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 4 & 2018/2019 Quarter 1

Version 1.0

18 December 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 Q4 reporting period relates to audits conducted during April, May and June 2018, and the 2018/2019 Q1 reporting period relates to audits conducted during July, August and September 2018.

Medsafe publishes these updates to the pharmacy sector as an integral part of implementing the risk based audit framework. Feedback from the pharmacy sector is welcomed and should be provided by email to medicinescontrol@moh.govt.nz (addressed to the Manager, Medicines Control).

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 2017/2018 audit year, with full implementation from February 2018.

	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

A total of 235 audits were conducted in the pharmacy quality audit programme during the reporting periods:

Reporting Period	Pharmacy Quality Audits	Inspection Audits
2017/2018 Q4	39	161
2018/2019 Q1	2	33

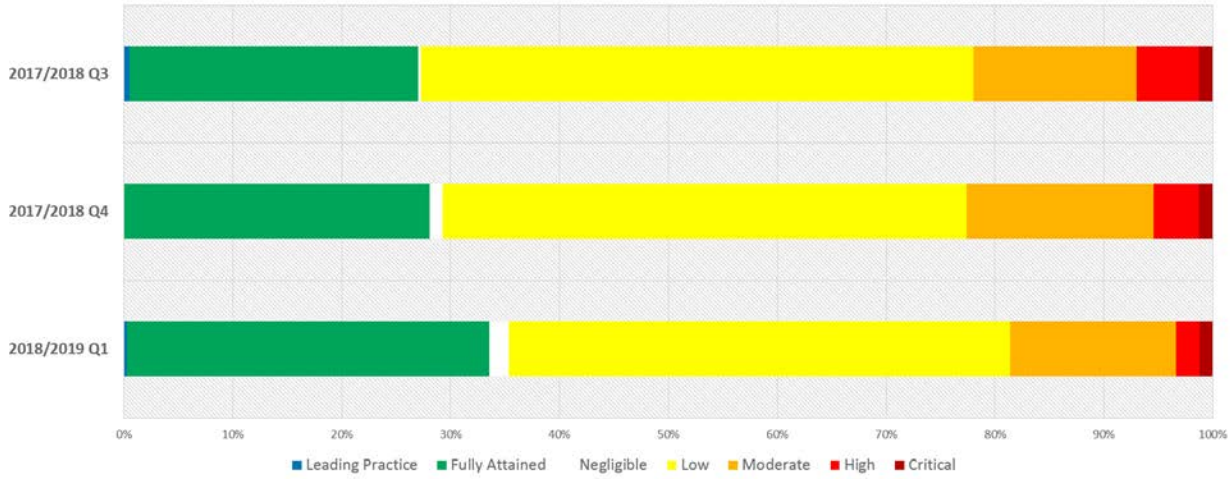
3.2. Attainment Risk Summary

The following table summarises the attainment risks[7] for the audits[8] conducted, 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	49	1	139	33	3	2
2.02.01	0	13	4	167	42	1	0
3.03.02	1	20	3	133	67	3	0
4.01.02	0	117	0	50	51	11	2
4.01.04	0	82	5	80	38	16	8
5.01.02	0	108	0	72	32	11	3
5.02.01	0	109	8	73	20	11	8
5.05.04	1	91	1	97	29	4	1
5.07.04	0	45	5	85	59	26	5
5.10.03	0	14	2	182	9	1	0
Total	2	648	29	1,078	380	87	29
%	0.1	28.8	1.3	47.9	16.9	3.9	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 "total audits 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 2017/2018 Q4 and 2018/2019 Q1 reporting periods, against the profile from the previous reporting period (2017/2018 Q3).

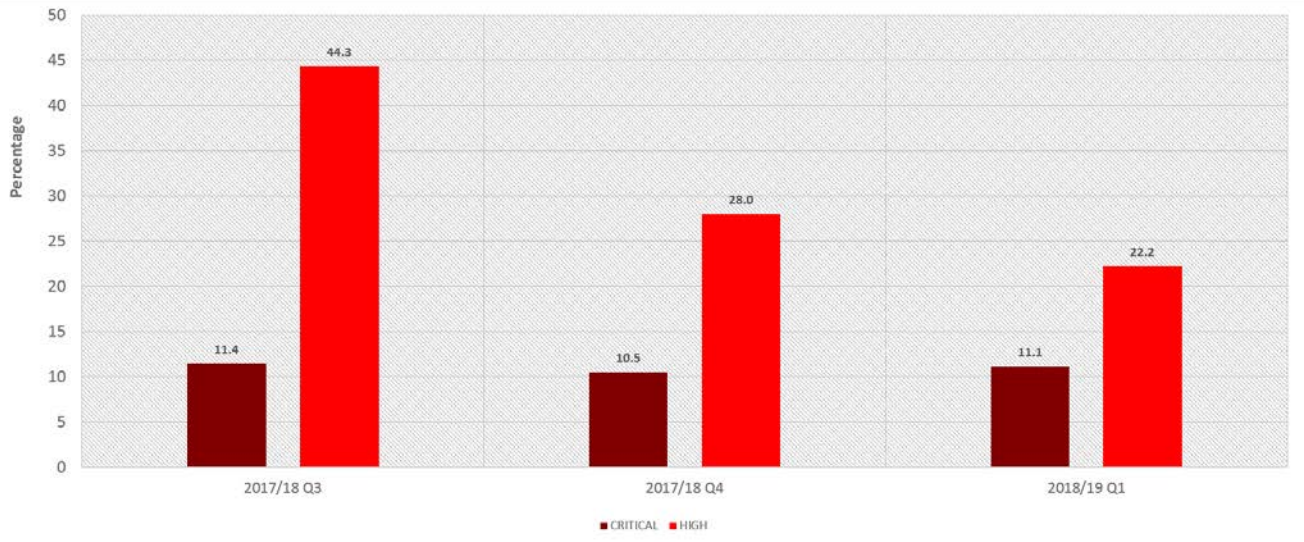


This indicates, overall:

- A reduced level of critical and high risk non-compliance.
- A small increase in fully attained compliance.
- A significant proportion of low risk non-compliance.

3.3. Critical and High Risk Trends

The following chart displays the percentage of audits within each reporting period at which one (or more) critical, or one (or more) high risk non-compliances were identified.



Whilst it is encouraging that the percentage of audits with high risk non-compliances is reducing over time, it is of concern that a significant level of serious non-compliance continues to be identified at audit.

3.4. Rating Indicators

3.4.1. Criterion Rating Indicators

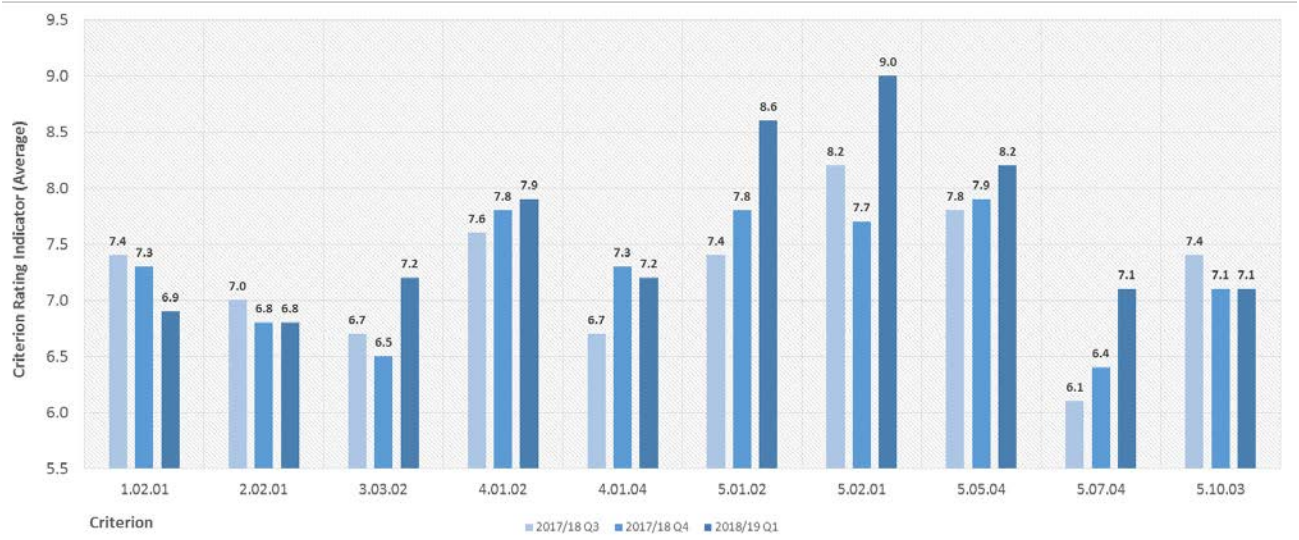
Note – Criterion Rating Indicators for 2018/2019 Q1 "PQA"

As noted in section 3.1, during Q1 2018/2019 the number of pharmacy quality audits conducted was very small (2 audits).

Whilst the criterion rating indicators have been calculated and displayed for "PQA" audits in the Q1 reporting period it should be noted that the rating indicators are not statistically reliable and caution is required when interpreting these results.

The criterion rating indicators for 2018/2019 Q1 "Combined" and "Inspection Audits (IA)" are statistically reliable.

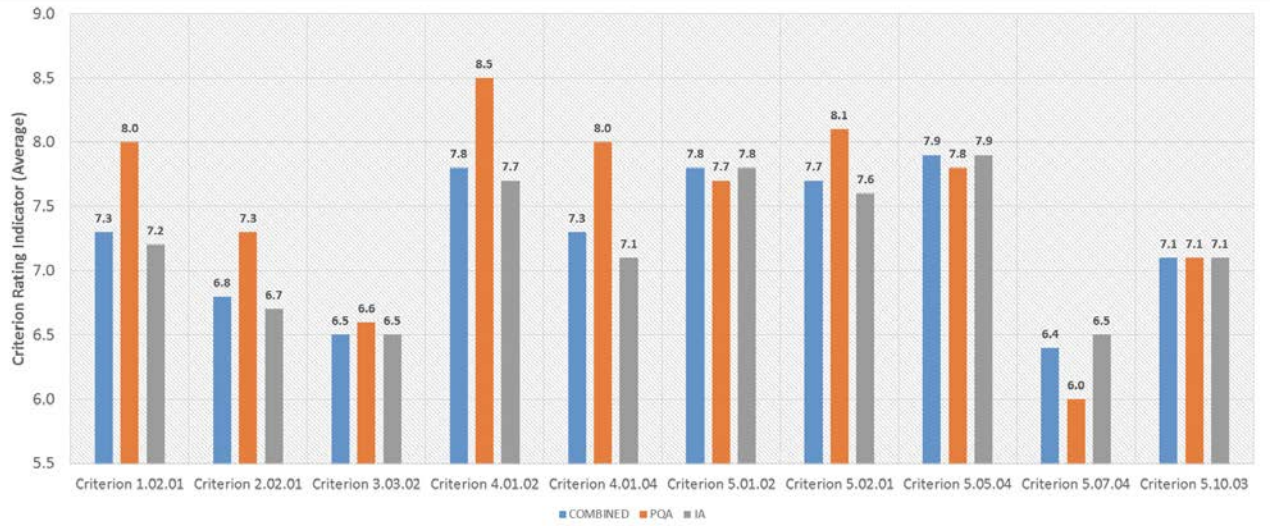
The following chart displays the criterion rating indicators for each of the 10 risk based criteria. The trend over time within a criterion is illustrated using a separate bar for each reporting period.



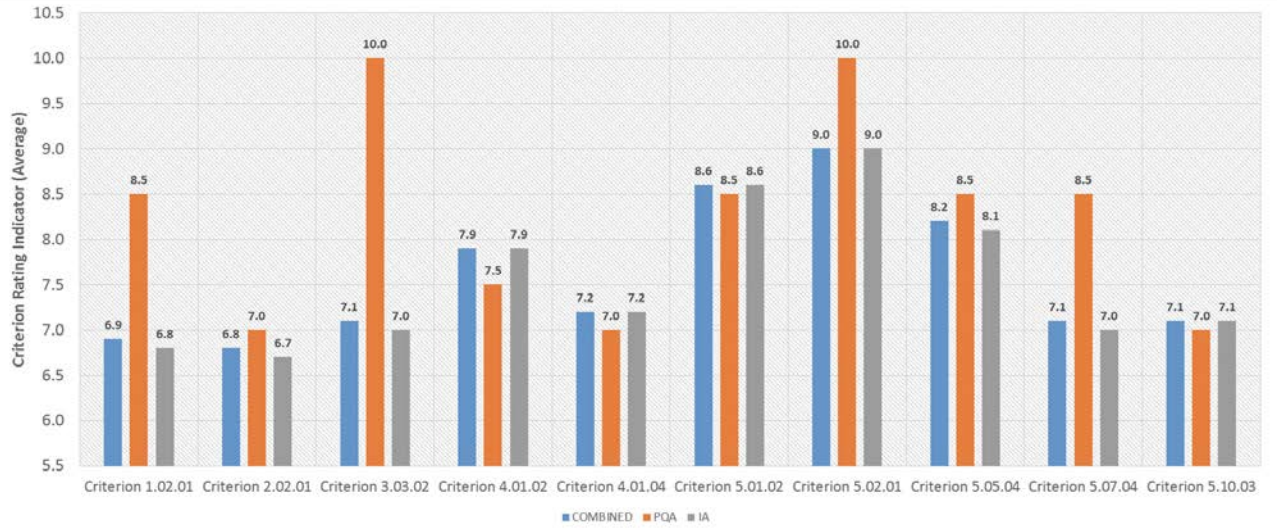
The following two charts allow for a comparison of the indicator rating between the two types of audit (PQA and IA) within a criterion, for each reporting period.

Note: that PQA data for 2018/2019 Q1 is not statistically reliable.

2017/2018 Q4



2018/2019 Q1



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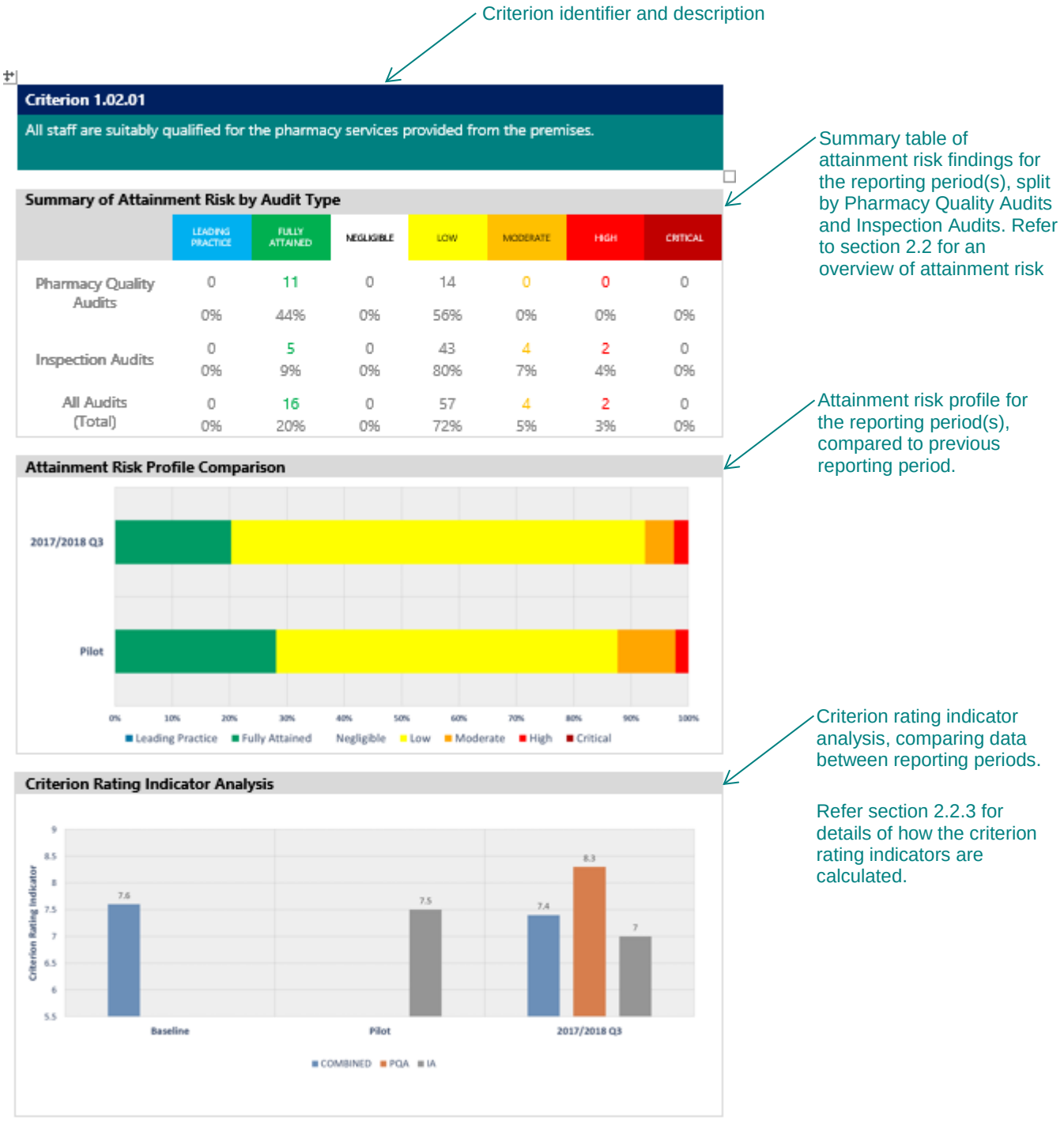
3.5. Summary of Audit Findings by Criterion

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.

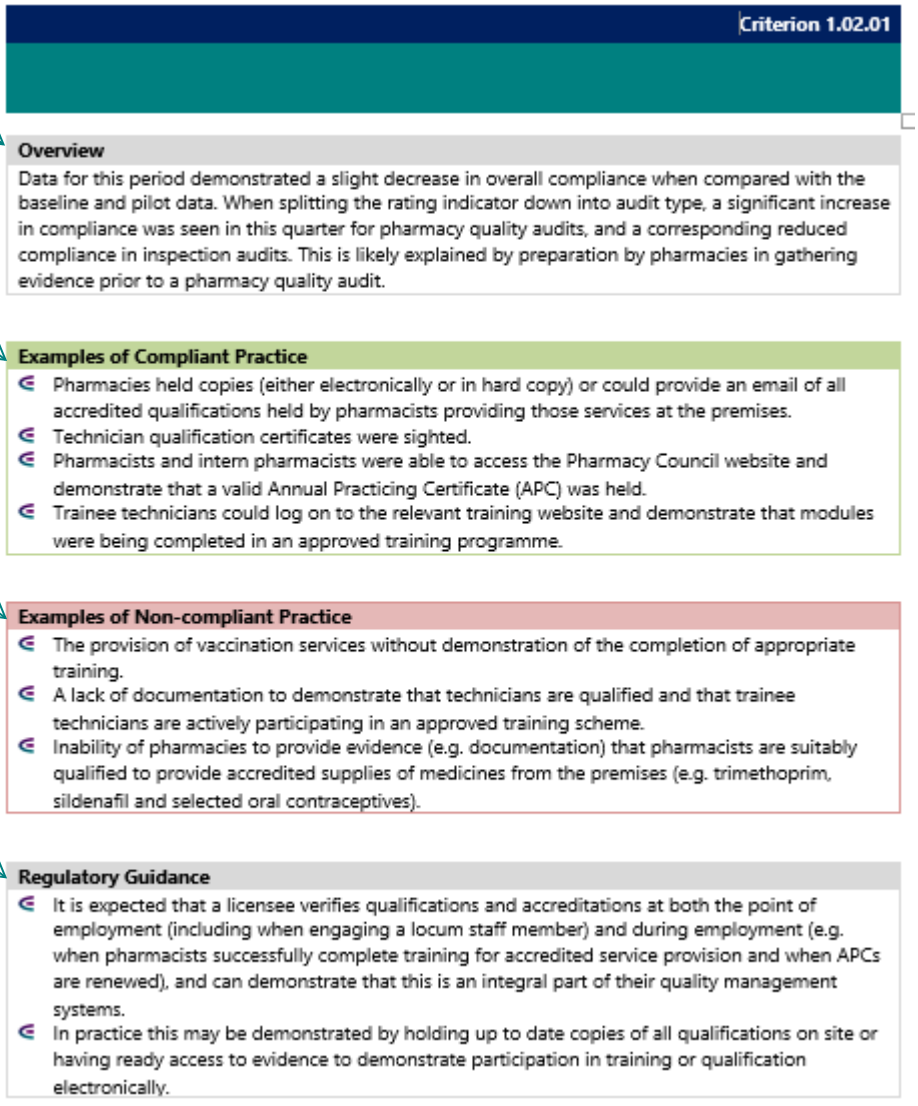


Overview of the audit findings for the criterion during the reporting period.

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.

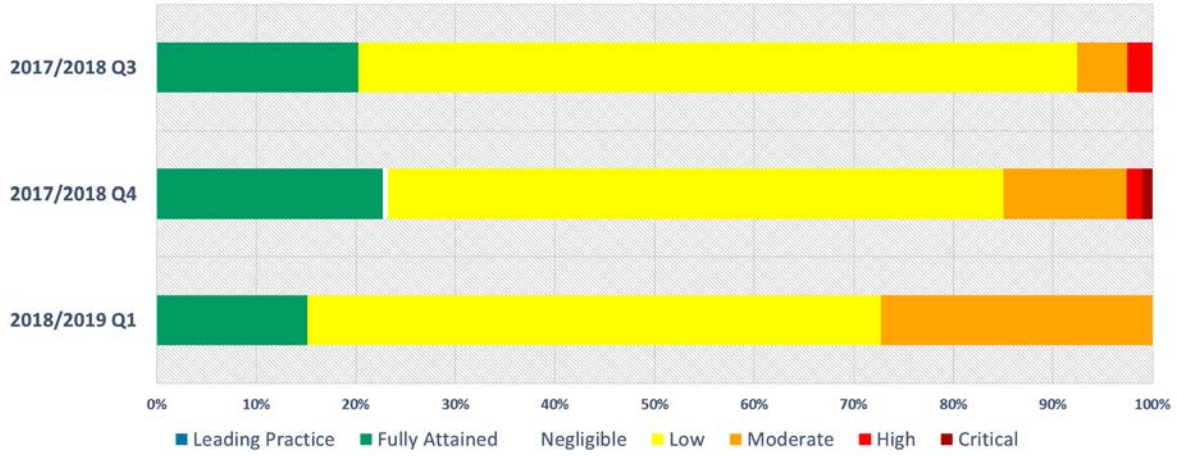
Criterion 1.02.01

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

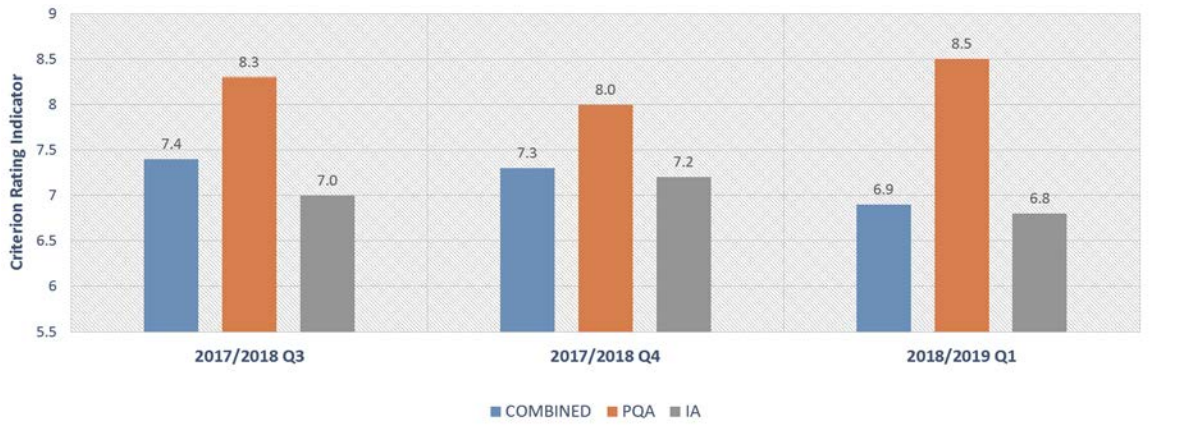
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0	18	0	16	5	1	0
	0%	45.0%	0%	40%	12.5%	2.5%	0%
Inspection Audits	0	31	1	123	28	2	2
	0%	16.6%	0.5%	65.8%	15.0%	1.1%	1.1%
All Audits (Total)	0	49	1	139	33	3	2
	0%	21.6%	0.4%	61.2%	14.5%	1.3%	0.9%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Criterion 1.02.01

Overview

It was pleasing to see that no critical or high risk non-compliance was seen in the most recent reporting period (2018/2019 Q1), however, it is of concern that full attainment in this criterion remains very low overall.

Full attainment is higher at pharmacy quality audits, where the pharmacy has had time to prepare. For a criterion in which full attainment is easily achievable, it is of concern that so few pharmacies are able to demonstrate that all staff are qualified for the services they provide, reflecting the need for robust HR systems and processes within pharmacies.

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

- Inability of pharmacies to provide evidence (e.g. documentation) that pharmacists are suitably qualified to provide accredited supplies of medicines from the premises.
- A lack of documentation to demonstrate that technicians are qualified and that trainee technicians are actively participating in an approved training scheme.
- Compounding being performed by staff who do not hold appropriate qualifications (for example by level 4 technicians and technicians training in the level 4 training scheme).
- Activities constituting pharmacy practice being performed by a staff member who no longer holds a current APC, or other qualification which allows them to work in a dispensary.

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.

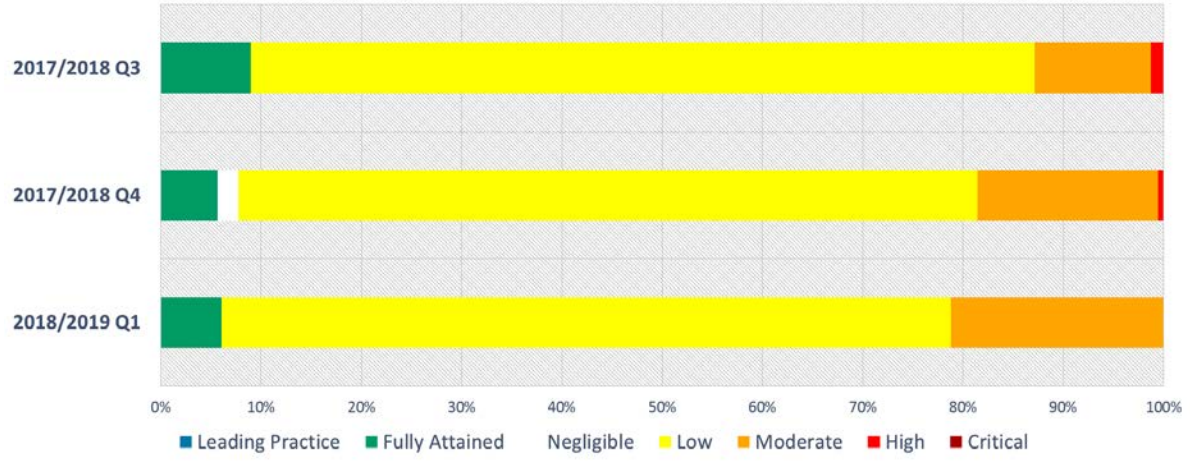
Criterion 2.02.01

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	5	0	33	2	0	0
	0%	12.5%	0%	82.5%	5%	0%	0%
Inspection Audits	0	8	4	134	40	1	0
	0%	4.3%	2.1%	71.7%	21.4%	0.5%	0%
All Audits (Total)	0	13	4	167	42	1	0
	0%	5.7%	1.8%	73.6%	18.5%	0.4%	0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Criterion 2.02.01

Overview

The overall level of risk as indicated by the combined rating indicator remained constant in the two reporting periods (and was slightly worse than in the previous reporting period, Q3).

It was pleasing that there was no significant risk seen in the most recent reporting period (Q1), however the level of full attainment remains extremely low. Full compliance is higher at pharmacy quality audits, reflective of a period of preparation.

As with criterion 1.02.01, it is concerning that the overall level of non-compliance remains extremely high, albeit primarily low risk, for a criterion for which full attainment is readily achievable.

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 which had been customized to include all the required legislation.

Examples of Non-compliant Practice

- Resuscitation equipment was not available at a pharmacy which offered vaccination services, nor were they aware of the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.
- Electronic scales (and weights) had not been certified in the 12 months prior to the audit, and had been used as part of the compounding process.
- 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.

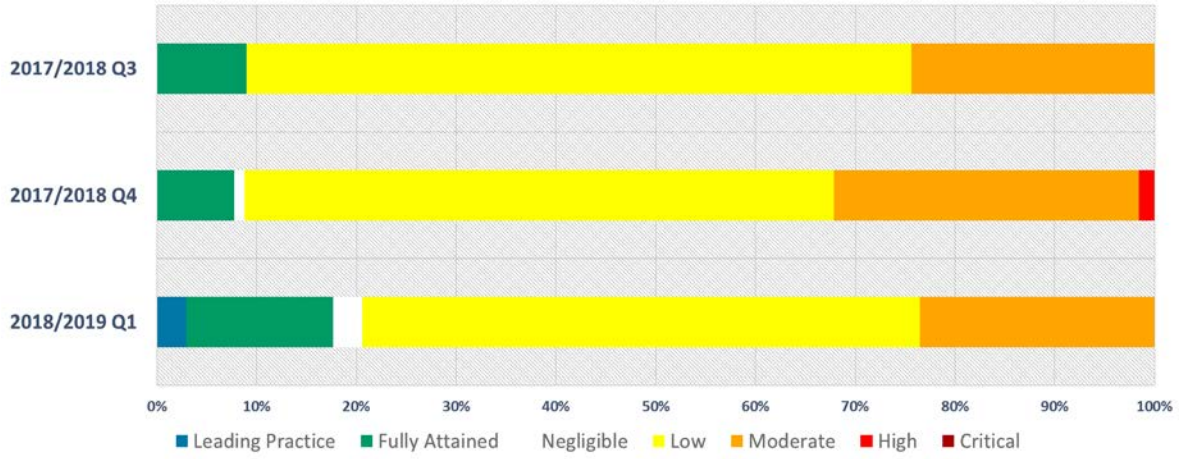
Criterion 3.03.02

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%	7 17.5%	0 0%	22 55%	11 27.5%	0 0%	0 0%
Inspection Audits	1 0.5%	13 7.0%	3 1.6%	111 59.4%	56 30.0%	3 1.6%	0 0%
All Audits (Total)	1 0.4%	20 8.8%	3 1.3%	133 58.6%	67 29.5%	3 1.3%	0 0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Overview

Pleasingly, full attainment in 2018/2019 Q1 has increased significantly (from the previous two quarters where the combined criterion rating indicator remained relatively static). Accompanying this increase in full attainment in Q1, there was leading practice, and no significant (high and critical) risks were seen. This is reflected in the overall risk rating for this criteria which shows significant improvement in Q1.

Whilst this improvement is encouraging there is still a significant amount of low or moderate risk non-compliance, highlighting the 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.

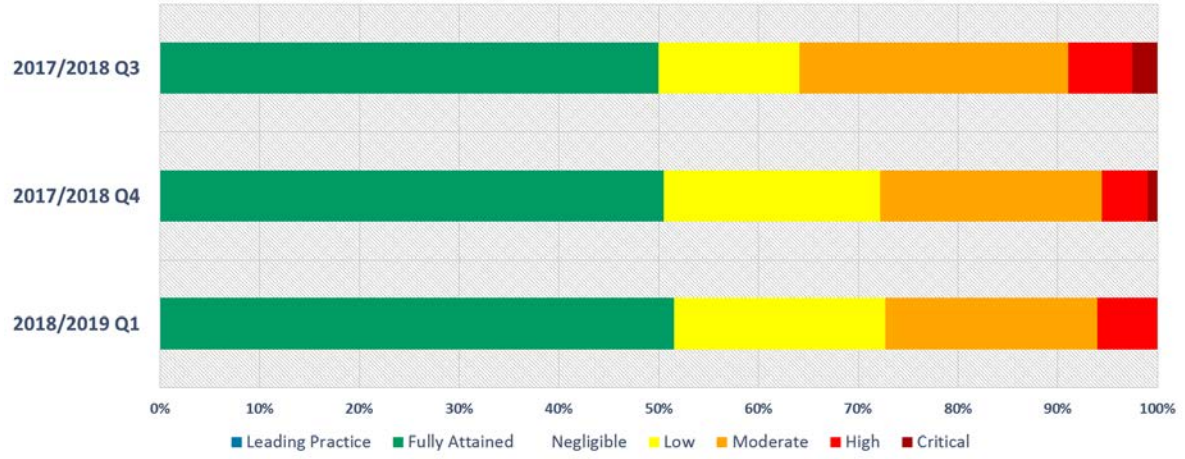
Criterion 4.01.02

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 0%	23 57.5%	0 0%	11 27.5%	6 15%	0 0%	0 0%
Inspection Audits	0 0%	94 49.2%	0 0%	39 20.4%	45 23.6%	11 5.8%	2 1.1%
All Audits (Total)	0 0%	117 50.7%	0 0%	50 21.7%	51 22.1%	11 4.8%	2 0.9%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Overview

The Q4 reporting period attainment risk profile indicates a shift from more significant to lesser risk, where non-compliance is identified. When comparing the most recent reporting quarter with Q4, this shift had been sustained, and where there was significant risk, this had shifted to being completely high risk (with no critical risk identified in this most recent period).

Whilst overall full compliance remains relatively static (at approximately 50%), it is expected that appropriate storage of controlled drugs occurs in every premises.

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 pharmacy had a 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. In some cases the quantity of controlled drugs stored in this way was considerable, and it could be demonstrated that they had been stored in this way for an extended period of time.
- Non-secured controlled drugs commonly included, methadone (both dispensed and bulk stock), codeine and dispensed controlled drugs awaiting collection.
- Controlled drugs 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.

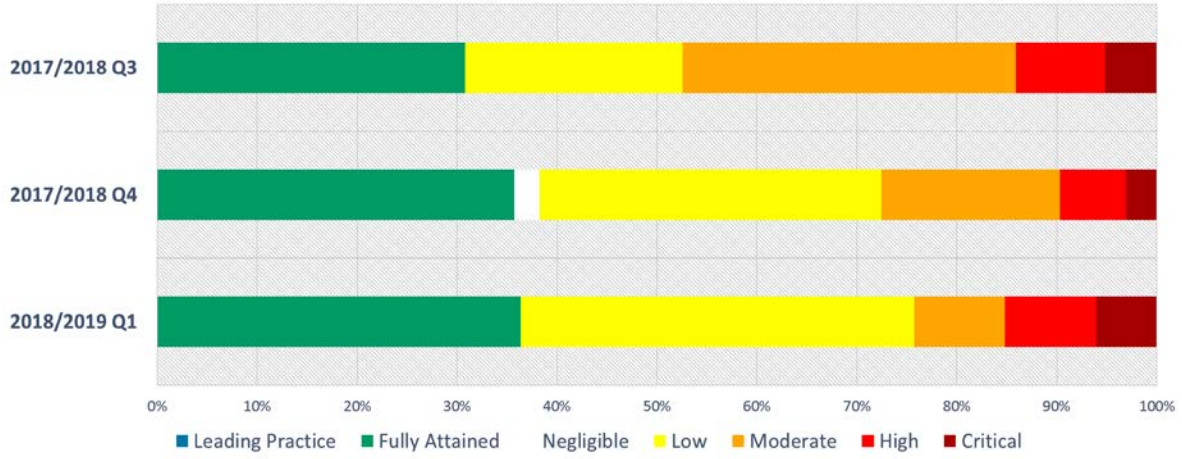
Criterion 4.01.04

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

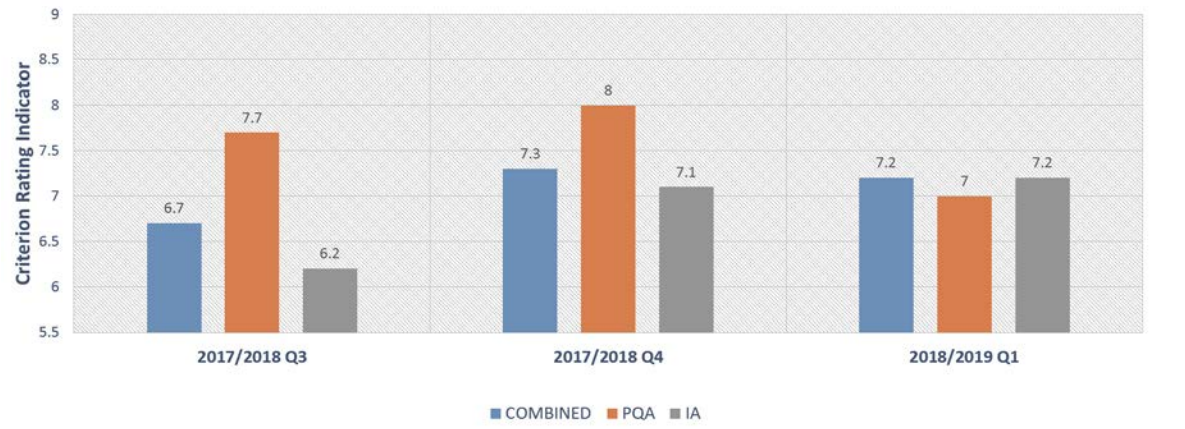
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	20 50%	0 0%	11 27.5%	7 17.5%	2 5%	0 0%
Inspection Audits	0 0%	62 32.8%	5 2.7%	69 36.5%	31 16.4%	14 7.4%	8 4.2%
All Audits (Total)	0 0%	82 35.8%	5 2.2%	80 34.9%	38 16.6%	16 7%	8 3.5%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

The risk profiles demonstrate an increase in full attainment in Q4 (and this was sustained in Q1). In addition to this there is a shift from moderate to low risk non-compliance. This is reflected in the combined criterion rating indicator.

It is concerning that there remains a significant level of critical and high risk non-compliance demonstrating that serious breaches in cold chain are occurring.

Examples of Compliant Practice

- Pharmacies demonstrating that cold chain is appropriately maintained for products requiring refrigeration have implemented and maintained robust systems for cold chain management.
- 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.
- Regular verification and annual servicing of fridges is observed to be a contributing factor to compliance with cold chain management.

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, or had been modified.
- 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.
- Staff involved in fridge temperature monitoring, could not demonstrate how to use the monitoring equipment, or that they were aware of the actions to take should deviations occur.

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).

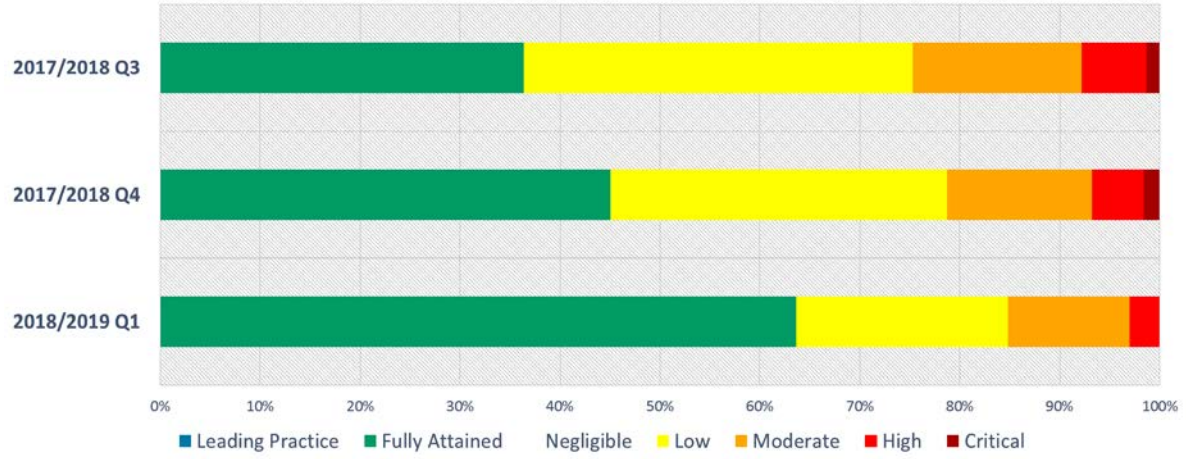
Criterion 5.01.02

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	16	0	18	4	1	1
	0%	40%	0%	45%	10%	2.5%	2.5%
Inspection Audits	0	92	0	54	28	10	2
	0%	49.5%	0%	29%	15.1%	5.4%	1.1%
All Audits (Total)	0	108	0	72	32	11	3
	0%	47.8%	0%	31.9%	14.2%	4.9%	1.3%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Criterion 5.01.02

Overview

A significant improvement has been seen in full attainment in this criterion over the periods covered by this report. Whilst there has been significant improvement in this space, there was still high or critical risk non-compliance identified.

When comparing types of audit, the criterion rating indicator demonstrates that there is little (if any) notable difference between pharmacy quality audits and inspection audits, and this is consistent across reporting periods.

Overall there is positive trend towards increased and sustained compliance.

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

- Medicines were 'lent' to patients.
- Emergency supplies were seen to be made in quantities in excess of the allowable supply period and to patients who had not been previously prescribed the medicine in New Zealand.
- Where the quantity of an emergency supply exceeded the allowable limits, the quantity was at times considerable (e.g. supply of 90 omeprazole 20mg capsules).
- Controlled drugs (e.g. benzodiazepines) provided as an emergency supply.
- Medicines repackaged and supplied as an OTC supply pursuant to a patient request which can only be supplied in an approved pack (e.g. repackaged Gee's linctus, ibuprofen 200mg tablets).
- 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).

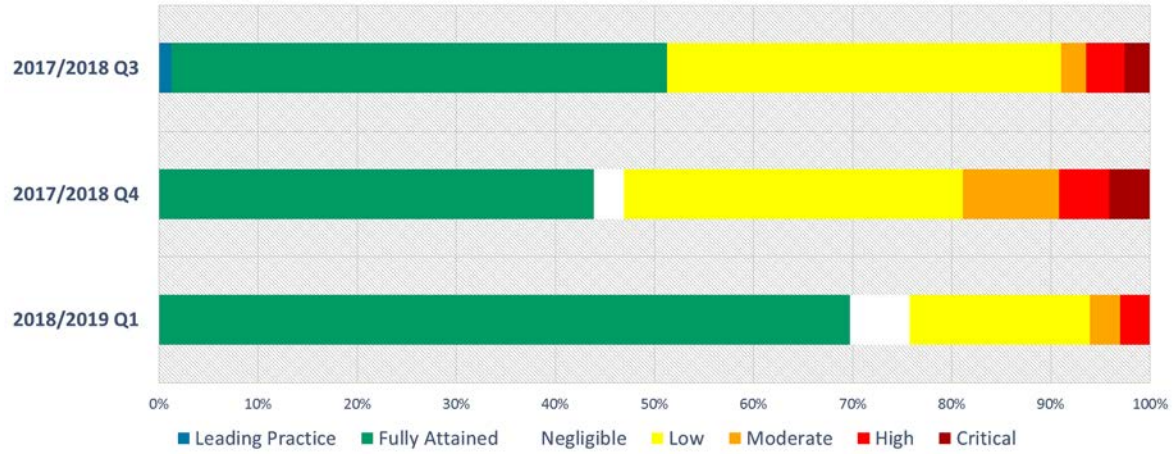
Criterion 5.02.01

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

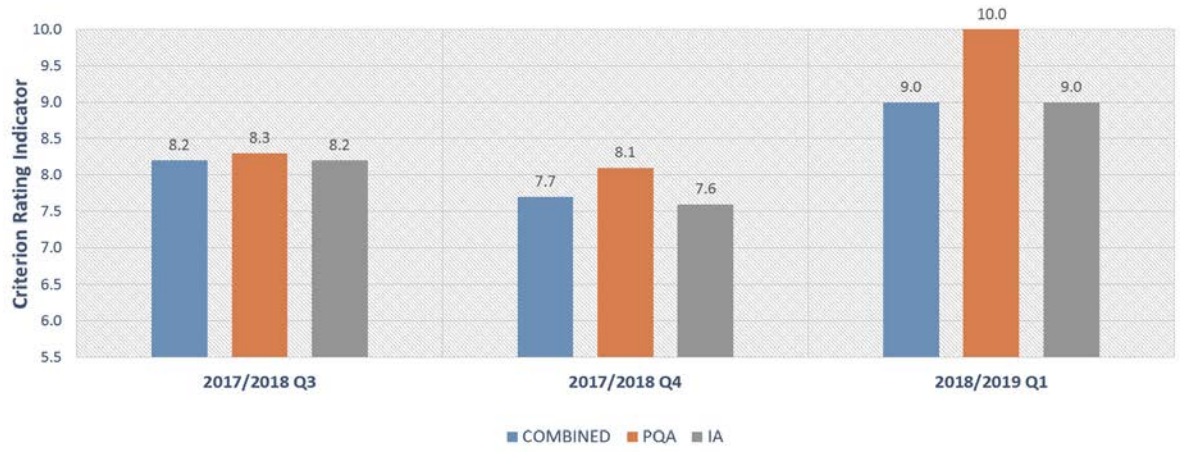
Summary of Attainment Risk by Audit Type

	LEADING PRACTICE	FULLY ATTAINED	NEGLIGIBLE	LOW	MODERATE	HIGH	CRITICAL
Pharmacy Quality Audits	0 0%	20 50%	0 0%	15 37.5%	4 10%	1 2.5%	0 0%
Inspection Audits	0 0%	89 47.1%	8 4.2%	58 30.7%	16 8.5%	10 5.3%	8 4.2%
All Audits (Total)	0 0%	109 47.6%	8 3.5%	73 31.9%	20 8.7%	11 4.8%	8 3.5%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis



Overview

Results from 2018/2019 Q1 demonstrated marked improvement on the previous two quarters. The proportion of full attainment sat just below 70% and whilst there was still some significant risk this was relatively low.

The overall increase in compliance was reflected in the criterion rating indicator for that reporting period also.

It is pleasing to see the marked improvement over previous reporting periods, demonstrating an improvement in the retention and maintenance of controlled drugs registers.

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.
- There were controlled drugs on hand that did not have a page in the controlled drugs register.
- Entries had not been made in the register for significant periods of time (weeks).
- The current register was not available at the pharmacy (had been taken home by the pharmacist).
- Expired controlled drugs were still recorded as 'stock'.
- A liquid bottle identified at a pharmacy had a dispensary label attached that included both "Oxynorm" and "Ra-Morph" on the label.

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.

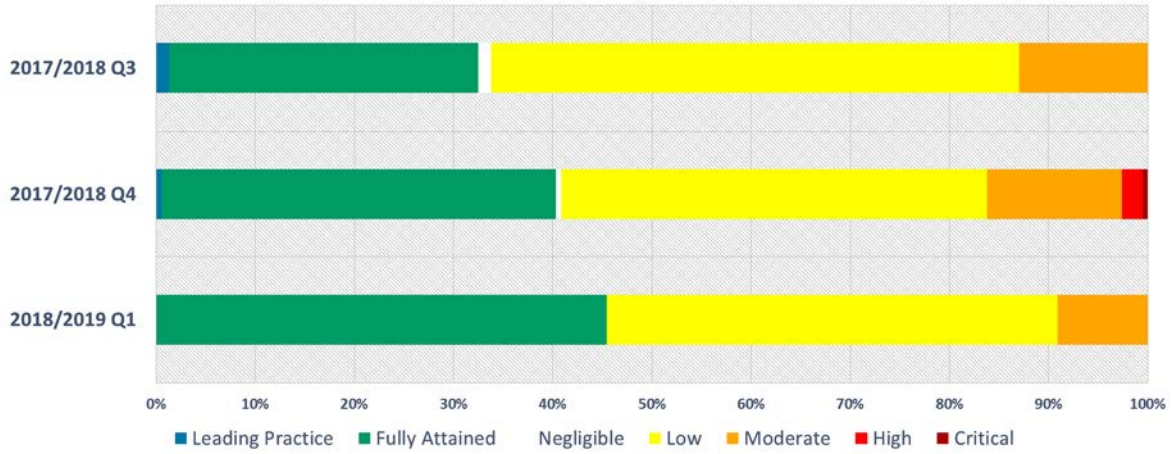
Criterion 5.05.04

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%	16 41%	0 0%	15 38.5%	8 20.5%	0 0%	0 0%
Inspection Audits	1 0.5%	75 40.5%	1 0.5%	82 44.3%	21 11.4%	4 2.2%	1 0.5%
All Audits (Total)	1 0.5%	91 40.6%	1 0.5%	97 43.3%	29 13%	4 1.8%	1 0.5%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Overview

Whilst the results demonstrate a trend of increasing compliance (full attainment) over the last three quarters, there is still a considerable proportion of low risk non-compliance. The improvement is reflected in the criterion rating indicator with a small increase over time.

Of concern was the number of significant risk non-compliances identified in Q4, indicating very poor practice with regards to the maintenance of compounding records, however, this appears to have been isolated to this quarter (with none identified in the previous or following quarters).

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.
- Staff were unaware of the requirement to complete the details on compounding records.
- Records lacked, for example, copies of product labels, assigned expiry dates, signature of the pharmacist checking and releasing the final product, and 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.

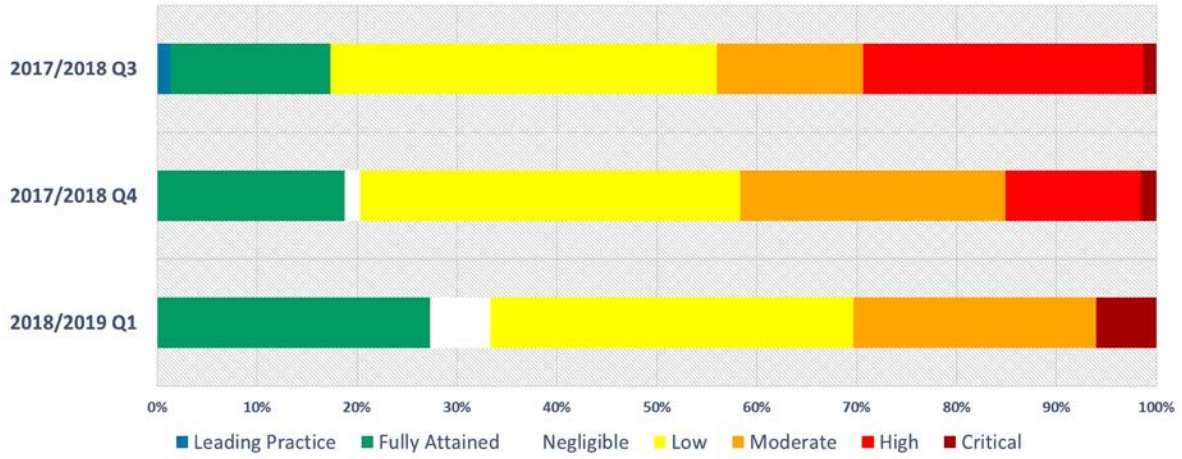
Criterion 5.07.04

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%	7 18.4%	0 0%	10 26.3%	16 42.1%	4 10.5%	1 2.6%
Inspection Audits	0 0%	38 20.3%	5 2.7%	75 40.1%	43 23%	22 11.8%	4 2.1%
All Audits (Total)	0 0%	45 20%	5 2.2%	85 37.8%	59 26.2%	26 11.6%	5 2.2%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Overview

The attainment risk profile appears to be trending in the right direction, demonstrated by a shift to a greater proportion of full attainment, and a corresponding reduction in significant non-compliance. This trend is also reflected in the combined criterion rating indicator for each period.

However, despite the improvement, the level of full attainment remains relatively low. This 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 (age, blood pressure, 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 (e.g. 15, 20, 24 tablets);
  - in broken packs (e.g. 5 or 6 tablets).
- Where no form had been completed (or assessment conducted) the explanation given was that it had been previously prescribed by a doctor.
- Pharmacies could not always demonstrate that there was a system in place for recording the consultation related to the resupply of sildenafil.
- Labels for sildenafil did not always contain adequate instructions (e.g. maximum daily dose).
- Trimethoprim supplied in quantities in excess of 3 tablets (e.g. 5 tablets).

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.

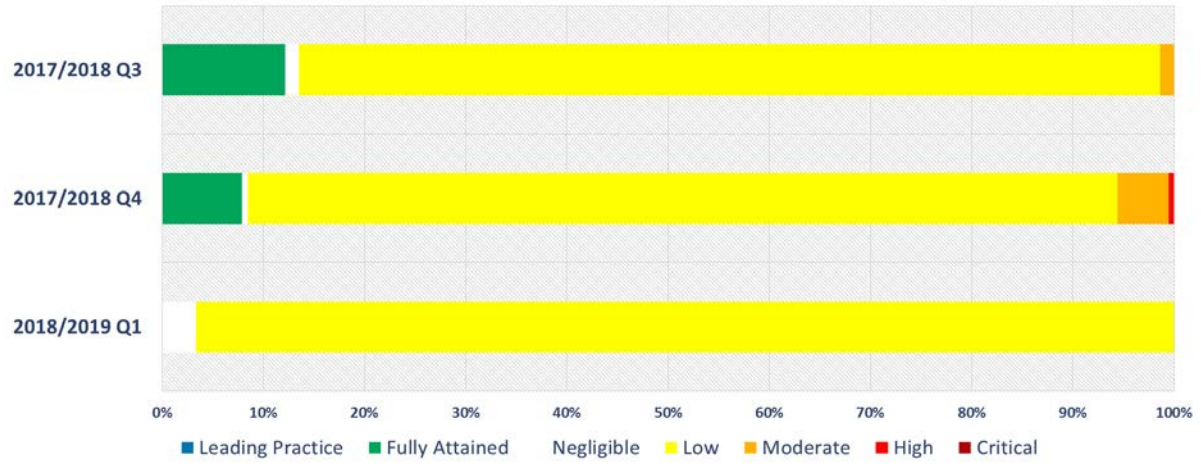
Criterion 5.10.03

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%	2 5.6%	0 0%	33 91.7%	1 2.8%	0 0%	0 0%
Inspection Audits	0 0%	12 7.0%	2 1.2%	149 86.6%	8 4.7%	1 0.6%	0 0%
All Audits (Total)	0 0%	14 6.7%	2 1%	182 87.5%	9 4.3%	1 0.5%	0 0%

Attainment Risk Profile Comparison



Criterion Rating Indicator Analysis

Criterion 5.10.03

Overview

No full compliance has been noted for this criteria in Q1. Whilst the proportion of full compliance has a history of being very low, this is of significant concern when this criteria primarily relates to the provision of clear instructions to patients in often a vulnerable group.

It should be noted that in Q1 all non-compliance was of low or negligible risk, which is an improvement on the previous quarter where there were high and moderate risks identified. Despite the lack of high and moderate non-compliance, the overall risk rating remained consistent with Q4, and the level of risk increased when compared to Q3.

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.
- Instructions were not provided in English (only in the patient's primary language).
- Printing on labels were misaligned, with print placed over perforations in such a way that information would be unclear should blisters be removed.

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.