quality Audit Framework

2.1. Overview

The following table outlines the risk-based framework for pharmacy quality audits, which has been progressively introduced in the current 2017/2018 audit year, and will be fully implemented from the 2018/2019 audit year.

	Risk-Based Framework
Description	50 pharmacy quality audits and 450 inspection audits conducted across the DHBs per audit year.
Number of pharmacies audited per audit year[1]	Up to 500
% licensed pharmacies audited per audit year	47.6% (estimated)
Interval between audits at a pharmacy	2.0 years (estimated)

The following table outlines the key differences between a pharmacy quality audit and an inspection audit within the risk-based pharmacy quality audit framework.

	Pharmacy Quality Audit	**Inspection Audit**[2]
Description	A full audit assessing all services provided from the premises. Scheduled according to risk assessment by premises, including prioritisation for: 1. New premises (including pharmacy relocations) 2. Change of ownership (new operators) 3. Audits required subsequent to an inspection audit	A risk based audit assessing some of the services provided from the premises. Scheduled according to risk assessment by premises. May also be conducted to verify the implementation of corrective actions after a pharmacy quality audit.
Notification	At least 15 working days	No notification (unannounced)
Audit scope	All audit criteria applicable to the pharmacy services provided from the premises (up to 67 criteria)	The 10 current risk-based criteria[3]
On site duration	6-8 hours (average)	1-2 hours (average)

[1] Where appropriate, multiple audits may be conducted at a premises during an audit year.
[2] Note. Inspection audits are also conducted outside of the pharmacy quality audit framework, as occurs currently, in response to specific issues. The audit criteria assessed during these audits is determined on a case by case basis and approved by the Manager, Medicines Control.
[3] Additional audit criteria may be included at the discretion of the auditor where significant non-compliances are identified during the site audit, and with the approval of the Manager, Medicines Control.

2.2. Attainment Risk Ratings

Medicines Control auditors assign an attainment risk rating to each criterion assessed during an audit, based on the audit evidence and findings.

2.2.1. Attainment

The following attainment levels are incremental and based on a continuous quality improvement model[4].

	Attainment Level	Description
LP	Leading Practice	The auditee can clearly demonstrate achievement beyond the expected full attainment and evidence is available of actions taken based on findings from an internal review as part of a robust quality management system.
FA	Fully Attained	The auditee can clearly demonstrate implementation (such as practice evidence, training, records, visual evidence) of the process, systems or structures in order to meet the criterion.
PA	Partially Attained	The auditee is able to demonstrate evidence of appropriate process (such as policy/ procedure/ guideline), system or structure implementation without the required supporting documentation; or a documented process (such as policy/procedure/ guideline), system or structure is evident but the auditee is unable to demonstrate implementation where this is required.
UA	Unattained	The auditee is unable to demonstrate appropriate processes, systems or structures to meet the criterion.
NA	Not Applicable	The criterion is not applicable to the licensed activities and does not therefore apply.

[4] Adapted from NZS 8134.0:2010 Health and Disability Services (general) Standards (https://www.standards.govt.nz/)

2.2.2. Risk

When a partially attained (PA) or unattained (UA) attainment is assigned, a risk is then determined by the auditor, with reference to the Risk Management Matrix[5]. The auditor considers both safety and regulatory consequences, and the likelihood of occurrence, to determine the risk[6].

		LIKELIHOOD				
		frequent	likely	occasional	seldom	rare
SAFETY CONSEQUENCE	Consumers or service providers are at **extreme risk of harm or actual harm is occurring**	Critical	Critical	High	Moderate	Moderate
	Consumers or service providers are at **significant risk of harm**	Critical	High	Moderate	Moderate	Moderate
	Consumers or service providers are at **moderate risk of harm**	High	Moderate	Moderate	Low	Low
	Consumers or service providers are at **minimal risk of harm**	Moderate	Low	Low	Low	Negligible
	Consumers or service providers are at **insignificant risk of harm**	Low	Low	Negligible	Negligible	Negligible
REGULATORY CONSEQUENCE	**Serious and/or significant** deviation from regulatory requirements	Critical	Critical	High	Moderate	Moderate
	Moderate deviation from regulatory requirements	High	Moderate	Moderate	Low	Low
	Minimal deviation from regulatory requirements	Moderate	Low	Low	Negligible	Negligible

[5] Adapted from NZS 8134.0:2010 Health and Disability Services (general) Standards (https://www.standards.govt.nz/)
[6] Note. Where the safety and regulatory risks assigned differ, the greater risk is assigned.

2.2.3. Rating Indicators

Rating indicators are a key component of the risk based audit framework, and are used by Medsafe to indicate the risk associated with a specific premises or the risk associated with a specific audit criterion.

$$\text{Premises Rating Indicator} = \frac{\text{Sum of attainment risk values for all criteria assessed during the site audit}}{\text{Number of criteria audited during the site audit}}$$

$$\text{Criterion Rating Indicator} = \frac{\text{Sum of attainment risk values for the audit criterion during a specified time period}}{\text{Number of times audit criterion audited during a specified time period}}$$

The following table outlines the attainment risk values:

Attainment Risk		Attainment Risk Value
Leading Practice		15
Fully Attained		10
PA Negligible		9
UA Negligible		8
PA Low		7
UA Low		6
PA Moderate		5
UA Moderate		4
PA High		3
UA High		2
PA Critical		1
UA Critical		0

Whilst these rating indicators are an important tool for Medsafe, it is important to note that they are *indicators*, and have limitations. For example a pharmacy with a high premises rating indicator may still have critical/high risk non-compliances, and a pharmacy with a lower premises rating indicator may have a leading practice attainment. A premises rating indicator is therefore *one indicator* of the standard of pharmacy practice at a pharmacy.

Criterion rating indicators are primarily used by Medsafe to identify where regulatory resource should be prioritised when conducting audits, and to monitor changes in compliance over time.

As the risk based framework evolves over time, the rating indicators will also evolve to take account of additional relevant factors (for example regulatory licensing information, including incidents occurring at premises).

2.3. Risk Based Audit Criteria

The 10 current risk based criteria are generally applicable to all pharmacies, irrespective of any specialised services that may be provided from the premises. The criteria were selected with reference to their criterion rating indicator for the 2015/16 and 2016/17 audit years (approximately 18 months of 'baseline' data), and consideration of the number of critical and high risk non-compliances identified during this time period:

Criterion	Description
1.02.01	All staff are suitably qualified for the pharmacy services provided from the premises.
2.02.01	There is ready access at the premises to all the required pharmacy equipment.
3.03.02	Appropriate corrective actions are implemented, documented and reviewed contributing to continuous quality improvement.
4.01.02	Controlled drugs requiring storage in a safe, are securely held in an approved controlled drugs safe.
4.01.04	Fridge temperatures are consistently maintained between 2-8°C.
5.01.02	Prescription medicines are supplied in accordance with regulatory and professional requirements.
5.02.01	An approved form of controlled drugs register is appropriately and accurately maintained, and retained on the premises for four years.
5.05.04	Compounding records for individually compounded products are appropriately maintained and stored on the premises for at least three years.
5.07.04	Medicines requiring supply by an accredited pharmacist are recorded, sold and labelled in accordance with regulatory and professional requirements.
5.10.03	Compliance packaging is labelled sufficiently in accordance with regulatory and professional requirements.

A pharmacy quality audit includes assessment of all criteria within the audit tool, including the risk based criteria. Inspection audits are focused on the 10 risk based criteria, noting that additional criteria may be included at the discretion of the auditor where significant non-compliances are identified.

Section 3: Audit Findings

3.1. Audits Conducted During Reporting Period

During the January to March 2018 reporting period, 25 pharmacy quality audits and 54 inspection audits were conducted within the pharmacy quality audit programme (a total of 79 audits). These audits were conducted at 78 discrete premises (1 premises had multiple audits conducted during the reporting period.

3.2. Attainment Risk Summary

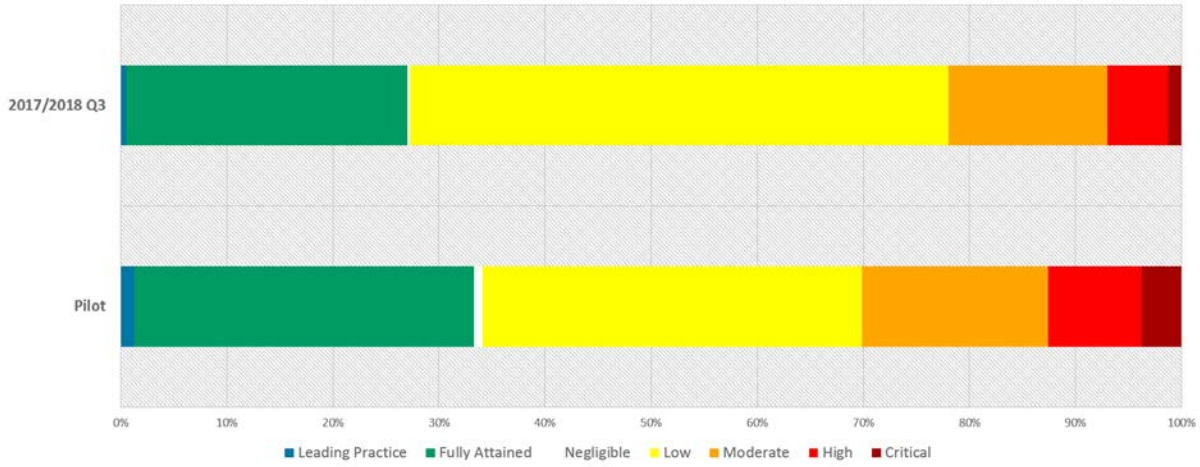
The following table summarises the attainment risks[7] for the 79 premises[8] audited during the pilot, for the 10 risk based audit criteria (refer section 2.3).

CRITERION	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
1.02.01	0	16	0	57	4	2	0
2.02.01	0	7	0	61	9	1	0
3.03.02	0	7	0	52	19	0	0
4.01.02	0	39	0	11	21	5	2
4.01.04	1	24	0	17	26	7	4
5.01.02	0	28	0	30	13	5	1
5.02.01	1	39	0	31	2	3	2
5.05.04	1	24	1	41	10	0	0
5.07.04	1	12	0	29	11	21	1
5.10.03	0	9	1	63	1	0	0

Total	4	205	2	392	116	44	10
%	0.5	26.5	0.3	50.7	15.0	5.7	1.3

[7] Unattained and partially attained findings have been grouped by risk (e.g. 'unattained high' and 'partially attained high' attainment values have been grouped by 'high').
[8] The total number of attainment risk values is less than 790 (79 x 10) as a number of criteria were not assessed where for example the premises did not provide all services (e.g. compliance packaging), or the scope of the audit was refined.

The following chart compares the attainment risk profile for audits conducted in the reporting period with the profile from the risk based audit pilot.



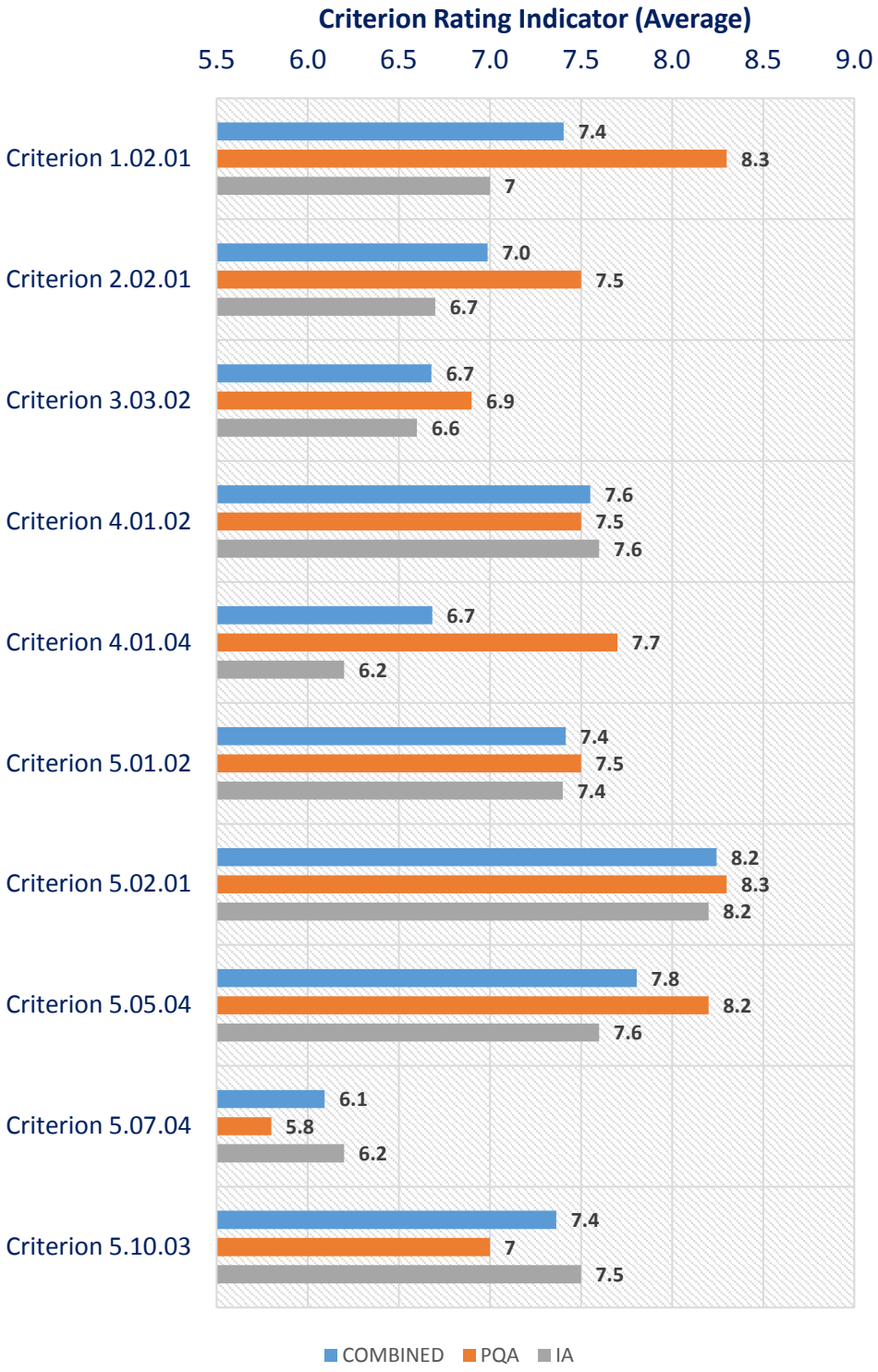
This indicates, overall:

- A reduced level of compliance (leading practice and fully attained), 33% reduced to 28%.
- A decrease in the proportion of non-compliances classified as critical and high risk, although there was a significant increase in low risk observed (36% increased to 50%).

3.3. Rating Indicators

3.3.1. Criterion Rating Indicators

The following chart displays the criterion rating indicators for the 10 risk based criteria for audits conducted within the reporting period, and compares the indicators for all audits against the pharmacy quality audits (PQA), and inspection audits (IA).



3.4. Summary of Audit Findings by Criterion

This section contains a summary of the audit findings for each of the 10 risk based criteria (refer section 2.3). For each criterion an overview of the attainment risk, examples of compliant and non-compliant practice, and regulatory guidance is provided. The following example outlines how the information is presented for each criterion.

Criterion identifier and description

Criterion 1.02.01

All staff are suitably qualified for the pharmacy services provided from the premises.

Summary table of attainment risk findings, split by Pharmacy Quality Audits and Inspection Audits. Refer to section 2.2 for an overview of attainment risk ratings.

Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0	11	0	14	0	0	0
	0%	44%	0%	56%	0%	0%	0%
Inspection Audits	0	5	0	43	4	2	0
	0%	9%	0%	80%	7%	4%	0%
All Audits (Total)	0	16	0	57	4	2	0
	0%	20%	0%	72%	5%	3%	0%

Attainment risk profile for the reporting period, compared to the risk based audit pilot.

Attainment Risk Profile Comparison

Criterion rating indicator analysis, comparing baseline data, risk based audit pilot data and data from the reporting period.

Refer section 2.2.3 for details of how the criterion rating indicators are calculated.

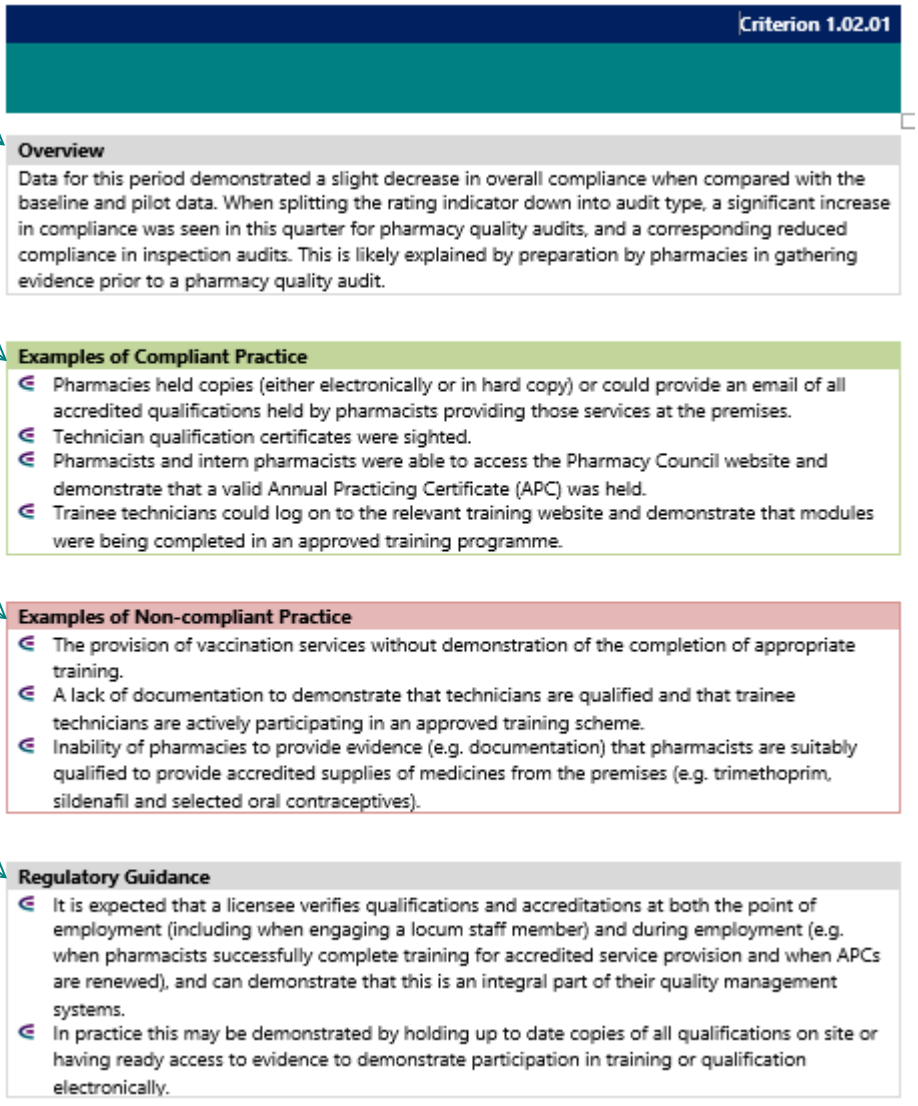
Criterion Rating Indicator Analysis

Overview of the audit findings for the criterion during the reporting period.

General examples of compliant practice identified at audits during the reporting period.

General examples of non-compliant practice identified at audits during the reporting period.

Regulatory guidance provided to assist licensees to meet the requirements of the criterion. The guidance provided responds to the audit findings identified during the reporting period, and is not intended to be a comprehensive guide for all aspects of the criterion.



Criterion 1.02.01

Overview

Data for this period demonstrated a slight decrease in overall compliance when compared with the baseline and pilot data. When splitting the rating indicator down into audit type, a significant increase in compliance was seen in this quarter for pharmacy quality audits, and a corresponding reduced compliance in inspection audits. This is likely explained by preparation by pharmacies in gathering evidence prior to a pharmacy quality audit.

Examples of Compliant Practice

- Pharmacies held copies (either electronically or in hard copy) or could provide an email of all accredited qualifications held by pharmacists providing those services at the premises.
- Technician qualification certificates were sighted.
- Pharmacists and intern pharmacists were able to access the Pharmacy Council website and demonstrate that a valid Annual Practicing Certificate (APC) was held.
- Trainee technicians could log on to the relevant training website and demonstrate that modules were being completed in an approved training programme.

Examples of Non-compliant Practice

- The provision of vaccination services without demonstration of the completion of appropriate training.
- A lack of documentation to demonstrate that technicians are qualified and that trainee technicians are actively participating in an approved training scheme.
- Inability of pharmacies to provide evidence (e.g. documentation) that pharmacists are suitably qualified to provide accredited supplies of medicines from the premises (e.g. trimethoprim, sildenafil and selected oral contraceptives).

Regulatory Guidance

- It is expected that a licensee verifies qualifications and accreditations at both the point of employment (including when engaging a locum staff member) and during employment (e.g. when pharmacists successfully complete training for accredited service provision and when APCs are renewed), and can demonstrate that this is an integral part of their quality management systems.
- In practice this may be demonstrated by holding up to date copies of all qualifications on site or having ready access to evidence to demonstrate participation in training or qualification electronically.

Criterion 1.02.01

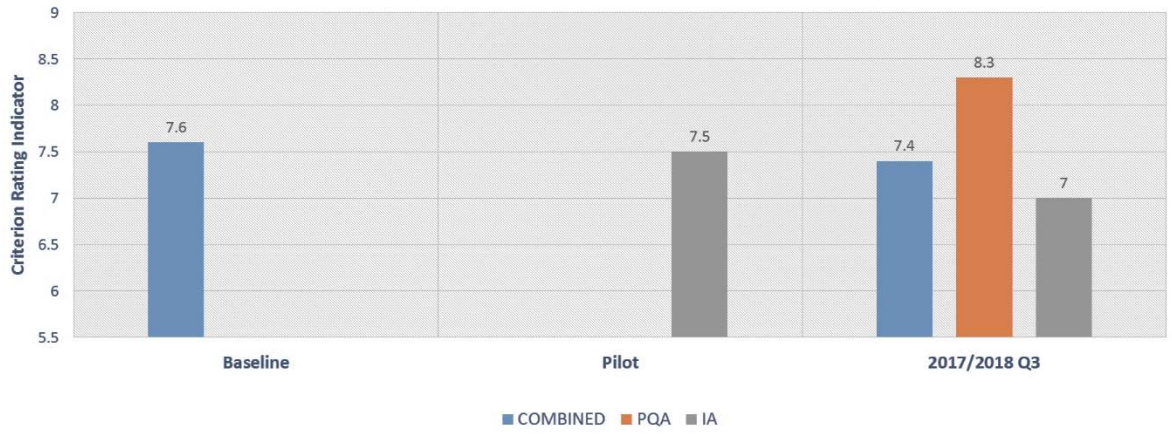
All staff are suitably qualified for the pharmacy services provided from the premises.

Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	11 44%	0 0%	14 56%	0 0%	0 0%	0 0%
Inspection Audits	0 0%	5 9%	0 0%	43 80%	4 7%	2 4%	0 0%
All Audits (Total)	0 0%	16 20%	0 0%	57 72%	4 5%	2 3%	0 0%

Attainment Risk Profile Comparison

Criterion Rating Indicator Analysis



Criterion 1.02.01

Overview

Data for this period demonstrated a slight decrease in overall compliance when compared with the baseline and pilot data. When splitting the rating indicator down into audit type, a significant increase in compliance was seen in this quarter for pharmacy quality audits, and a corresponding reduced compliance in inspection audits. This is likely explained by preparation by pharmacies in gathering evidence prior to a pharmacy quality audit.

Examples of Compliant Practice

- Pharmacies held copies (either electronically or in hard copy) or could provide an email of all accredited qualifications held by pharmacists providing those services at the premises.
- Technician qualification certificates were sighted.
- Pharmacists and intern pharmacists were able to access the Pharmacy Council website and demonstrate that a valid Annual Practicing Certificate (APC) was held.
- Trainee technicians could log on to the relevant training website and demonstrate that modules were being completed in an approved training programme.

Examples of Non-compliant Practice

- The provision of vaccination services without demonstration of the completion of appropriate training.
- A lack of documentation to demonstrate that technicians are qualified and that trainee technicians are actively participating in an approved training scheme.
- Inability of pharmacies to provide evidence (e.g. documentation) that pharmacists are suitably qualified to provide accredited supplies of medicines from the premises (e.g. trimethoprim, sildenafil and selected oral contraceptives).

Regulatory Guidance

- It is expected that a licensee verifies qualifications and accreditations at both the point of employment (including when engaging a locum staff member) and during employment (e.g. when pharmacists successfully complete training for accredited service provision and when APCs are renewed), and can demonstrate that this is an integral part of their quality management systems.
- In practice this may be demonstrated by holding up to date copies of all qualifications on site or having ready access to evidence to demonstrate participation in training or qualification electronically.

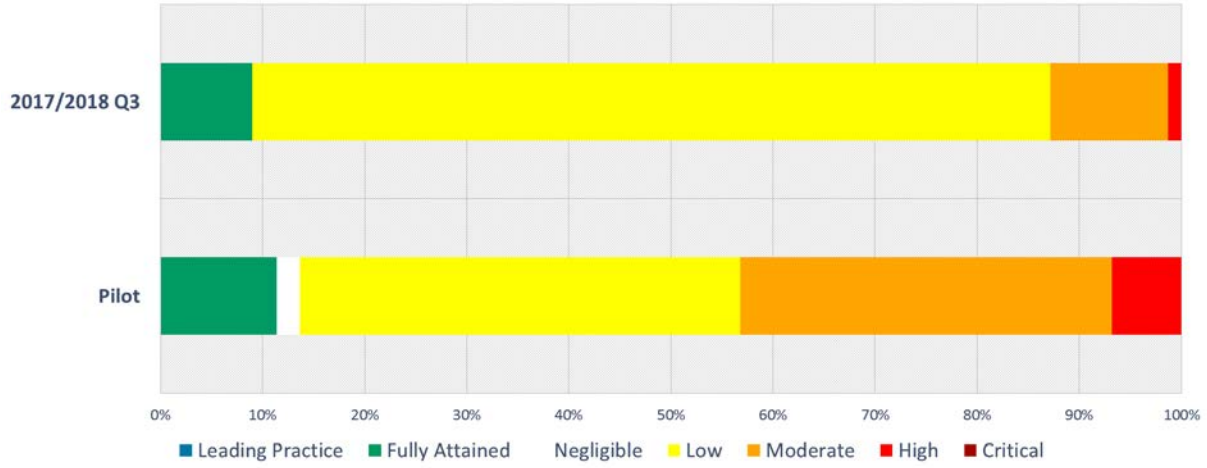
Criterion 2.02.01

There is ready access at the premises to all the required pharmacy equipment.

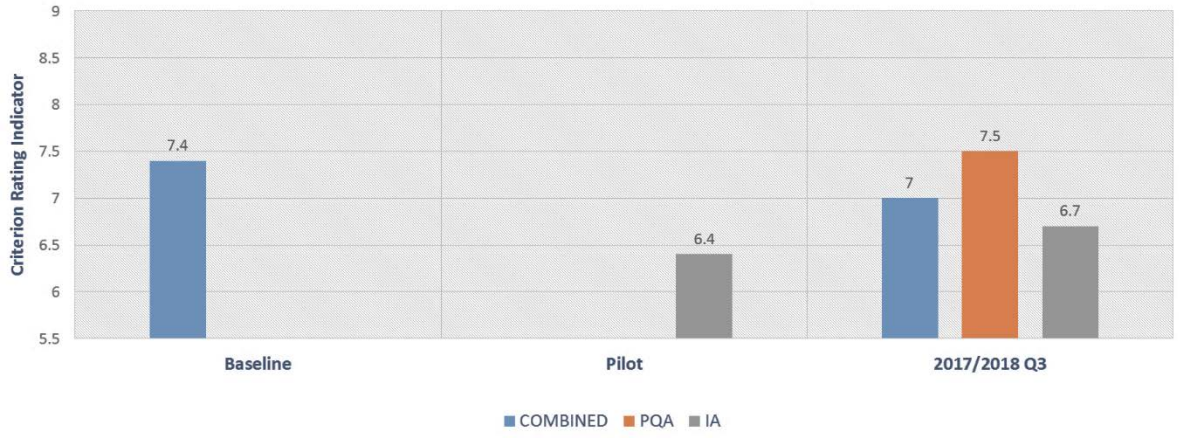
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	5 20%	0 0%	19 76%	1 4%	0 0%	0 0%
Inspection Audits	0 0%	2 4%	0 0%	42 79%	8 15%	1 2%	0 0%
All Audits (Total)	0 0%	7 9%	0 0%	61 78%	9 12%	1 1%	0 0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Criterion 2.02.01

Overview

- Overall full compliance remained relatively static when compared with the pilot data. Of the non-compliances there was a significant shift to a lower level of risk with a significant reduction in high or critical risk.
- Whilst there was an improvement in overall risk when compared with the pilot, it was still below that seen with the baseline data.
- The data demonstrates that increased compliance is observed when a pharmacy quality audit is conducted, as the notification period before the audit enables preparation to occur. The lower level of compliance observed at inspection audits indicates that greater attention is required by licensees to ensure all required equipment is available and maintained at a premises.

Examples of Compliant Practice

- Pharmacies could demonstrate that all required equipment was present and maintained in a suitable condition.
- Where the pharmacy had a physical copy of references they were the current edition or had been published in the last five years, as appropriate, and had been stamped on the inside cover with the pharmacy dispensing stamp.
- Where the pharmacy accessed references electronically, staff could demonstrate ready access to the full version.
- Pharmacies had an RSS web feed set up to enable reference to the required legislation.

Examples of Non-compliant Practice

- Electronic scales had not been certified since 2013, and had been used as part of the compounding process. The pharmacist was unaware that regular certification of weighing equipment used for compounding medicines was a requirement.
- Pharmacy staff were unable to demonstrate access to electronic resources.
- Required equipment was not available at the premises.
- Equipment at the premises was damaged requiring repair or replacement.

Regulatory Guidance

- Licensees are encouraged to ensure that they have ready access to all of the pharmacy equipment and references described in the current version of the 'Requirements for Pharmacy Equipment' document, and have robust processes in place for ensuring that equipment is maintained in good condition, and in accordance with the Requirements.
- In particular, references should be checked on a regular basis to ensure that they are within date (i.e. have been published with in the last five years, or are the current version, as appropriate) and any out of date references are no longer readily available. In addition, equipment must be free of damage and, where required, tested on a regular basis as per the Requirements.

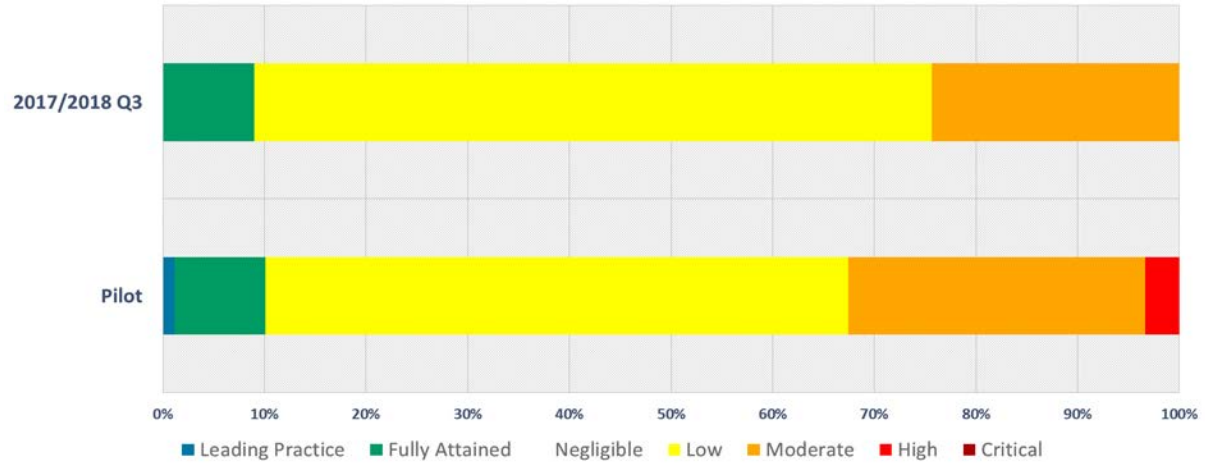
Criterion 3.03.02

Appropriate corrective actions are implemented, documented and reviewed contributing to continuous quality improvement.

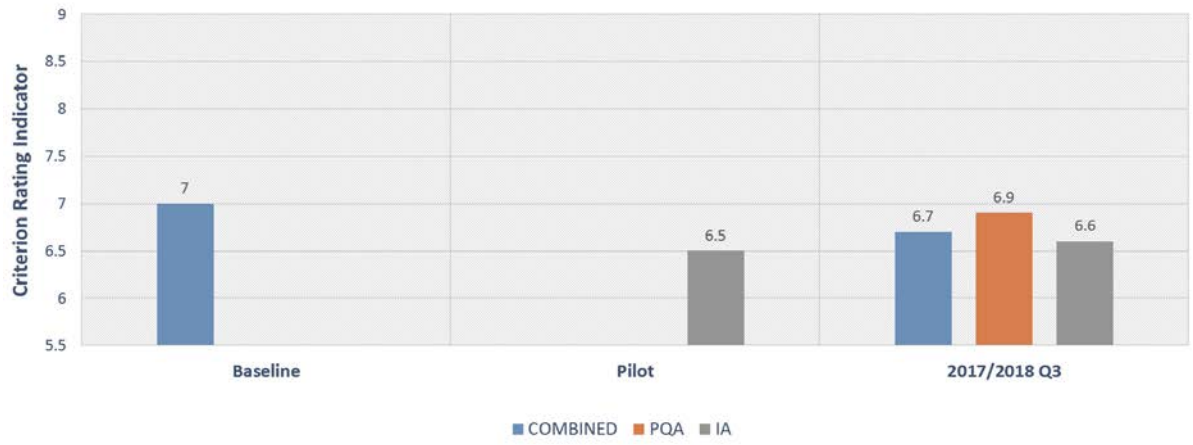
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	4 16%	0 0%	17 68%	4 16%	0 0%	0 0%
Inspection Audits	0 0%	3 6%	0 0%	35 66%	15 28%	0 0%	0 0%
All Audits (Total)	0 0%	7 9%	0 0%	52 67%	19 24%	0 0%	0 0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

Encouragingly, no high or critical risk non-compliances were identified during the last reporting period, although of concern is that full compliance remains very low. This highlights a need for improvement in the pharmacy sector to ensure robust quality management systems are implemented and maintained, particularly in respect of risk management, contributing to public safety.

Examples of Compliant Practice

- Dispensing error documentation included corrective actions implemented to prevent the error from recurring.
- Documentation of reviews of dispensing incidents (near misses and dispensing errors) were seen demonstrating that a review occurred on a regular basis, and included corrective actions implemented as a result of the review. Evidence was seen that the result of the review was discussed with staff.
- Records seen of reviews included an assessment of the effectiveness of previously implemented corrective actions.

Examples of Non-compliant Practice

- The pharmacy has no review system in place, or where a system could be described was not in use, for near miss events.
- Dispensing error documentation was incomplete, lacking details of any corrective actions taken and implemented.
- The pharmacy could not demonstrate that reviews of dispensing incidents occur.

Regulatory Guidance

- Licensees are encouraged to implement robust quality management systems, particularly with regards to risk management to ensure pharmacy practice activities are being conducted in a manner that ensures public safety.
- A full review of all dispensing incidents should occur on a regular basis and be fully documented, including details of trends identified, corrective actions put in place to prevent further errors, and an assessment of the effectiveness of previously implemented corrective actions.
- The pharmacy must have a system for discussing the outcome of reviews with staff.

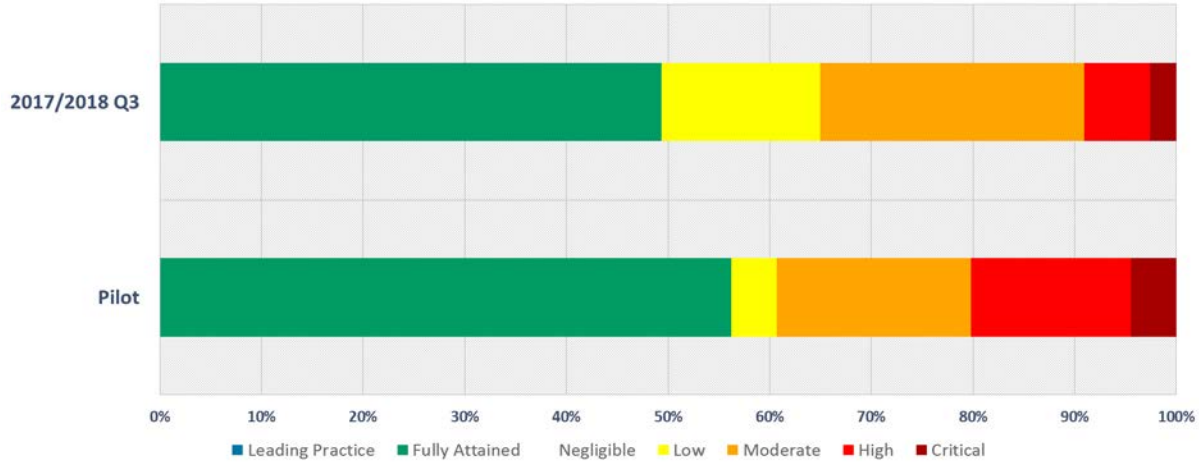
Criterion 4.01.02

Controlled drugs requiring storage in a safe, are securely held in an approved controlled drugs safe.

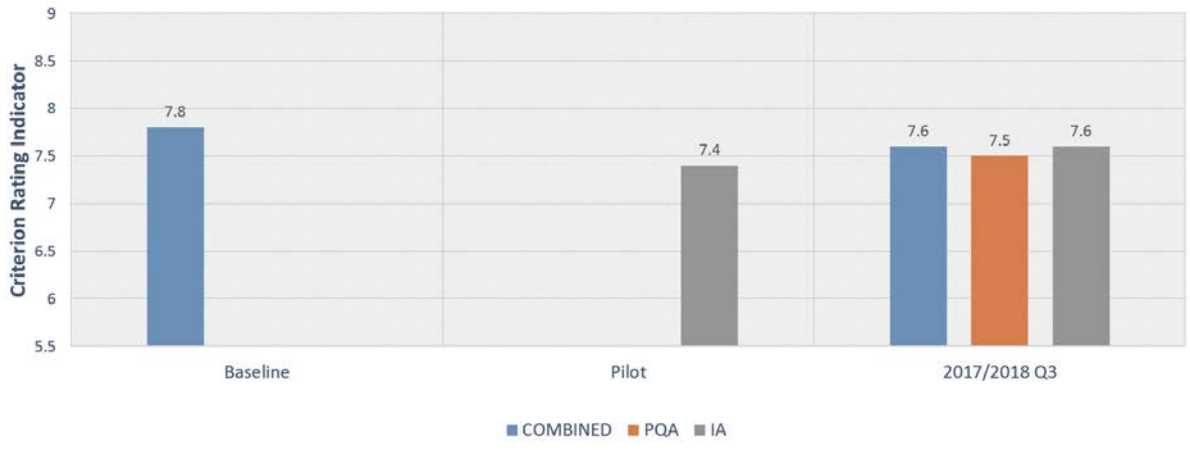
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0	12	0	3	8	2	0
	0%	48%	0%	12%	32%	8%	0%
Inspection Audits	0	27	0	8	13	3	2
	0%	51%	0%	15%	24%	6%	4%
All Audits (Total)	0	39	0	11	21	5	2
	0%	50%	0%	14%	27%	6%	3%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

- The overall level of compliance remained similar to the pilot, however, remained lower than baseline data. Of note is that the pharmacy quality audit indicator and inspection audit indicator for the reporting period were almost equal.
- When the data is split into the attainment risk, full compliance was lower than in the pilot, however, it is encouraging to note there is a smaller proportion of high and critical risk.
- The lack of full compliance is of concern for a criteria for which compliance is readily achievable.

Examples of Compliant Practice

- Where the safe was of steel construction, it met the requirements of the Ministry of Health 'Requirements for the Custody of Controlled Drugs: Steel Safes' document in both construction and fixing to the premises.
- Where the safe did not meet the requirements the pharmacy was able to demonstrate that an approval was held, or where an older safe not solely constructed of steel, the safe was affixed to the premises and deemed to be of sufficient security.
- All controlled drugs requiring storage in a controlled drugs safe (including those awaiting collection) were appropriately secured in the safe.
- The safe was appropriately secured at all times when not in immediate use (and the key was not kept in the lock).

Examples of Non-compliant Practice

- Controlled drugs were identified to be stored outside of a controlled drugs safe, or were in the safe but the safe door was open, or where closed, not secured.
- Controlled drugs safes were identified to be:
  - not attached, or inappropriately attached to the premises
  - an inadequate size for the volume of controlled drugs requiring storage at the premises.

Regulatory Guidance

- The pharmacy must ensure that all controlled drug safes are of suitable construction and are appropriately fixed to the premises. In addition, all controlled drugs requiring storage in a controlled drugs safe (including codeine, dihydrocodeine, methadone and controlled drugs awaiting collection) are appropriately secured at all times when not in immediate use.
- The licensee is reminded that keeping a key in the lock of the safe does not constitute secure storage.

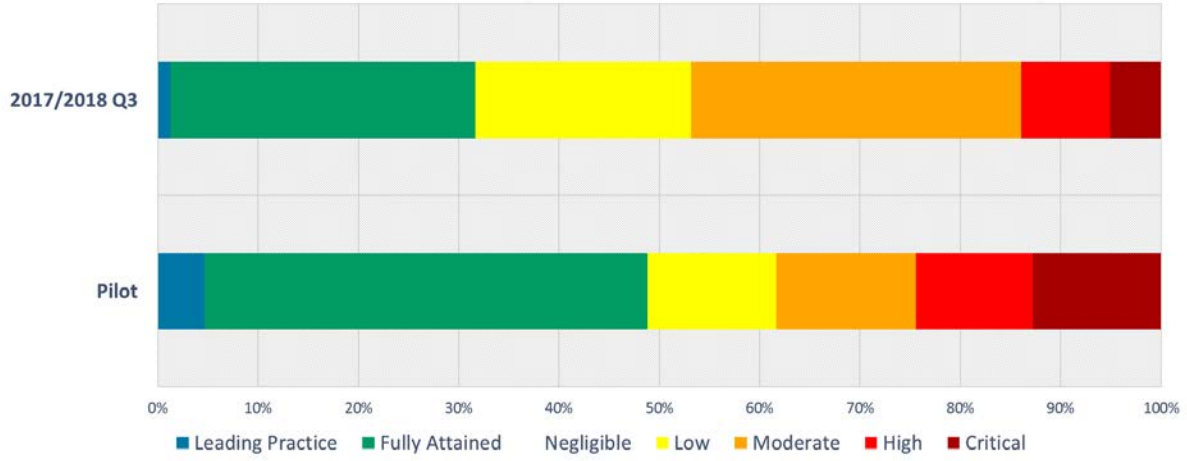
Criterion 4.01.04

Fridge temperatures are consistently maintained between 2-8°C.

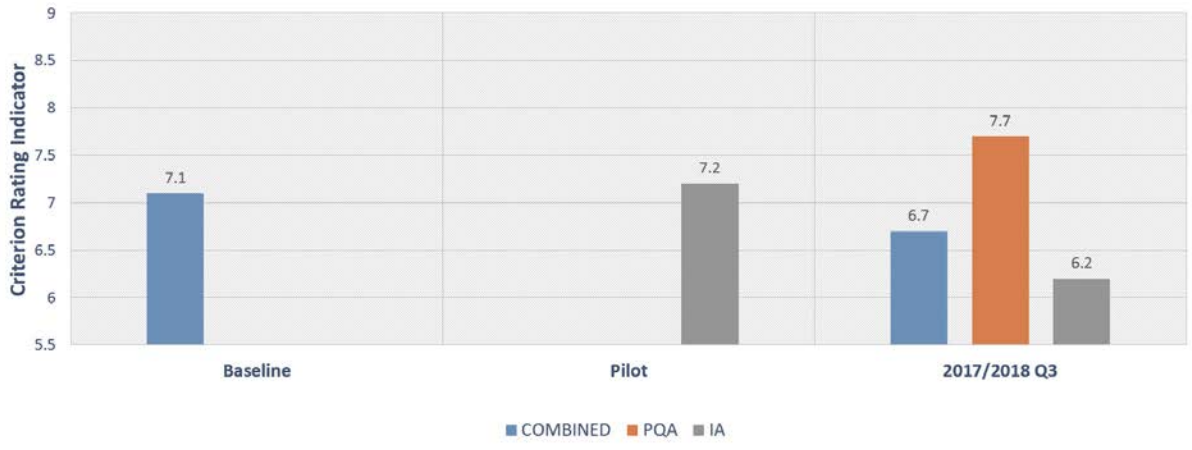
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0	14	0	3	5	2	1
	0%	56%	0%	12%	20%	8%	4%
Inspection Audits	1	10	0	14	21	5	3
	2%	18%	0%	26%	39%	9%	6%
All Audits (Total)	1	24	0	17	26	7	4
	1%	30%	0%	22%	33%	9%	5%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

- The data demonstrated that overall risk appears to have increased (as demonstrated by a reduction in overall risk rating indicator for this reporting period) when compared to the baseline and pilot data.
- It is concerning that the proportion of pharmacies achieving a fully attained rating has dropped significantly, with full compliance only being demonstrated by approximately one third of pharmacies.
- It is encouraging that there was a reduction in critical and high risk, and that a leading practice was seen.
- Compliance is observed to be greater for pharmacy quality audits than inspection audits, due to preparation by pharmacies in gathering evidence prior to a pharmacy quality audit.

Examples of Compliant Practice

- Pharmacies held an appropriate fridge for the activities undertaken. Pharmacies providing immunisation services had a pharmaceutical grade fridge that was regularly serviced (annually) and maintained cold chain accreditation.
- Temperatures were monitored on a daily basis from an appropriate thermometer, and data-loggers were downloaded weekly.
- Documentation was seen demonstrating that where temperatures had deviated from the acceptable range, corrective actions had been implemented where necessary.

Examples of Non-compliant Practice

- Fridge temperature records demonstrated that medicines were stored at temperatures consistently out of the required range (including below 0 degrees Celsius) for extended periods of time.
- Fridge temperature records were not available.
- When temperature deviations had been identified, the pharmacy could not demonstrate that corrective actions had been implemented to ensure the products remained of an appropriate quality for dispensing to patients.

Regulatory Guidance

- Pharmacies must be able to demonstrate that there are robust and appropriate systems in place for cold chain management. This includes maintaining accurate records of fridge temperatures, and demonstrating that corrective actions are quickly implemented in response to temperature deviations.
- Where a pharmacy offers vaccine services they must be able to demonstrate that they are compliant with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.
- Information regarding cold chain management in the National Immunisation Programme is available on the Ministry of Health website (www.health.govt.nz/coldchain).

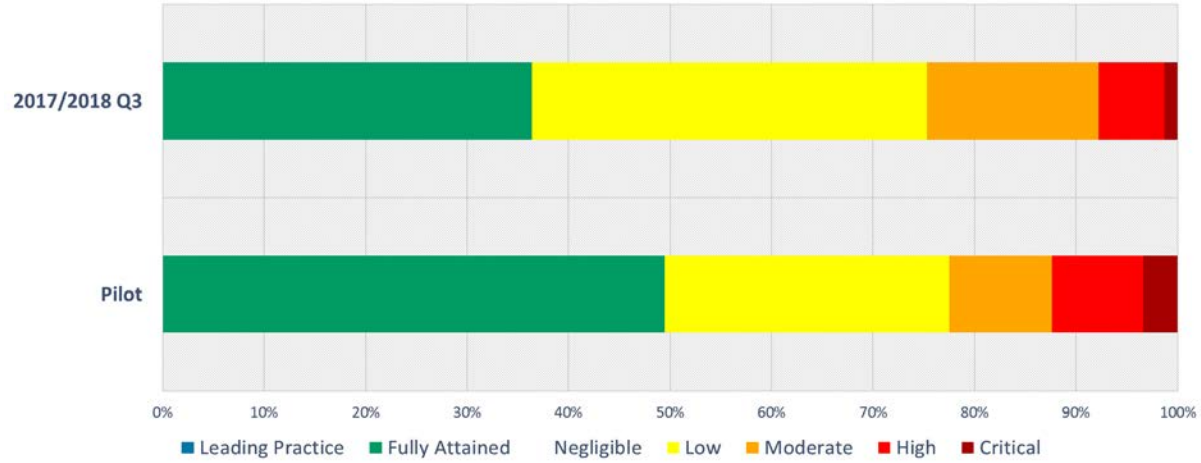
Criterion 5.01.02

Prescription medicines are supplied in accordance with regulatory and professional requirements.

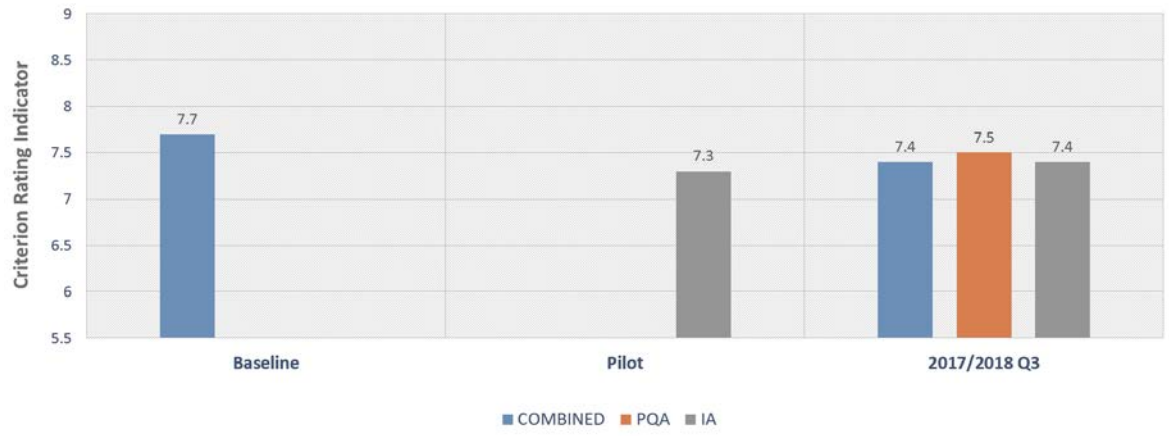
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	11 44%	0 0%	7 28%	4 16%	3 12%	0 0%
Inspection Audits	0 0%	17 33%	0 0%	23 44%	9 17%	2 4%	1 2%
All Audits (Total)	0 0%	28 36%	0 0%	30 39%	13 17%	5 7%	1 1%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

- The overall risk for this reporting period was seen to be only slightly lower than the baseline level, however, on the positive, this was an improvement from the pilot result.
- When splitting the data into the risk profiles, the proportion of low and moderate risk had increased significantly, with a corresponding decrease at either end of the spectrum (full compliance and critical and high), when compared to the pilot data.
- Whilst overall risk appears to have changed little, it is of concern that full compliance has reduced.

Examples of Compliant Practice

- Records demonstrated that emergency supplies of medicines were only made in quantities sufficient for 72 hours or less of therapy, or one indivisible unit, and all required details (including the name of the pharmacist) were recorded.
- Where emergency supplies were made they were easily identifiable as an emergency supply (often 'emergency supply' was included on the label).
- Pharmacists could describe how to access the Medsafe Classification Database.
- There was no evidence seen to demonstrate that medicines are supplied outside of their classification. For example repackaging of Gees Linctus, ibuprofen tablets or large supplies of paracetamol tablets.

Examples of Non-compliant Practice

- Emergency supplies were seen to be made in quantities in excess of the allowable supply period.
- Medicines supplied as an OTC supply but in quantities that constituted the supply of a prescription medicine not pursuant to a prescription. These supplies were at times in excessive quantities, far exceeding the allowable pharmacy only or pharmacist only supply.
- Records of the sales did not always include sufficient detail including the name of the patient and the name of the pharmacist making the sale.
- Pharmacists were not able to describe how they would check the classification of a medicine.

Regulatory Guidance

- All licensees must ensure that all pharmacists are only supplying medicines from the premises in accordance with the legislation (both for supply and recording).
- Where unsure all pharmacists must be familiar with a mechanism for accessing that information. For example by accessing the Medsafe Classification Database (www.medsafe.govt.nz).

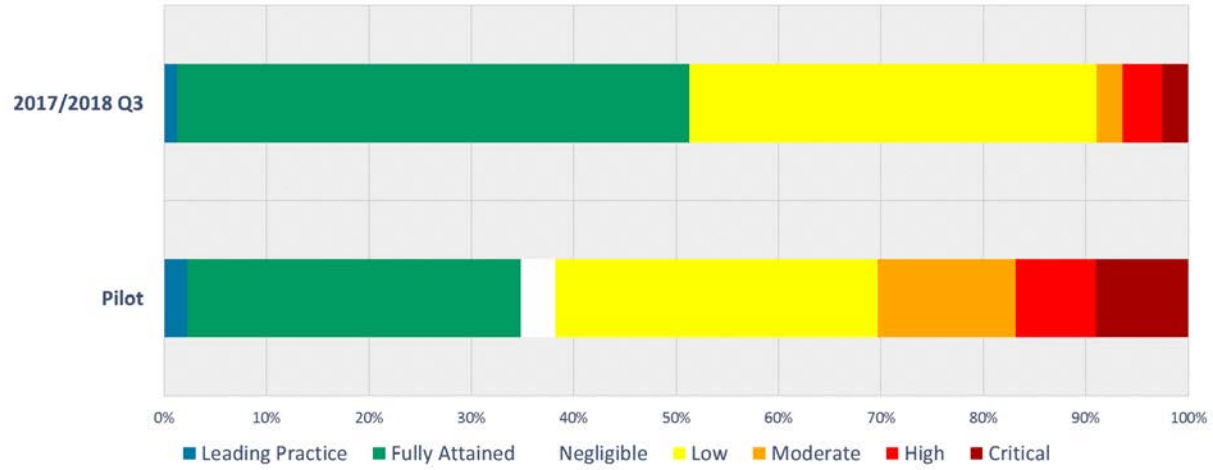
Criterion 5.02.01

An approved form of controlled drugs register is appropriately and accurately maintained, and retained on the premises for four years.

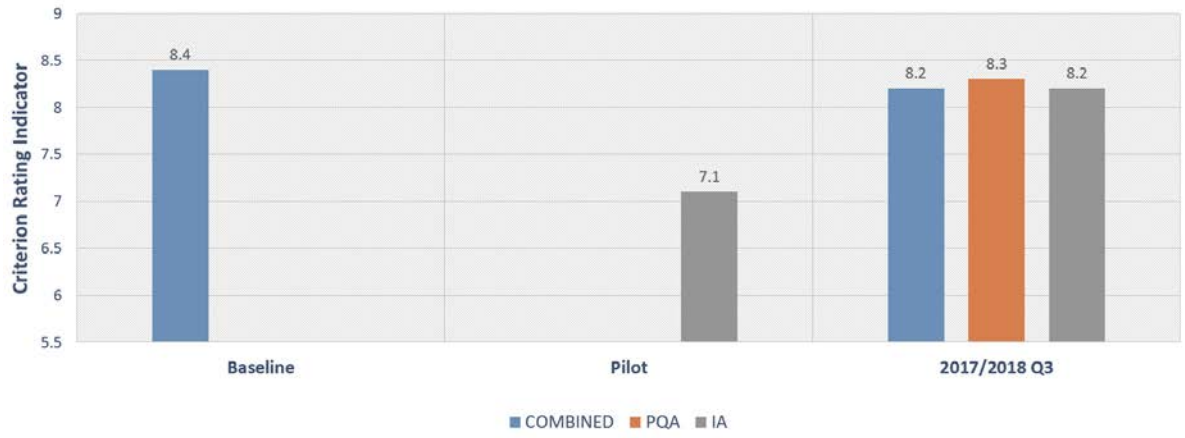
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	14 56%	0 0%	8 32%	2 8%	0 0%	1 4%
Inspection Audits	1 2%	25 47%	0 0%	23 43%	0 0%	3 6%	1 2%
All Audits (Total)	1 1%	39 50%	0 0%	31 39%	2 3%	3 4%	2 3%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

- Whilst it is pleasing that there has been significant improvement in the overall risk profile from the pilot, it has remained just below that seen for the baseline data. It was interesting to see that risk rating was the same for both pharmacy quality audits and inspection audits for this reporting period, indicating that there was no difference in performance when notice was given to the pharmacy that an audit was to be conducted.
- The increase in compliance relative to the pilot data is reflected in the risk attainment profile with an increased proportion of full attainment (and leading practice).
- In comparison to other criterion, the overall the rating indicator is relatively high, indicating a relatively good compliance overall for this quarter.

Examples of Compliant Practice

- Controlled drugs registers are retained on the premises for four years.
- Entries are made in an indelible form, and corrections are made in an approved manner (with no overwriting or crossing out).
- All entries in the register were seen to be in a chronological form, indicating that entries are made by the end of the next business day.
- When the stock take was conducted no discrepancies were seen (aside from a small amount of overage for liquid controlled drugs) between the physical stock on hand and the running balance in the register.

Examples of Non-compliant Practice

- Significant discrepancies were seen between the stock on hand and the recorded running balance in the register.
- Records were not always indelible.
- Significant overwriting and/or obliteration of entries was seen.
- Entries not made in chronological order (indicating that entries are not always made by the end of the next business day).
- The pharmacy could not demonstrate that registers were retained on the premises dating back four years.

Regulatory Guidance

- It is expected that the controlled drugs register is an accurate reflection of the physical stock on hand in the controlled drugs safe, and thus entries must be made in the appropriate time frame.
- In addition, entries in the register must be made an indelible fashion, with no obliteration.

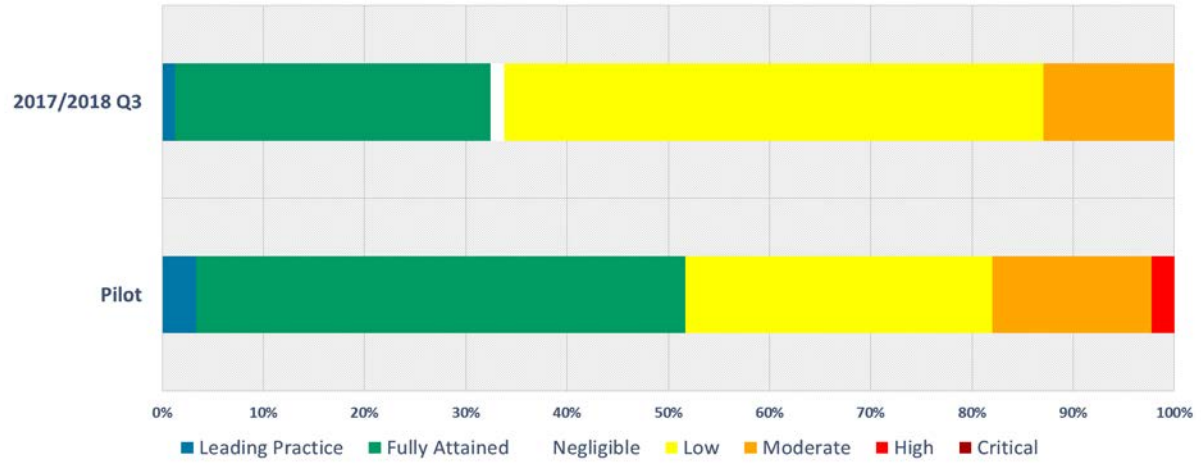
Criterion 5.05.04

Compounding records for individually compounded products are appropriately maintained and stored on the premises for at least three years.

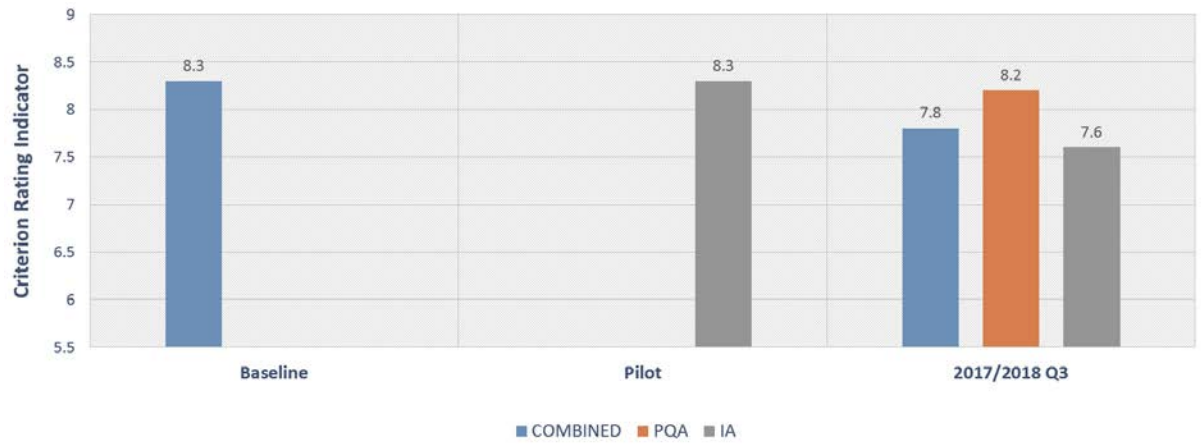
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	10 42%	1 4%	11 46%	2 8%	0 0%	0 0%
Inspection Audits	1 2%	14 26%	0 0%	30 57%	8 15%	0 0%	0 0%
All Audits (Total)	1 1%	24 31%	1 1%	41 54%	10 13%	0 0%	0 0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Criterion 5.05.04

Overview

- The risk rating indicator for this criterion has dropped significantly in comparison to both the baseline and pilot data. Although the increase in risk appears to be related to inspection audits rather than pharmacy quality audits conducted during this reporting period.
- Pleasingly there was no critical or high risk identified this quarter, although the drop in full compliance is of concern.

Examples of Compliant Practice

- Compounding records are retained on site for three years.
- Records are completed in full with a copy of the product label attached.
- Records are kept in an orderly manner (e.g. a folder).

Examples of Non-compliant Practice

- Compounding records were not available or incomplete.
- Records lacked, for example, copies of product labels, assigned expiry dates, signature of the pharmacist checking and releasing the final product, batch numbers and expiry dates of starting materials.

Regulatory Guidance

- It is expected that all compounding records, being a record of the manufacturing process of a product, are completed in full. This should include all relevant starting material details, checks, dates, and have the product label attached. Records must be retained on the premises for three years, in an orderly manner.

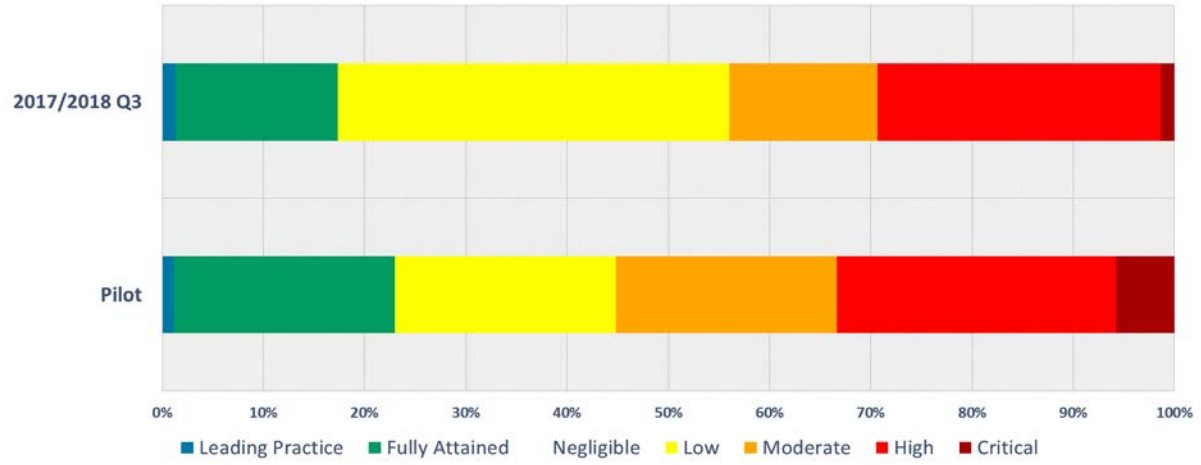
Criterion 5.07.04

Medicines requiring supply by an accredited pharmacist are recorded, sold and labelled in accordance with regulatory and professional requirements.

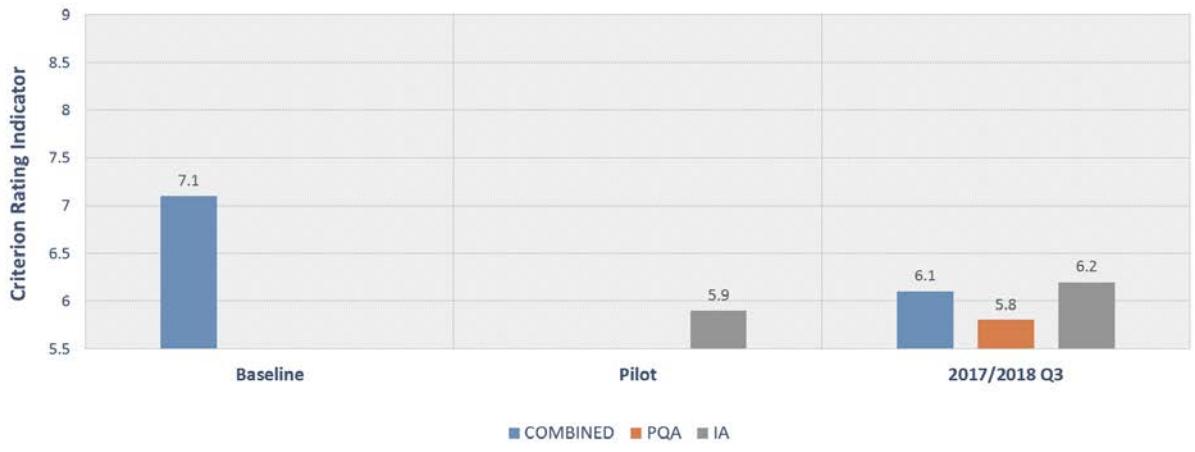
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	4 17%	0 0%	6 26%	7 31%	5 22%	1 4%
Inspection Audits	1 2%	8 15%	0 0%	23 44%	4 8%	16 31%	0 0%
All Audits (Total)	1 1%	12 16%	0 0%	29 39%	11 15%	21 28%	1 1%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

- Criterion 5.07.04 demonstrates the highest level of risk overall when looking at all ten criteria.
- Overall performance in this quarter has improved slightly from the pilot findings however is significantly lower than baseline data.
- The lack of improvement is clearly seen in the risk attainment profile where the proportion of critical and high risk remains very high (at over 25%), and full attainment has dropped down to under 20%.
- The significant level of non-compliance is concerning, and the pharmacy sector is encouraged to work towards significant improvement in this area, particularly in respect of the supply of sildenafil.

Examples of Compliant Practice

- Appropriate consultation forms are used for each medicine, and are completed in full.
- With regards to sildenafil:
    - supplies were seen to be made within the approved parameters and within the 12 months following a full assessment;
    - the pharmacy could demonstrate there is a system in place of recording the consultation related to each resupply;
    - resupplies of sildenafil were made in quantities of 4, 8 or 12 tablets; and
    - labels for all accredited supplies contained all required details, and the pharmacist was recorded as the prescriber.

Examples of Non-compliant Practice

- Sildenafil supplied:
    - to patients outside of the allowable parameters (bp, pulse, smoker etc);
    - to patients where forms have not been completed in full or where no form has been completed;
    - in quantities in excess of 12 tablets;
    - in broken packs (e.g. 5 or 6 tablets).
- Pharmacies could not always demonstrate that there was a system in place for recording the consultation related to the resupply of sildenafil.

Regulatory Guidance

- Licensees must ensure that all accredited supplies are made in accordance with the classification of the medicine supplied as an accredited supply, including documentation, supply and labelling.

Criterion 5.10.03

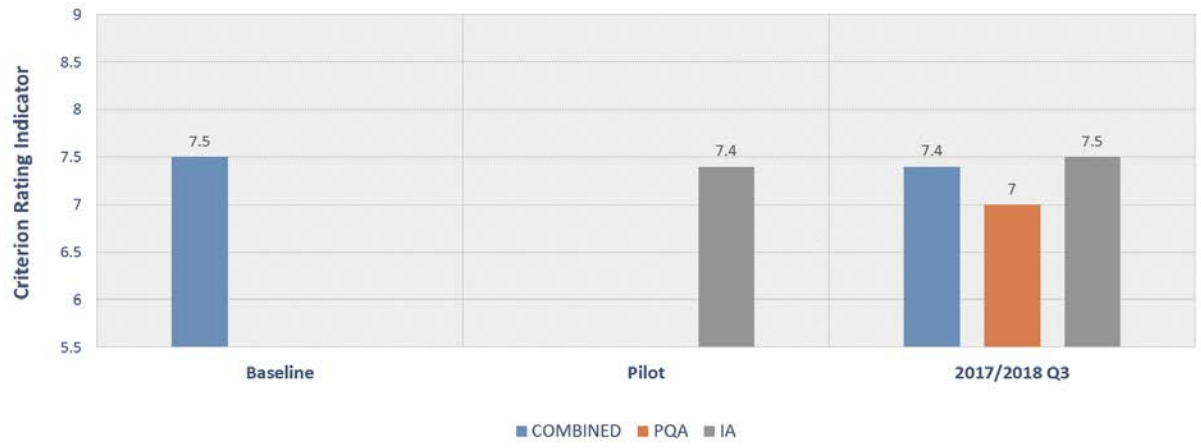
Compliance packaging is labelled sufficiently in accordance with regulatory and professional requirements.

Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	1 4%	0 0%	21 92%	1 4%	0 0%	0 0%
Inspection Audits	0 0%	8 16%	1 2%	42 82%	0 0%	0 0%	0 0%
All Audits (Total)	0 0%	9 13%	1 1%	63 85%	1 1%	0 0%	0 0%

Attainment Risk Profile Comparison

Criterion Rating Indicator Analysis



Criterion 5.10.03

Overview

- The rating indicators for this criterion during the reporting period are relatively static when compared to the pilot and baseline data. Surprisingly, pharmacies seemed to perform at a lower level during pharmacy quality audits than inspection audits.
- Of note, is the large proportion of low risk non-compliance seen for this criteria overall, indicating a lack of attention to detail with regards to ensuring full instructions are present. This is consistent with earlier audit findings.

Examples of Compliant Practice

- Labels on compliance packs were well aligned, had full instructions with no truncation, including cautionary and advisory labelling.

Examples of Non-compliant Practice

- Instructions on compliance packs were commonly truncated, and lacked cautionary and advisory information.
- Printing on labels were misaligned, with print placed over perforations in such a way that information would be unclear should blisters be removed.
- Where changes were made to medicines in packs, this wasn't fully reflected on labelling.

Regulatory Guidance

- Licensees must ensure that all labelling on compliance packs is clear, well aligned and contains all legally required details.
- It is recommended that pharmacies perform a self-check against the requirements as set out in the Pharmacy Services Standards to ensure labelling of compliance packs is compliant.