

Quality Care Pharmacy Program
2ND Edition
Implementation Information & Rulings

Please note: The most recent additions to this document are highlighted in **red**.

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Implementation Information and Rulings

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General Questions & Answers

QCPP & The Professional Practice Standards

How has the Quality Care Pharmacy Program (QCPP) 2nd edition recognised the requirements of the Pharmaceutical Society of Australia's (PSA) Professional Practice Standards, including the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy (S2/S3)?

As part of the overall QCPP Review, the Pharmaceutical Society of Australia reviewed the Professional Practice Standards and the University of Sydney reviewed the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy (S2/S3).

These two sets of Standards have been included in the Australian Pharmaceutical Formulary and Handbook (APF – 20) and have been combined and published in the Professional Practice Standards Version 3 (PPS).

The QCPP 2nd edition acknowledges the contribution of the PSA and the University of Sydney in reviewing the standards and allowing the use of those materials as reference materials in the 2nd edition.

The PPS are no longer specifically incorporated into QCPP as QCPP 2nd edition has been developed into a true Quality System. To understand why, it is first important to understand how a Quality System such as QCPP 2nd edition works and what accreditation means.

A Quality System is a set of minimum requirements (or standards) that a business entity must comply with. If the business entity can prove compliance with the standards to an external (third party) observer, the assessor, the accrediting body will accredit the business entity.

It is important to note that accreditation is about the business entity and not individual personnel. Individuals are not accredited, only the business entity.

The PPS have been designed as a set of standards for an individual pharmacist. The forward to the PPS states *"The Standards have been designed for use by individual pharmacists to assess their own professional practice"*.

Given that QCPP 2nd edition is about accrediting a business entity, it was agreed not to incorporate the PPS directly into QCPP 2nd edition. Instead to comply with the design of the PPS as an individual pharmacist's responsibility, QCPP 2nd edition requires the business entity to satisfy itself that individual pharmacists working in the pharmacy complete their own individual assessment against the PPS. This means the PPS are being used in exactly the way they were designed to be used by the PSA, i.e. self assessment by individual pharmacists.

QCPP 2nd edition Standard 1 Action 4 states *"Ensure all pharmacists complete a self-assessment against the Professional Practice Standards and the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy at least once a year."*

In this action, 2nd edition has endorsed the PSA's position and mandated that individual pharmacists complete the self assessment against the PPS at least once a year. QCPP 2nd edition goes beyond the PSA's requirement and requires that the pharmacy proprietor or manager is satisfied that each individual pharmacist employed by the pharmacy has completed the self assessment at least annually.

The pharmacy proprietor or manager is required to provide a declaration that states *"I have confirmed all pharmacists employed or contracted to work in my pharmacy have undertaken a self assessment against the PSA Professional Practice Standards within the past 12 months and I am satisfied with the results of the self assessments."*

Any pharmacy does not provide this declaration cannot be an accredited member of the QCPP.

Beyond this requirement, QCPP 2nd edition has used the PPS as reference material in developing the rest of the professional requirements of the program. These professional requirements have been developed from the perspective of a business entity rather than an individual pharmacist.

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Assessments

Is it permissible for part or all of an assessment to be conducted outside of opening hours to allow for less disruption to the pharmacy?

The Documentation Audit may be undertaken outside of opening hours or away from the pharmacy premises. The rest of the assessment process must be conducted during normal opening hours.

The reason for this is that in QCPP 2nd edition, many of the mandatory requirements of the program are contained in the procedures. As the 'Evidence required at assessment' often requires proof a procedure is followed, the assessor must be able to observe pharmacy staff undertaking their normal daily activities to confirm they are following their procedures. This ensures all mandatory requirements are being met.

How many remedial actions can a pharmacy be given?

When a pharmacy is not compliant with the requirements of an action within a Standard, the pharmacy will receive a remedial action which states what needs to be done to achieve compliance and what evidence will be required.

Although there is no specific number of remedial actions a pharmacy may receive, there may come a point during an assessment where there is such a significant number of remedial actions, the assessor may decide there is no assessable system in place. That may be due to the pharmacy using the assessment as a means of obtaining a list of things to do to achieve accreditation, without actually having read and implemented the program as a whole.

If such a point is reached during the assessment, the assessment will stop. The pharmacy will not be given remedial actions, but asked to implement the program as a whole, and once completed, contact a QCPP licensed assessor to book another assessment.

When booking an assessment, the pharmacy will find that assessors ask a series of questions to try and ensure the pharmacy has implemented the program sufficiently.

When checking compliance with procedures, the assessor may interview staff members. How many staff members may be interviewed and who chooses which staff members are involved.

The assessor may interview a maximum of five staff members during the course of the assessment. It is up to the assessor to decide which staff members he/she will interview.

Are assessors allowed to access data on any of the pharmacy's computers?

Assessors are not permitted to touch, use or personally access data on any pharmacy computer. However a pharmacy authorised representative may show the assessor information stored on a computer as proof of evidence requirements where appropriate.

Documentation Audits

What is a documentation audit?

Many of the mandatory requirements of QCPP 2nd edition are required as actions in procedures or fields in templates. As these are mandatory requirements they will need to be checked by the assessor.

The documentation audit is the process where the assessor will check every procedure and template the pharmacy is required to have, to ensure each of those mandatory requirements is met.

This will be a lengthy process and must be carried out prior to the rest of the assessment process. The documentation audit may occur on the same day as the assessment or up to three months prior to the assessment.

If the pharmacy proprietor/manager is agreeable, he/she may provide a copy of their operations manual for the assessor to check back at their own business premises.

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Evidence Requirements

When the 'Evidence required at assessment' asks for a procedure, does that procedure need to be a written procedure?

Yes, a written procedure is required. Where a written procedure is not required, the evidence will ask for an explanation only.

If a procedure is not required as part of the 'Evidence required at assessment', but the procedure contains mandatory actions, is the pharmacy required to produce such a procedure?

As the procedure is not required as part of the 'Evidence required at assessment' the assessor will not require the pharmacy to produce such a procedure, even though the sample procedure contains mandatory steps.

However, if the pharmacy has such a procedure, as part of the documentation audit the assessor will ensure the procedure has all the mandatory actions. A remedial action will be issued if the procedure does not contain all the mandatory actions.

At a pharmacy's first assessment for QCPP 2nd edition, there will be a number of instances where although a standard has been implemented, there may not be sufficient records produced to satisfy the evidence requirements. Are these standards marked as compliant or non-compliant?

An example of this situation might be Standard 12 action 4 where the pharmacy is asked to provide a written offer of employment for staff employed in the previous two years. Given that a staff member may have been employed one year ago, before QCPP 2nd edition was implemented, that staff member may not have a written offer of employment.

In this situation the assessor would confirm with the pharmacy QCPP coordinator that the pharmacy will be supplying new employees with a written offer of employment and ask to see a copy of the template they intend to use.

Once this information has been supplied, the pharmacy would be marked as compliant. Note that this would apply to the first assessment only under QCPP 2nd edition.

The evidence required at assessment sometimes requires the assessor to sight records for a maximum of five staff. Who chooses which staff member records the assessor will view.

It is up to the assessor to decide which staff member records he/she sights. An assessor may ask for records for a specific staff member when checking compliance.

Can a pharmacy present an affidavit as evidence of compliance with an action within a Standard?

The evidence required at assessment is clearly stated for each Standard and Action. An affidavit may not replace the evidence required, as this is not allowed for in the rules of the program.

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Standards

1 Compliance with legal and professional obligations.

Action	Additional information & rulings
1	No additional information.
2	<p><i>Will the assessor check the pharmacy complies with all legislative requirements?</i></p> <p>No, the evidence required by the assessor for compliance with this standard is the signed declaration T1A. It is the pharmacy proprietor's or manager's responsibility to ensure compliance with legislation before signing the declaration. Once the assessor has sighted this document the pharmacy is compliant.</p> <p>Assessors are not legal experts and only check for compliance with QCPP Standards. There may be instances where a QCPP requirement is also assessable or enforceable by another authority. In such cases the assessor is checking for QCPP compliance purposes and not for legislative compliance.</p> <p><u>What needs to be done if the assessor finds information that needs to be changed in a -T1A that was already sent?</u></p> <p><u>The revised T1A must be re-sent to QCPP. The assessor must also create and sign/close-off a remedial against Standard 7 Action 7.</u></p> <p><u>How many signed and sent T1A's need to be sighted at assessment?</u></p> <p><u>The assessor is required to sight two T1A forms for a pharmacy that has been previously accredited. Only the most current- T1A will need to be sighted by the assessor for pharmacies being assessed for the first time.</u></p>
3	<p><i>Is the pharmacy required to have a copy of the latest edition of the Professional Practice Standards and the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy?</i></p> <p>The pharmacy is not required to have a copy of the PSA booklet just access to the documents. For example, if the pharmacy has the latest edition of the APF, it contains a copy of the documents.</p> <p><u>PSA Professional Service Standards – Pharmacy needs to prove that they have access. It is not enough to have an icon or to have it in their favourites. It should be noted that the Professional Service Standards are not in APF21, therefore if a pharmacy is relying on APF they will need to retain APF20.</u></p> <p><u>What is evidence is required to close a remedial for not being able to demonstrate access to the latest edition of the Professional Practice Standards and the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy?</u></p> <p><u>A facsimile of the first page of the above documents or an email of the downloaded document to the assessor is sufficient to close off a remedial for this action.</u></p>
4	<p><i>Does the assessor need to see a copy of each pharmacist's PPS self assessment sheets?</i></p> <p>No, the assessor is only required to sight the declaration by the proprietor or manager that the self assessment has been completed.</p>

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- 5 ***At the first assessment under QCPP 2nd edition, will the assessor need to sight the signed undertakings in relation to maintaining confidentiality, for staff who were employed previous to implementing QCP 2nd edition?***
- Yes, the evidence requires the assessor to sight the signed undertakings for all staff (to a maximum of five staff identified using the pharmacy roster). If the pharmacy is unable to produce the evidence, a remedial must be raised against Standard 11 Action 1.
- If a pharmacy does not employ any staff do they need a Confidentiality Policy and signed undertakings?***
- The pharmacy still must have a Confidentiality Policy but as there is no staff, there will be no signed undertakings.
- 6 ***As proof of maintaining the various insurances, can the pharmacy show the assessor the annual invoice or policy document?***
- No, the annual invoice or policy document may not show the exact type of insurance involved or may not indicate if payment has occurred. Also the assessor would not be able to tell if the insurance has since been cancelled.
- The evidence required asks for a certificate of currency for the various insurances and this is the proof that must be sighted by the assessor.
- 7 ***Why do employed or contracted pharmacists need to maintain individual professional indemnity insurance? Are they not covered under the pharmacy's professional indemnity insurance?***
- There is certainly a degree of coverage under the pharmacy's professional indemnity insurance, however the extent of that insurance is still a 'grey' area. When an error occurs and legal action is taken, that action will be taken against as many business entities and individuals as possible to ensure the person(s) involved receives full compensation.
- This means that legal action may be taken individually against the pharmacy, the proprietor and other individual pharmacists. To protect the public and ensure full compensation is received from all involved parties, QCPP has decided that all pharmacists working in QCPP accredited pharmacies should have individual insurance.
- Given the possibility of liability outside the pharmacy environment and the small cost of PI insurance, it would be hard to imagine why a pharmacist would not want this coverage.
- It should be noted that "Locum" pharmacists should be treated as "third-party" providers/sub-contractors and should have all the appropriate insurances and registrations in place. It is the responsibility of the pharmacy to check the currency of the insurances and registrations prior to allowing the pharmacist to represent the pharmacy as a pharmacist.

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2 Supply of medicines, medical devices and poisons

Action	Additional information & rulings
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1	<i>Can the pharmacy continue to use the PDL 'Guide to good dispensing' as their dispensing procedure?</i>
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The 'Guide to good dispensing' is a very useful checklist for the dispensing process.

However the Dispensing Procedure required by this standard, covers the process from when a prescription is first presented, to when the customer leaves with the dispensed medications.

As such the 'Guide to good dispensing' is not comprehensive enough to cover the requirements of this standard. The pharmacy will need to use the sample procedure on Dispensing (P2A) or develop their own procedure ensuring the mandatory requirements of the sample procedure are included.

2	<i>Can the pharmacy just use the sample policy (P2B) provided in the QCPP 2nd edition manual?</i>
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The document P2B is not a sample policy. It is a document that provides issues for the pharmacy to consider when formulating their own policy. P2B as written in the manual would not be acceptable to an assessor as a policy document.

3	<i>What is the definition of Distance Supply?</i>
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Distance supply is considered to be when a pharmacy supplies a dispensed medicine, Pharmacist Only medicine or Pharmacy Medicine to a consumer via a delivery service that is run by a contractor. That is, if an item is delivered by a member of the pharmacy's staff it is considered to be a delivery (covered under Standard 11 Action 5). If it's delivered by a contractor, it's considered to be distance supply.

How many items need to be dispensed at a distance before this action needs to be implemented by a pharmacy?

Unlike QCPP 1st edition where a defined number of items had to be dispensed at a distance before the Standard needed to be implemented, if one item is dispensed at a distance this action must be implemented.

Within three months of commencing Distance Dispensing, the owners are to complete the 'Accreditation–Change of Pharmacy Services' form (available from the QCPP website) and forward it to: Director, Quality Care Pharmacy Division. The information provided on the form will be used to determine if and when additional assessments will be undertaken. Failure to lodge the declaration within three months may result in sanctions being applied.

What is the Distance Supply Checklist?

The Distance Supply Checklist (T2A) is a checklist based on a standard template of requirements for the Delivery of Health Programs and Services. Most of these Health Programs and Services are implemented under Standard 3 but as Distance Supply is considered to be a dispensing function, it has been included under Standard 2.

The checklist is found in the templates section of the QCPP 2nd edition Manual. The checklist defines the actions that need to be implemented to meet each Program requirement, along with the evidence requirements.

The pharmacy should use this checklist to implement the actions and the assessor will use the checklist to check evidence requirements.

If a pharmacy provides a distance supply service but does not provide Internet pharmacy, how will they be scored for the actions on checklist template T2A that refer to Internet pharmacy?

When completing checklist template T2A, if the pharmacy does not provide an internet pharmacy service, any action relating to internet pharmacy will be deemed not applicable (as per Program & Assessment Rule 18) and not be assessed or scored.

How will the assessor check the pharmacy is following their procedure for Distance Supply if no items are dispensed at a distance on the day of the assessment?

The 'evidence required at an assessment' asks for 'Proof the procedure includes or makes reference to'. An assessor will check the procedure to ensure it includes or makes reference to the items contained in the

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	<p>checklist. However as there is no statement which ask for proof the procedure is being followed, compliance with following the procedure as written will not be checked.</p> <p>The reason for this is that the pharmacist has already declared the procedure is being followed as part of the PPS self assessment and proprietor's/manager's declaration T1A.</p>
4	<p><i>What is 'Simple Compounding'?</i></p> <p>Simple Compounding is the usual extemporaneous dispensing that takes place in a community pharmacy. (E.g. making creams, ointments, mixtures).</p> <p>The term Simple Compounding was used to distinguish this type of compounding from the more complex compounding processes that have been developed by specialist groups such as Professional Compounding Chemists of Australia (PCCA).</p> <p><i>Template T2B the Compounding Worksheet contains mandatory fields. Does this mean the pharmacy must complete a Compounding Worksheet for every compounded item they dispense?</i></p> <p>The 'evidence required at assessment' for this action requires the pharmacy to have a Simple Compounding procedure. The sample procedure P2C has an action (action 6) which requires a compounding worksheet to be developed. This action 6 however is not a mandatory action (no *). Therefore the use of a compounding worksheet is not mandatory.</p> <p>If the pharmacy did want to use a compounding worksheet/<u>notebook</u>, their procedure should reflect this and the compounding worksheet they use must contain the mandatory fields.</p>
5	<p><i>If a pharmacy does not normally 'count out' and re-package cytotoxic drug products, do they need to have a procedure and any associated equipment?</i></p> <p>Whilst a pharmacy may not normally re-package cytotoxic drug products, they should have a procedure in place in case the need arises in response to, for example, a specific Doctor request.</p> <p>The pharmacy would not be expected to have the separate counting equipment and protective clothing on hand, as the chances of having to re-package are remote, and the required equipment can be quickly obtained.</p> <p><u>A typical list of cytotoxic drugs is included as an appendix to this document.</u></p>
6	<p>No additional information.</p>
7a	<p><i>The Pharmacy Medicines and Pharmacist Only Medicines checklist has a program requirement number 6 (Facilities to support the program) which requires no direct access to Pharmacy Medicines by consumers. What does this mean?</i></p> <p>Consumers must not be able to directly access Pharmacy Medicines. There needs to be a physical barrier which prevents consumers from directly selecting Pharmacy Medicines from the shelves. Examples of a physical barrier might be a counter, Perspex barriers, portable stands, tape and poles similar to those used to assist people in forming a queue, or similar barriers.</p> <p>Staff members or staff/patient education would not be considered acceptable as a means of preventing direct access to Pharmacy Medicines by consumers.</p> <p><i>What is the Pharmacy Medicines and Pharmacist Only Medicines Checklist?</i></p> <p>The 'Pharmacy Medicines and Pharmacist Only Medicines' Checklist (T2C) is a checklist based on a standard template of requirements for the Delivery of Health Programs and Services. Most of these Health Programs and Services are implemented under Standard 3 but as supplying <i>Pharmacy Medicines</i> and <i>Pharmacist Only Medicines</i> is a supply of medicines function, it has been included under Standard 2.</p> <p>The checklist is found in the templates section of the QCPP 2nd edition Manual. The checklist defines the actions that need to be implemented to meet each Program requirement, along with the evidence requirements.</p> <p>The pharmacy should use this checklist to implement the actions and the assessor will use the checklist to check evidence requirements.</p> <p><i>The Pharmacy Medicines and Pharmacist Only Medicines checklist has a program requirement number 2 (Training and qualifications) which in the first action requires all staff who supply</i></p>

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Action

Additional information & rulings

Pharmacy Medicines to complete a recognised training course. Does this include Pharmacists?

Qualifying as a pharmacist is recognised training in *Pharmacy Medicines*. However ongoing refresher training is a requirement for all staff involved in the supply of *Pharmacy Medicines* including Pharmacists.

The Pharmacy Medicines and Pharmacist Only Medicines checklist has a program requirement number 6 (Facilities to support the program) which in the second action states 'Mandatory 1 March 2008'. If a pharmacy is non compliant with this action, how are they scored?

This action asks that *Pharmacy Medicines* are located in the Professional Services Area. The requirement is not a mandatory requirement until 1 March 2008. Until that time any pharmacy that is non compliant with this action will be scored the same as if they were non compliant with any non mandatory action. That is, they would score 0 out of a possible score of 2 and would be given a remedial action.

The pharmacy would then decide whether or not they choose to complete the remedial action to gain a score of at least 90% and be recommended for accreditation by the assessor.

Once the action becomes mandatory on 1 March 2008, the pharmacy must be compliant with this action to be recommended for accreditation.

The Pharmacy Medicines and Pharmacist Only Medicines checklist has a program requirement number 3 (Reference material) which in the third action requires a list of Recordable Pharmacist Only medicines that conforms with relevant legislative requirements. How is this action scored if there are no legislative requirements for any Recordable Pharmacist Only medicines?

The action will be deemed not applicable (as per Program & Assessment Rule 18) and not be assessed or scored.

In the Pharmacy Medicines and Pharmacist Only Medicines checklist, there is a requirement for "refresher" training. What is the "refresher" training?

The "refresher" training is to be some training specifically relevant to the supply of these schedule 2 medicines. The Guild Training Department is to release a guideline on the delivery and recording of training. It is expected that there is a minimum of 3 hours refresher training per year after the initial accredited training is completed. The training may be delivered within the pharmacy and may include guild approved training provided by pharmaceutical companies.

It will be recognised that Pharmacy Assistants that have less than three months employment in the pharmacy may not have had the opportunity to participate in a scheduled training sessions. No remedial action will be raised for refresher training for staff with less than three months employment in the pharmacy (time elapsed, not full time equivalent). No Pharmacy Assistant should be supplying S2 and/or S3 medicines until they have completed the mandatory S2/S3 training.

In the checklist there is a requirement that the pharmacy have sufficient resources to service the customers. How is this defined?

The QCPP Standards Committee is reluctant at this time to define an appropriate service aspiration, however the Assessor have been asked to survey the pharmacy a number of times during the assessment to determine waiting times, and record the information on the Assessment Report. Assessors are asked to checked service times at three separate times, separated by at least 45 minutes during the assessment to determine a waiting time. They will do this by noting the time a customer enters the pharmacy and the time at which they are first acknowledged by a member of the pharmacy staff. The time elapsed should be recorded.

What references should the pharmacy have available?

A pharmacy should have a minimum of two of the following references: PSA Counselling Guide, eMIMS, AMA prescribed, APF therapeutics, AMH, APP

Pharmacies should have a system of signage that encourages consumers to seek advice from pharmacy staff. What is the minimum requirement of the system of signage?

The QCPP Standards Committee is reluctant to prescribe the minimum level of "system of signage" however it should be evident within the pharmacy that the pharmacist and pharmacy staff welcome requests for advice from the customers.

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7b	<p><i>What is the Supplying Pseudoephedrine Checklist?</i></p> <p>The Supplying Pseudoephedrine Checklist (T2D) is a checklist based on a standard template of requirements for the Delivery of Health Programs and Services. Most of these Health Programs and Services are implemented under Standard 3 but as supplying Pseudoephedrine is a supply of medicines function, it has been included under Standard 2.</p> <p>The checklist is found in the templates section of the QCPP 2nd edition Manual. The checklist defines the actions that need to be implemented to meet each Program requirement, along with the evidence requirements.</p> <p>The pharmacy should use this checklist to implement the actions and the assessor will use the checklist to check evidence requirements.</p> <p><i>The Supplying Pseudoephedrine checklist has a program requirement number 2 which requires all staff to be trained in the sale of products containing Pseudoephedrine. Does this include Pharmacists.</i></p> <p>Yes, a training record is required.</p> <p><i>The Supplying Pseudoephedrine checklist has a program requirement number 3 which requires the pharmacy to have a list of products on sale within the pharmacy that contain pseudoephedrine and access to Project Pseudo-guidelines. If a pharmacy has no staff, do they need these documents?</i></p> <p>Yes, these documents are required by all pharmacies.</p> <p><i>The Supplying Pseudoephedrine checklist has a program requirement number 6 which requires that all solid dose "pseudoephedrine plus antihistamine" and single-entity pseudoephedrine products including sustained release single ingredient products are placed out of reach and out of sight of customers.</i></p> <p>In addition to this evidence, all products that are required to be out of sight of the customer must contain more than 30 mg of pseudoephedrine per dosage unit e.g. a single tablet.</p> <p><i>The Supplying Pseudoephedrine checklist has a program requirement number 7 which requires the pharmacy to have a procedure for the supply of pseudoephedrine products. Can a pharmacy use their procedures for the sale of 'Pharmacy Medicines' and 'Pharmacist Only' medicines to satisfy this requirement?</i></p> <p>The pharmacy can use their procedures for the sale of 'Pharmacy Medicines' and 'Pharmacist Only' medicines to satisfy this requirement however they must ensure the procedures make reference to pseudoephedrine and the extra evidence requirements of this action such as criterion for refusal of sale. (See 'Supplying Pseudoephedrine Checklist' for full details of evidence requirements)</p> <p>Template T2D has a mandatory requirement "Ensure that not more than one shelf facing per product type of any pseudoephedrine product is displayed". It has been decided by the QCPP committee that this will be changed to not more than one package spacing per product type i.e. multiple facings formed by packages placed on-top of each other are permitted. The now non-mandatory requirement is still recommended.</p>
7c	<p><i>What is a Medical Device?</i></p> <p>A medical device is defined in the Pharmaceutical Society of Australia's Professional Practice Standards in the Glossary of Terms.</p> <p>In practical terms the definition would include items such as Nebuliser Pumps, Asthma spray spacer device, Vaporiser, Blood Glucose monitor, Blood Pressure measuring devices etc.</p> <p>Although the additional information on this standard provides for this action being not applicable to some pharmacies, given the scope of the definition, it would be hard to imagine any community pharmacy that does not stock or order in for customers any such devices.</p>
7d	<p><i>What is defined as a Poison for the purposes of this action?</i></p> <p>A poison, for the purposes of this action, is defined as a Schedule 7 Dangerous Poison as defined in the</p>

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Action	Additional information & rulings
	<p>Standard for Uniform Scheduling of Drugs and Poisons.</p> <p><u>If a pharmacy identifies that they do not handle poisons, then they score 0/0 i.e. Not applicable, rather than 2/2.</u></p>
8	<p><i>Can the pharmacy just use the sample policy (P2H) provided in the QCPP 2nd edition manual?</i></p> <p>The document P2H is not a sample policy. It is a document that provides issues for the pharmacy to consider when formulating their own policy. P2H as written in the manual would not be acceptable to an assessor as a policy document.</p>
9	<p><i>Can the pharmacy just use the sample policy (P2I) provided in the QCPP 2nd edition manual?</i></p> <p>The document P2I is not a sample policy. It is a document that provides issues for the pharmacy to consider when formulating their own policy. P2I as written in the manual would not be acceptable to an assessor as a policy document.</p>
10	<p><i>The procedure for Return of Unwanted Medicines (P2J) requires the pharmacy to have a RUM approved container. Is the 'RUM' bin provided by the Return of Unwanted Medicines project the only bin acceptable to the assessor?</i></p> <p>No, there are other companies that provide suitable containers for the return of unwanted medicines. It is important that the container provided has the features required such as a liner with a tamper proof seal and a lid that will firmly attach. Also how the company disposes of the unwanted medicines is important.</p> <p>The pharmacy may check with the assessor prior to the assessment to ensure the alternative arrangement they have is acceptable.</p> <p><i>Is it mandatory for a pharmacy to have a RUM approved container?</i></p> <p>This action is mandatory and requires a procedure for Return of Unwanted Medicines and proof the procedure is followed. Action 1 of the procedure is mandatory and states '<i>Ensure the pharmacy has a RUM approved container</i>'. Therefore it is mandatory for a pharmacy to have a RUM approved container.</p>
11	<p><u>The RUM program has changed the rules, so that the liner and sealer are no longer provided. Is it permissible to just leave out the liner with the new tamper evident lid?</u></p> <p><u>Yes. The standard requires the liner and seal, however as they are no longer available a blanket concession has been granted so that a remedial will be raised, but then closed with reference to this concession. The Concession number is Concession P2J – PJR 0901</u></p>
12	<p><u>What is the definition of refresher training?</u></p> <p><u>The requirements for refresher training has been determined and published to all members of QCPP. The guidelines are detailed on the web. The basic requirement is for 3 hours of refresher training per year for every person involved in the supply of S2 and/or S3 medicines. For new Pharmacy Assistants the 3 hours training may be pro rata applied for the period of time they have been employed by the pharmacy.</u></p>

Implementation Information and Rulings

3 Delivery of health programs and services

All of the actions for standard 3 are assessed using the Template Checklists for any health programs and services, as defined on the QCPP website, that the pharmacy provides.

Template	Additional information & rulings
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T3A

2. Training and qualifications

If a pharmacist underwent “on the job” training in opioid substitution therapies a number of years ago, how would he or she prove their training?

The pharmacist would just need to produce a Training Record (T15B) and state on the training record approximately when the training occurred and what it covered.

If a pharmacy has started an opioid substitution program at the pharmacy just before their assessment, how do they satisfy the requirement for ongoing training in the area of substance abuse and treatment?

In this situation the assessor would only expect to see the initial training record in opioid substitution therapies. The requirement for ongoing training would not need to be satisfied. This action would be deemed to be not applicable to the pharmacy at this stage and would be scored 0 out of 0 for the ongoing training requirement.

Is a foil wrapped medicine considered to be child proof as required by the standard?

No. As per most state guidelines, foil wrapped Opioid substitution medicines need to be in a container with a child proof cap.

There is a requirement for a drug safe if the pharmacy is offering Opioid Substitution. What is the specification of the drug safe?

The standard does not set a specification for the drug safe; however various regulatory bodies do define in some detail the specification for the drug safe. The Assessor will expect the drug safe to be capable of being securely locked and large enough to store any drugs of dependence. If the dosage device is large and intended/or practice is, to stay on the original container until the container is emptied, then the container and device shall be able to be stored in the drug safe. If in doubt the Assessor should ask for a demonstration that the medicine can be stored in the safe. The Assessor may draw the legal/regulatory guidelines to the attention of the pharmacist; however a remedial action will only be raised if the safe fails the simple QCPP requirement of lockable/secure and large enough.

The template requires the person receiving the dose has access to drinking water. How accessible should be water be?

The drinking water shall be available free of charge and accessible without requiring the person to move from the immediate counselling area. A glass/cup of water provided separately with the dose is permissible.

T3B

2. Training and qualifications

Does the term ‘support staff’ mentioned in this action, refer to pharmacists?

No, the term ‘support staff’ refers to non pharmacist staff who may assist the pharmacist in the packing of Dose Administration Aids.

Implementation Information and Rulings

- T3C 4. Equipment to support the Program
- What does “Proof equipment complies with Australian Standards” mean for this action?***
- This evidence statement is phrased incorrectly. To comply with Australian requirements all medical devices must be registered with the TGA. The sponsor/manufacturer needs to supply a data sheet to the TGA and if acceptable the equipment is included on the Australian Register of Therapeutic Goods (ARTG) and given an ARTG number.
- The ARTG number is not required by any labelling requirements to be on the product or packaging. To check a product has an ARTG number, the pharmacy should look up the sponsor/product on the public viewing area of the TGA website.
- As evidence, the Pharmacy can print out the relevant entry on the TGA website or simply show the assessor the entry on the website on the day of the assessment.
5. Equipment Calibration and maintenance
- Do I need to calibrate my blood pressure monitor?***
- Unless specifically stated in the BP monitor instructions, there is no requirement to calibrate the BP monitor. A pharmacy is still required to maintain the BP monitor. Proof can be provided using T5B “Equipment Calibration Schedule” Proof can include “change battery 6 monthly” or “Send monitor in for service” or “Replace Monitor”
- T3D ***Are you providing a Needle and Syringe Service?***
- In every state, all pharmacies intending to offer needle and syringe programs to their clients, need to apply to the appropriate body in their jurisdiction. This is usually the appropriate section of the State/Territory Department of Health. Proof of registration is required.
- Source: Pharmacist Facilitator Manual: from the PSA web site: under - National Illicit Drug Training for Pharmacy Project <http://www.psa.org.au/site.php?id=59>**
- T3E 2. Training and qualifications
- What proof is required to show that pharmacists involved in a HMR process maintain appropriate accreditation.***
- The accredited pharmacist would need to have a copy of their current accreditation certificate at the pharmacy for the assessor to sight.
- T3F 8. Recording system
- The third action in this program requirement asks the pharmacist to “Maintain patient records that include:”. The proof of this action is “Proof there is a medication profile”. What information is required as part of the medication profile.***
- The assessor will require that all the information listed in the dot points of the action is being maintained as part of the records for each patient.
- T3G **The template T3G step 8.3 has a mandatory requirement for a contract with each residential aged care facility. How detailed should this contract be?**
- The Assessor will expect to find a written and signed contract with each facility; however the 4 dot points in the evidence area of the template are for guidance purposes. The contract will be reviewed by the Assessor to ensure it is appropriate for the relationship with the pharmacy. The intent of the contract is to protect both the pharmacy and the facility.

Implementation Information and Rulings

T3H

Are you providing a Health Promotion Service?

"Health Promotion" refers to health education and public health promotion to individuals and the community. It is the process of enabling people to take greater control of their health in order to improve it that involves more than the supply of product.

Health promotion may such as but are not limited to:

- Pharmacy health care and monitoring service
- Smoking cessation programs and weight loss
- Programs working with groups within the community

Implementation Information and Rulings

4 Advertising and promotions

Action	Additional information & rulings
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1	<i>How does the pharmacy and the assessor know whether the advertising or promotional material relating to therapeutic products complies with the Therapeutic Goods Advertising Code?</i>
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The pharmacy should obtain a copy of the Therapeutic Goods Advertising Code from the TGA website on the internet. The assessor will use this document in assessing this standard.

2	No additional information.
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3	No additional information.
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4	No additional information.
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5	<i>Can a pharmacy write their own Price List Policy as with other policies?</i>
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No, the QCPP Price List Policy (P4A) is QCPP's policy, not the pharmacy's policy. If the pharmacy provides price lists of Scheduled Medicines to the general public then every requirement of this policy must be strictly adhered to.

How will the pharmacy be scored if they do not have any price lists as defined by this action?

If the pharmacy does not have any price list as defined by this action, the action will be deemed not applicable (as per Program & Assessment Rule 18) and not be assessed or scored.

In August 2007, the QCPP Committee ruled that the:

- QCPP *Standard 4 Action 5* Price List Policy (P4A) and with it the TGA Price Information Code of Practice be a **non-mandatory** action for assessment.
- Non-mandatory ruling for P4A to stand for, at least, the period of accreditation.
- Decision, in relation to the Price Information Code, will not change until such time as the TGA has arranged for the Price Information Code to be underpinned by legislation, in which case it will then be covered by the T1A declaration form.

Currently the TGA Price Information Code already (and only) legally applies in Queensland.

Implementation Information and Rulings

5 Pharmacy premises and equipment

Action	Additional information & rulings
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1	<i>How often is the pharmacy required to complete the Pharmacy Appearance Checklist (T5A)?</i>
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There is no requirement for the pharmacy to complete the Pharmacy Appearance Checklist. This checklist will be completed by the assessor on the day of the assessment.

If the pharmacy would like to use this checklist as a tool to regularly check the appearance of the pharmacy, it is up to them how often they use it. The timeframes shown on the checklist are only a guide for pharmacies as to how often they might check items on the list.

The Pharmacy Appearance Checklist (T5A) requires that the focus of the shopfront when viewed from the public domain is healthcare related. What does that mean and decides compliance?

This requirement will be assessed for compliance by the assessor. The criteria for compliance is based around whether or not you would be able to readily identify the premises as a pharmacy when viewed from the public domain.

Window displays of health and beauty products, sun care, giftware etc. would all be acceptable. A good example of what might not be acceptable would be a pharmacy that has the front windows and fascia of the shop painted over with for example Tattsлото agency signage.

The Pharmacy Appearance Checklist (T5A) has a mandatory requirement that "Product shelf labels are neat and legible". Does this mean that product shelf labels are mandatory?

No. If a pharmacy does not have product shelf labels, this action will be deemed not applicable (as per Program & Assessment Rule 18) and not be assessed or scored.

Implementation Information and Rulings

2

Does a pharmacy have to have a Professional Services Area?

Yes, this is a mandatory action.

Does the pharmacy have to have a sign that states “Professional Services Area”?

No, the professional services area does not require a specific sign that states “Professional Services Area”. However, an assessor will expect to see some signage within the area to indicate that this is an area where professional activities are undertaken.

Examples of such signage might be “Dispensary”, “Prescriptions” or “Professional Services Area”.

The signage itself does not necessarily have to distinguish the area within the pharmacy as other factors such as different fit-out, colour, lighting or floor materials may also act to distinguish the area.

In a pharmacy that has limited shop space, is it acceptable to keep items such as confectionary or cosmetic promotions on a counter that is located within the Professional Services Area?

No, the ‘Evidence required at assessment’ states ‘Proof products stored in the Professional Services Area exclude non-health related products and services’. Any non health related products such as perfume, gifts, confectionary, cosmetics etc. will not be able to be stored within the area.

Are products such as Glucojels™, Butter Menthols™, Sugar Free lollies etc. allowed in the Professional Services Area?

Sometimes there is a fine line between products that purport to provide a therapeutic effect and confectionery. Obvious lines of confectionery such as chocolate bars and sweets are not allowed in the Professional Services Area. However confectionery lines that purport to offer a mild therapeutic effect such as some “cough lollies” or soothing throat preparations are allowed in the area.

Products such as Glucojels™ and sugar free lollies may have some application to diabetic patients and as such are allowed within the Professional Services Area.

Other products may not be so easy to classify and therefore the decision will rest with the QCPP Licensed Assessor at the assessment.

What are the requirements of the Professional Services Area (PSA)?

The PSA is partially defined in a number of areas of the standard, but the full specification is not given. The overall specification is:

- Distinguishable from the general trading area (Standard 5 Action 2) e.g. by a system of signage (Template T2C Action 4)
- Supervised by a pharmacist (Standard 5 Action 2 and Template T2C Action 6)
- Includes the dispensary area (Standard 5 Action 2)
- Includes an area for confidential conversations (Standard 5 Action 2)
- Includes a professional trading area (Standard 5 Action 2)
- Excludes non-health related products and services (Standard 5 Action 2)
- Includes all Pharmacy Medicines (Standard 8 Action 7 and Template T2C Action)
- Trained pharmacy staff members are visible in the PSA (Template T2C Action 1)
- No direct access for consumers to Pharmacist Only Medicines (Template T2C Action 6)
- It should be noted that there is no requirement for the PSA to be a regular shape. It is permissible for the shape of the PSA to be curved or U-shaped; however it must be a continuous area and not have “holes” in it.

3

The second sentence of the ‘Evidence required at assessment’ for this action states ‘Proof the procedure is followed’. What procedure is this referring to?

The inclusion of this sentence ‘Proof the procedure is followed’ is a printing error. This sentence will be ignored in assessing this action.

Implementation Information and Rulings

- 4 ***How often does the pharmacy need to get equipment calibrated?***
It is up to the pharmacy to determine the appropriate time intervals and type of calibration for any equipment. The assessor will not comment on timeframes but just ensure equipment calibration records show that calibration is occurring as per the pharmacy's schedule.
- 5 ***On the Temperature Record (T5C) there is only one space for recording temperatures above 8 °C and below 1 °C. If the pharmacy simply puts a mark in these squares, how will they have a record of how far out of temperature the fridge reached?***
This chart was designed to put a mark in the squares to indicate temperatures from 1°C to 8°C. For temperatures outside this range, the chart was designed to actually write the temperature reached in the >8°C or <1°C squares.
The records of the daily fridge temperatures should be retained for the full accreditation cycle. i.e. two years.
Vaccine Fridges using automatic monitoring will only be accepted if the pharmacy can demonstrate that they are advised 'actively' when/if the fridge drifts outside of control parameters in any 24 hour period.
What happens if the pharmacy does not have their Cold Chain Testing Centre certificate at the assessment?
It is important for a pharmacy to commence the Vaccine Refrigerator certification process well in advance of the assessment. If the certificate is not available at the assessment, the pharmacy will not be able to be recommended for accreditation at that time and will be given a remedial action to obtain the certificate within three months.
This not only holds up the pharmacy's accreditation but also any incentive payments that may be applicable to the pharmacy once they become accredited.
The standard requires "...certified by the Cold Chain Testing Centre not more than six months prior to an assessment." This is to be changed to require a valid Cold Chain test certificate from the Cold Chain Testing Centre. Certificates are currently valid for one year.
- 6 ***Does every pharmacy require an air-conditioner?***
A pharmacy needs to be able to demonstrate that it is able to prevent the temperature from exceeding 25° C in the professional, trading and storage areas. If the pharmacy does not have air-conditioning, they must be able to produce reasonable data to support their claim that the temperature would not exceed 25° C throughout the year.
This data might include readings from temperature logging devices or local temperature recordings by the Australian Bureau of Meteorology. In the absence of air-conditioning, it is the responsibility of the pharmacy to provide the necessary data.
- 7 ***How will the assessor know if the lighting within the pharmacy is at least 400 Lux?***
The assessor will have a light meter which is a device for measuring light in units of Lux.
How will the light meter be used?
The Assessor will test for the level of lighting in a number of places in the pharmacy including areas used for the preparation of DAA, dispensary, methadone area, between shelves in dispensary, in several places around the shop area. A minimum of 400 Lux should exist in all areas tested.
- 8 No additional information.
- 9 ***If a pharmacy is located in a shopping centre complex, does this mean the pharmacist is required to have a key to the complex?***
No, it may be that if the pharmacist requires access, he/she may need to contact centre management or security staff to obtain access.

Implementation Information and Rulings

6 Operating an effective and profitable business

Action	Additional information & rulings
1	No additional information.
2	Will the assessor want to sight the pharmacy's purchasing policy? No, the 'evidence required at assessment' only requires a reasonable explanation of the pharmacy's purchasing policy.
3	Will the assessor want to sight the pharmacy's pricing policy? No, the 'evidence required at assessment' only requires a reasonable explanation of the pharmacy's pricing policy, structure and review process.
4	Will the assessor want to sight the pharmacy's trading figures or contact the pharmacy's accountant? No, the assessor will only seek a reasonable explanation of how the pharmacy estimates, monitors and reports income.
5	No additional information.
6	No additional information.
7	What evidence does the assessor require as proof of the valuation of stock on hand? The assessor will require proof that stock on hand has been valued but the method of valuation will not be assessed.
8	<u>-If the owner is an active pharmacist in the pharmacy, who should the reports be given?</u> <u>There is no requirement to give the report to any other person/body than the owner. If the owner has the report then the score will be 2/2</u>

Implementation Information and Rulings

7 Complying with and improving our quality program

Action	Additional information & rulings
1	<p><i>If a pharmacy has no staff, does a person still need to be nominated as having responsibility for QCPP matters?</i></p> <p>Yes</p>
2	<p><i>If a pharmacy has no staff, does the person responsible for QCPP matters still need a document that defines the responsibilities?</i></p> <p>Yes</p>
3	No additional information.
4	<p><u><i>There is a requirement that all QCPP materials are maintained. Does this mean the pages of the QCPP materials should not be used in the working copy of the Operations Manual?.</i></u></p> <p><u>No. The QCPP materials are designed to be used if the pharmacy wants. The intent is that the QCPP materials are available for the pharmacy to use or refer to. Any updates issued by QCPP shall be placed in the manual at the appropriate places. If the QCPP disk has been misplaced, no remedial will be raised as the information is still available in the manual.</u></p>
5	<p>How should the pharmacy demonstrate that it has reviewed all procedures and templates at least annually?</p> <p>At the front of the QCPP manual there is a template "Implementation and Review Page" that may be used to sign off that each procedure as it is reviewed. The pharmacy may use other mechanisms for recording the review of the procedure, including e-QCPP. The important issue is that each procedure and template is reviewed to ensure it remains relevant to the pharmacy and has been fully implemented. A responsible person within the pharmacy should record that the review has been completed. The Assessor will confirm that the mechanism used for recording the review is appropriate during the assessment.</p>
6	No additional information.
7	<p><i>Is the pharmacy required to forward the annual return (Page 2 of the Legal and Professional Obligations Declaration) to the QCP Division for their first assessment? The implementation Notes page for this action says "No initial implementation".</i></p> <p>Yes, the assessor will check at the first assessment to ensure the pharmacy has forwarded the annual return to QCP Division.</p> <p>The statement in the "What you need to do to implement this Standard" saying no initial implementation is a misprint.</p> <p><u>The pharmacy should have copies of the T1A for both years of the accreditation cycle, if it is being re-accredited. The pharmacy may request a copy from the QCPP office if it is unable to locate the T1A for one of the years.</u></p>
8	No additional information.

Implementation Information and Rulings

8 Requirements for pharmacy stock and services

Action	Additional information & rulings
1	No additional information.
2	No additional information.
3	<p><i>Why are tenancy leases excluded from contracts which restrict the pharmacy's ability to stock products or provide services that meet the therapeutic needs of the consumer?</i></p> <p>It is recognised that some major shopping centres may have policies in place that could restrict a pharmacy from providing such products or services. It is considered important for all consumers who visit shopping centres to have access to a Quality Care accredited pharmacy.</p>
4	<p><i>Having excluded tenancy leases from action 3 of this standard, why is it now listed as a separate action?</i></p> <p>Quality Care still considers it important that a pharmacy is not restricted in its ability to stock products or provide services that meet the therapeutic needs of the consumer. Therefore it is still listed here as a requirement of the program.</p> <p>However for the reasons explained in the question on action 3, Quality Care recognises that this may not be possible and therefore has this action as a non mandatory action.</p>
5	<p><u>Sampling information</u></p> <p><u>The Assessor will take the samples as described in the standard. If one of the items fails to meet the specification a second sample will be taken in the same way. If two or more items fail from either one or the combined samples then a remedial will be raised that requires all stock to be checked. If no items fail in the second sample and no more than one in the first sample, then a remedial will be raised, but may be closed if the pharmacy removes the fails items before the end of the assessment.</u></p>
6	<p><i>What does this action mean by 'will become out of date during a normal course of use' and how will an assessor check this?</i></p> <p>This action refers to the need for pharmacy staff to check when selling a product that it is currently in date and will remain in date for the normal course of use for that product.</p> <p>For example, a container of 90 multi vitamin tablets with a one a day dosage should have an expiry date at least 90 days from the date of sale and not just be 'in date' on the day of sale.</p> <p>An assessor will most likely check this by selecting a product and asking a staff member what sorts of checks he/she would make if selling the product.</p>
7	<p><i>The fourth line of the 'Action required to meet the standard' refers to 'Pharmacist Medicines and Pharmacist Only Medicines Checklist'. What does Pharmacist Medicine mean?</i></p> <p>This is a printing error and is to be implemented and assessed as 'Pharmacy Medicines and Pharmacist Only Medicines Checklist'.</p> <p><i>The fourth line of the 'Evidence required at assessment' refers to 'Pharmacist Medicines and Pharmacist Only Medicines Checklist'. What does Pharmacist Medicine mean?</i></p> <p>This is a printing error and will be assessed as 'Pharmacy Medicines and Pharmacist Only Medicines Checklist'.</p> <p><i>Why is this action here when it is already a requirement of the 'Supplying Pharmacy Medicines and Pharmacist Only Medicines Checklist' (T2C)?</i></p> <p>The storage of <i>Pharmacy Medicines</i> and <i>Pharmacist Only Medicines</i> is so important in pharmacy, that it was considered reasonable to reinforce the storage requirements for these medicines in the Standard dedicated to requirements for pharmacy stock.</p>

Implementation Information and Rulings

9 Ordering, receiving, storing and pricing stock

Action	Additional information & rulings
1	<p><i>Why is there no sample procedure for ordering stock?</i></p> <p>Given the diversity of pharmacy and the numerous possibilities of systems for ordering stock, there was no one procedure that could accurately represent a significant number of pharmacies.</p> <p>Therefore it was decided that each pharmacy should develop their own procedure based on their system of ordering.</p>
2	No additional information.
3	No additional information.
4	<p><i><u>If a medicine that needs refrigeration is sold, but not yet delivered, where should it be stored?</u></i></p> <p><u>While the medicine is under the control of the pharmacy it shall be treated in the same manner it is treated before sale. For example a refrigerated medicine is picked for supply, but the customer intends to pick it up later, then it should be prepared for sale i.e. labelled and bagged and then place back into the vaccine refrigerator. It should not be placed into a domestic refrigerator. All medicines should be handled in a professional manner while under the control of he pharmacy.</u></p>
5	No additional information.

Implementation Information and Rulings

10 Hiring equipment

Action	Additional information & rulings
1	<p><i>Why is the loan of equipment considered to be equivalent to the hire of equipment? Pharmacies do this to save the paperwork and now the pharmacy has to complete the paperwork anyway!</i></p> <p>The hire of medical equipment carries with it many legal, professional and moral responsibilities. The equipment must be in good working order, designed for the purpose it will be used for and the consumer must be given careful instruction on its use and any maintenance requirements.</p> <p>To not carry out any of these responsibilities could result in not only injury to the consumer but also serious legal action to the pharmacy.</p> <p>By loaning equipment and not receiving any financial gain for its use, the pharmacy is not absolving itself from its responsibilities. Therefore it was considered just as important in this situation for the pharmacy to have systems and procedures in place to protect the consumer and the pharmacy.</p> <p><i>The procedure for Acquisition of a New Piece of Hire Equipment, P10B, has mandatory actions. Is it mandatory for the pharmacy to have this procedure?</i></p> <p>The procedure P10B is not required as part of the 'evidence required at assessment'. Therefore the pharmacy is not required to have this procedure.</p> <p>However, if the pharmacy does have this procedure, it must contain the mandatory actions.</p>
2	<p><i>Is it mandatory for a pharmacy to have an Equipment Data (T10B) document for each piece of hire equipment?</i></p> <p>Yes, action one of this Standard requires a procedure (P10A) for hiring equipment. The procedure P10A requires, in a number of its mandatory actions, the use of an Equipment Data (T10B) document.</p>
3	No additional information.
4	No additional information.
5	No additional information.
6	No additional information.

Implementation Information and Rulings

11 Customer service

Action	Additional information & rulings
1	<p><i>This action seems to be the same as Standard 1 Action 5. Why the duplication?</i></p> <p>Although the evidence requirements for this action and Standard 1 Action 5 are identical, the actions are different.</p> <p>Standard 1 Action 5 is a requirement for patient confidentiality from the perspective of the business entity, the pharmacy.</p> <p>Standard 11 Action 1 is a requirement for patient confidentiality from the staff perspective.</p> <p>Although similar, confidentiality is such an important requirement it was necessary to include it from both perspectives.</p> <p><i>If a pharmacy does not employ any staff do they need a Confidentiality Policy and signed undertakings?</i></p> <p>The pharmacy still must have a Confidentiality Policy but as there is no staff, there will be no signed undertakings.</p>
2	<p><i>A pharmacy that operates in an area that is a holiday destination, may have a more relaxed approach to staff appearance to fit in with the holiday atmosphere. Is this allowed under this action?</i></p> <p>Yes, it is up to the proprietor or manager to formulate the pharmacy's Staff Dress and Behaviour Policy (P11A). As per the 'evidence required at assessment', the assessor will want to sight the policy and ensure that the policy is being applied. The assessor will not dictate the content of the policy.</p> <p><i>If a pharmacy does not employ any staff, do they need a "Staff Dress and Behaviour Policy" (P11A)? If not, how will this action be scored?</i></p> <p>No, a policy is not required and the action will be deemed not applicable (as per Program & Assessment Rule 18) and not be assessed or scored.</p>
3	<p><i>Where must the pharmacy's Customer Service Charter (P11B) be displayed?</i></p> <p>The 'evidence required at assessment' requires the charter to be displayed. As it does not state where the charter must be displayed, it will be up to the pharmacy to display it in a suitable location.</p> <p>As the Charter is meant for customers to read, <u>it shall</u> be displayed in an area easily visible to the public.</p>
4	<p>In the procedure P11E steps 8 and 9 there is a mandatory requirement that the sales person "Offer to package and offer to issue a receipt".</p>
5	<p><i>When is delivering a prescription considered to be a delivery rather than Distance Supply (as per Standard 2 Action 3)? Has it anything to do with the number of medications delivered?</i></p> <p>No, it has nothing to do with the number of medications delivered.</p> <p>If dispensed medicines are delivered by pharmacy staff then it is considered to be a delivery and covered under the requirements of this action.</p> <p>If dispensed medicines are delivered by a contractor (e.g. courier, bus company, Australia Post) then it is considered to be Distance Supply and covered under the requirements of Standard 2 Action 3 and will require compliance with the Distance Supply checklist.</p> <p>In procedure P11F step 5 there is a requirement to leave a note in the letterbox. This is to be changed to "Advise the patient that delivery was attempted". Advice may be by note in letterbox or contact by phone to patient or carer to confirm that delivery was attempted but the item(s) has been taken back to the pharmacy for collection or other arrangements.</p>

Implementation Information and Rulings

- 6 ***What are some further examples of third party service providers and is their any relevance as to the amount of time they spend at the pharmacy or in conducting their duties.***

The amount of time a third party service provider spends either at the pharmacy or in conducting their duties is not relevant. This action is relevant whether they spend a few hours or a few weeks providing services to the pharmacy.

Some further examples might be product demonstrators to the public, contracted consultant pharmacists (for HMRs), weight loss clinics held in-store by external companies, family or baby photo sessions held at the pharmacy by an external company.

If a pharmacy does not engage any third party service providers, do they need a policy?

This action has three possibilities –

- (i) The pharmacy does engage third party service providers – In this case the pharmacy must have a written policy.
- (ii) The pharmacy has not engaged any third party service providers in the past but might in the future – In this case the pharmacy must have a written policy in preparation for the possible engagement of a third party service provider.
- (iii) The pharmacy has a policy of not ever engaging third party service providers – In this case, that is therefore their policy and must be documented as a written policy.

When a Third Party Service Provider is delivering a service within the pharmacy, do they need to comply with the requirements of the standard?

If the service being offered is described in standard 2 or 3, then the Third Party Service Provider will need to meet the mandatory requirements of those standards. i.e. records management, access to information, qualification and training etc. It is the responsibility of the pharmacy to confirm that the Third Party Service Provider complies with the standard and any relevant policies, procedures and checklists in the pharmacies operations procedures. The Assessor will seek evidence that the pharmacy recognises the requirements and implements it.

- 7 ***For a pharmacy with PBS approval, what score will they be given for this action?***

For a Pharmacy with PBS approval (no sign required), the pharmacy will receive a score of 2 for this action.

Implementation Information and Rulings

12 Employing staff

Action	Additional information & rulings
1	<p>How many position descriptions will the assessor want to sight?</p> <p>The assessor will only need to sight a position description for every position, not for each member of staff.</p> <p>Will the assessor want to see signed copies of each staff member's position description?</p> <p>No, the 'evidence required at assessment' requires the assessor to sight a position description for all positions within the pharmacy. There is no requirements to see individual, signed position descriptions.</p> <p>Template T12A for Position Descriptions has a mandatory field called "Authority for the position". What does this mean?</p> <p>This field is meant to describe what authority the position may have. For example, the position may have the authority to recommend changes to procedures or may have authority to authorise changes to procedures.</p> <p>Another way of expressing this might be in the position responsibilities to state "may perform" certain duties or "may authorise" certain things or "may suggest" or "may recommend".</p> <p>The notes on the Implementation Notes page for this action states "If you have no staff, the pharmacy is deemed compliant". What does that mean?</p> <p>If the pharmacy has no staff, the pharmacy is considered to be compliant for this action and will be scored 2.</p>
2	<p>The notes on the Implementation Notes page for this action states "If no staff have been employed in the previous two years, the pharmacy is deemed compliant". What does that mean?</p> <p>If the pharmacy has not employed any staff in the past two years, the pharmacy is considered to be compliant for this action and will be scored 2. This would obviously include a pharmacy that never employs staff.</p>
3	<p>No additional information.</p>
4	<p>The T12E Checklist item 12 shows that it is a mandatory requirement that every employee sign the consent for audio recording for the Mystery Shopper visits. It has been agreed that the audio recording is not mandatory, although the pharmacy should advise the employee that the Mystery Shopper program may still proceed <u>without</u> the audio recording.</p>
5	<p>No additional information.</p>
6	<p>What sort of evidence will an assessor need to sight for proof that all interviewees not employed have been advised they were not selected?</p> <p>The assessor will need to sight physical evidence that the unsuccessful interviewees have been advised. Examples of suitable evidence might include a copy of a letter sent to the interviewees or a diary note that they were phoned and advised.</p>

Implementation Information and Rulings

13 Inducting staff

Action	Additional information & rulings
1	<p><i>Does the pharmacy need to complete the entire Induction Checklist (T13A) for every new employee including a minor part time position such as a delivery person working one hour a day?</i></p> <p>Every new employee, no matter what their position or number of hours worked per week, needs to be inducted into the pharmacy and an induction checklist completed.</p> <p>If using the Induction Checklist template T13A, the pharmacy will determine which items are relevant to the position and mark the other items as not applicable.</p> <p>The pharmacy may also produce their own induction checklists relevant to particular positions within the pharmacy. Each checklist might only contain the items relevant to the specific position. This is quite acceptable provided the pharmacy's checklists contain the mandatory fields of T13A.</p> <p><i>The Induction Checklist T13A requires induction on specific policies and procedures to be completed at certain times. Is this mandatory?</i></p> <p>There are certain policies and procedures on the Induction Checklist that are prefaced with a statement such as "to be completed on the first day of work" or "to be completed within the first five days of work".</p> <p>These statements have an asterisk next to them indicating that it is mandatory for the policies and procedures in that section to be discussed with the new inductee within the specified timeframes.</p> <p>The reason for this is that some information must be conveyed to a new employee either as soon as they commence work at the pharmacy or very soon after. For example a new staff member must be informed of and agree to confidentiality requirements before being in a position to hear confidential information.</p> <p>Some of the items within these sections may not be applicable to the employee's position at the pharmacy and may be indicated as not applicable in the appropriate field.</p>
2	<p><i>When implementing QCPP 2nd edition for the first time, do all employees have to be treated as new employees and complete the induction program?</i></p> <p>A new employee refers to a person who has been employed at the pharmacy in the two years prior to the assessment.</p> <p>If the pharmacy has just implemented the program for the first time, a new employee refers to any employee employed since this Standard was first implemented.</p> <p>Staff who are already employed at the pharmacy when this Standard is first implemented will not be required to undergo the induction process. However pharmacies may find the induction process a useful tool for introducing all employees to QCPP 2nd edition and a good way of ensuring all aspects of the program are covered in their training.</p>
3	<p>No additional information.</p>

Implementation Information and Rulings

14 Managing staff

Action	Additional information & rulings
1	<p><i>If all staff work regular weekly hours and they are informed of their hours in their Offer of Employment (T12E), does the pharmacy still need a written roster?</i></p> <p>The mandatory field on the Staff Roster T14A are based on the staff members name and the days and times of work. If this information is relayed to them via their initial Offer of Employment, then no further written roster is required.</p> <p>The format of the roster is up to the pharmacy as long as the information required by T12E is relayed to staff members. Other examples might be payslips, a permanent roster on the staff notice board or even verbal communication for a small staff.</p>
2	<p><i>Would a chat over morning tea be considered an acceptable communication system for a small staff?</i></p> <p>It will be up to the assessor to decide on the appropriateness of the communication system used by the pharmacy. This will be determined by asking staff about the communication system and verifying recent communications with various staff members.</p> <p>Generally speaking this would be considered a reasonable system for a small staff, but it would be up to the assessor to confirm that it is actually working.</p>
3	<p><i>Does the Performance Review System need to be a formal documented system?</i></p> <p>The '<i>evidence required at assessment</i>' for this action requires compliance with the Conducting a Performance Review procedure (P14C). This procedure has mandatory actions that would require a formal, documented review process.</p> <p><i>At the pharmacy's first assessment under QCPP 2nd edition, does the pharmacy need to have completed the performance reviews for all staff or just have the system in place ready for the first reviews?</i></p> <p>At the first assessment, the pharmacy does not need to have actually completed all staff reviews, but will need to be able to show the assessor evidence of the system they have implemented including evidence of any documentation requirements.</p>
4	No additional information.
5	No additional information.

Implementation Information and Rulings

15 Ongoing staff training

Action	Additional information & rulings
1	<p><i>This action requires a “Training Plan for each staff member”. Does the pharmacy have to produce an individual plan for each staff member or will one plan covering all staff be acceptable.</i></p> <p>Where the pharmacy determines the same training requirements for each staff member, a single plan for all staff is acceptable. Similarly a pharmacy may produce one planning document which contains different training requirements for each staff member. This is also acceptable.</p> <p><i>Where a pharmacy has individual staff training plans, will all plans need to be checked by the assessor?</i></p> <p>Where a pharmacy has individual Training Plans for each member of staff, the evidence required at assessment will involve the checking of all individual staff Training Plans up to a maximum of five plans.</p>
2	<p><i>When the assessor was assessing another standard and action to this one, he/she marked the pharmacy as non-compliant and then also marked this action as non compliant. Why?</i></p> <p>With some standards/actions the ‘evidence required at assessment’ requires a procedure and proof the procedure is followed. To determine if the procedure is being followed, the assessor may observe staff in what they do or ask the staff some questions.</p> <p>If the staff member is observed not following the procedure or answers a question that shows the staff member has no knowledge of the correct procedure, the standard/action in question will be marked as non compliant.</p> <p>However this also indicates that the staff member has not received sufficient ongoing training in their procedures and therefore the pharmacy is not compliant with this action as well.</p>
3	No additional information.

Implementation Information and Rulings

16 Dismissals and resignations

Action	Additional information & rulings
1	<p><i>The additional information for this Standard states “If you do not employ any staff you will not be assessed or scored against this Standard”. The notes on the Implementation Notes page states “If no staff have left in the previous two years, the pharmacy is deemed compliant”. These statements seem to oppose each other.</i></p> <p>If a pharmacy does not employ staff they will not be assessed or scored against this Standard. However, if a pharmacy does employ staff, but none have left in the previous two years, the pharmacy is deemed compliant.</p>
2	No additional information.
3	No additional information.
4	No additional information.
5	No additional information.

Implementation Information and Rulings

17 Maintaining safety and security

Action	Additional information & rulings
1	<p>Exactly which procedure is a pharmacy required to have for responding to emergencies?</p> <p>It is up to the pharmacy proprietor or manager to determine which procedures the pharmacy requires based on their own specific requirements.</p>
2	<p>Exactly which procedures is a pharmacy required to have for maintaining security?</p> <p>It is up to the pharmacy proprietor or manager to determine which procedures the pharmacy requires based on their own specific requirements.</p> <p>Does a pharmacy have to display the Bag Inspection Sign (T17C) at the entrance to the pharmacy?</p> <p>If the pharmacy has a procedure for Preventing Shoplifting (P17I) then the mandatory action 4 asks them to have a procedure for Bag Inspections (P17K) <u>where relevant</u>. If the pharmacy does not conduct bag inspections, no further procedure or signage is required.</p> <p>If the pharmacy does conduct bag inspections, they will need a Bag Inspection procedure (P17K). In this procedure action 1 lists the Bag Inspection Sign as a related template, but it is not mandatory to use or display it.</p> <p>If the pharmacy does have a bag inspection sign, then the sign must be displayed in a position that “a customer is able to read it prior to entering the pharmacy”, as stated on the template.</p> <p>The reason for the placement of the sign is that it is a condition of entry, so customers must be able to read any conditions of entry before actually entering the pharmacy.</p>
3	<p>Exactly which procedures is a pharmacy required to have for maintaining safety?</p> <p>It is up to the pharmacy proprietor or manager to determine which procedures the pharmacy requires based on their own specific requirements.</p> <p>Is a pharmacy required to have a safe lifting wall chart on display?</p> <p>If a pharmacy proprietor or manager decides the pharmacy requires a Manual Handling procedure, then that procedure must be compliant with the mandatory requirements of P17O.</p> <p>Manual Handling procedure P17O has a mandatory action, action 11, that requires a Safe Lifting Wall Chart (T17E).</p> <p>Safe Lifting Wall Chart T17E states ‘<i>This sign must be a minimum of A4 size and be displayed in the storage area</i>’. Therefore this pharmacy must have the Safe Lifting Wall Chart displayed in the storage area.</p>
4	<p>Do pharmacy owners that work in the pharmacy need to have a first-aid certificate?</p> <p>This is a non-mandatory requirement, however it is intended that all persons working as a pharmacist in a pharmacy has a first-aid certificate. This includes the pharmacy owner if he/she is working as a pharmacist in the pharmacy.</p> <p>The first aid training to be the “Senior First Aid” certificate and should be current as per the accredited training provider’s guidelines (usually renewed every three years).</p> <p><u>There is no requirement for the pharmacists to do the CPR competency every year. It may be done at the time of the triennial renewal.</u></p>

Implementation Information and Rulings

5

What impact does State legislative requirements for testing of electrical equipment, have on assessing how pharmacies test their safety systems?

State legislative requirements have no impact on assessing how pharmacies test their safety systems from a QCPP perspective.

The assessor will need to see the Testing Safety Systems Schedule (T17F) and ensure it is being completed in accordance with whatever frequency the pharmacy has on the form, and by whomever the pharmacy deems able to do the testing.

The assessor does not comment on who does it or how often, as the *'evidence required at assessment'* does not ask them to. The schedule is not for legislative purposes, it is a QCPP requirement only.

QCPP standards may be less than or more than legislative requirements in a particular State. Program requirements are for QCPP purposes only and not for legislative purposes.

Implementation Information and Rulings

18 Information technology

Action	Additional information & rulings
1	<p><i>Procedure P18A, in action 3, refers to setting the screen saver to automatically start (in password mode) when each computer is left idle for a short period. Does this refer to the computer in the front of shop as well?</i></p> <p>This action is about protecting computer records, of patient data, from unauthorised access. Therefore it is referring to any computer which has access to patient data. For some pharmacies this may include computers in the front of shop.</p> <p><i>Is a pharmacy able to allow all staff to have access to computer records?</i></p> <p>The ‘evidence required at assessment’ requires proof that patient data cannot be accessed by unauthorised personnel.</p> <p>A pharmacy may decide that all pharmacy staff are authorised to access patient data. In this case the assessor would only look for proof that patient data cannot be accessed by non pharmacy, unauthorised personnel.</p>
2	No additional information.
3	<p><i>A pharmacy’s backup program automatically creates a log of all backups of the pharmacy’s data. Would this be sufficient proof?</i></p> <p>Provided the backup log contains the data required by the mandatory fields on the Backup Schedule and Record template (T18A), this log would be sufficient.</p> <p><u>Back-up monitoring is acceptable only if the pharmacy can prove that they receive an immediate confirmaton that the backup process has not malfunctioned and that their information has been successfully backed up.</u></p> <p><i>If the backup program’s log is sufficient proof, what is required as proof of a ‘planned schedule’ as required by the ‘evidence required at assessment’?</i></p> <p>For a backup program that automatically backs up at specific time intervals, the schedule would be in the backup program. The pharmacy would need to show the assessor the schedule in the backup program.</p> <p>For non-automated backups, the pharmacy would need a documented backup schedule.</p>
4	<p><i>Does a pharmacy have to show the assessor the installed computer programs used to protect against potential external attack?</i></p> <p>The ‘evidence required at assessment’ requires an explanation only for the systems the pharmacy uses. The assessor is not required to sight evidence of installed programs.</p> <p>There are a number of automated and/or remote backup services being offered to QCPP members that comply with current “best practice” for backup of computer systems. The four mandatory steps in P18B should be considered guidance and the pharmacy should confirm that backups are performed and are effective and that the pharmacy has a process for detecting if the backup has not been successfully performed. Records confirming daily backup should be held by the pharmacy and retained for a full accreditation cycle.</p>
5	No additional information.
6	No additional information.
7	<p><i>Is the pharmacy required to purchase a copy of Adobe Acrobat™ for reading Adobe™ pdf files and MS Word™ for reading MS Word™ files?</i></p> <p>The pharmacy is not required to purchase a copy of these programs. The pharmacy only needs the ability to read Adobe™ pdf files and MS Word™ files. Both companies make available free versions of their programs to read their files.</p>

Implementation Information and Rulings

8 ***Is the pharmacy required to have a fax machine within the pharmacy?***

The pharmacy is required to have the ability to receive facsimile transmissions within the pharmacy. Whilst a fax machine is one suitable alternative, it is also reasonable for the pharmacy to receive facsimile transmissions via software installed on their computer system.

The assessor will require proof the software is installed and operational.

9 ***Is the pharmacy required to have an answering machine within the pharmacy?***

The '*evidence required at assessment*' requires proof the pharmacy directs after-hours enquiries to other health professionals in an emergency.

One way of achieving this would be an answering machine. Other ways might include diverting the pharmacy telephone to a mobile telephone number, using the telephone service provider features that provide answering machine facilities or after hours messages.

As the action does not specifically mention directing telephone enquiries, the pharmacy may also interpret this as customers visiting the pharmacy to find it is closed. Therefore, suitable signage visible to the public when the pharmacy is closed, would also be acceptable.

Implementation Information and Rulings

Appendix

List of Cytotoxic Drugs (Developed by Pharmacy Guild of Australia)

<u>DRUG</u>	<u>TRADE NAME</u>	<u>DRUG</u>	<u>TRADE NAME</u>
<u>Bevacizumab</u>	<u>Avastin</u>	<u>Hydroxyurea</u>	<u>Hydrea</u>
<u>Bleomycin</u>	<u>Blenoxane, Blenamax, Bleomycin</u>	<u>Idarubicin</u>	<u>Zavedos</u>
<u>Busulfan</u>	<u>Myleran, Busulfex</u>	<u>Ifosfamide</u>	<u>Holoxam</u>
<u>Capecitabine</u>	<u>Xeloda</u>	<u>Imatinib</u>	<u>Clivec</u>
<u>Carboplatin</u>	<u>carboplatin generics(no branded name)</u>	<u>Irinotecan</u>	<u>camptosar generics</u>
<u>Carmustine</u>	<u>Bi CNU, Gliadel Implant</u>	<u>Lapatinib</u>	<u>Tykerb</u>
<u>Chlorambucil</u>	<u>Leukeran</u>	<u>Lomustine</u>	<u>Cee NU</u>
<u>Cisplatin</u>	<u>Cisplatin</u>	<u>Melphanlan</u>	<u>Alkeran</u>
<u>Cladribine</u>	<u>Leustatin, Litak</u>	<u>Mercaptopurine</u>	<u>Puri-Nethol</u>
<u>Colaspase</u>	<u>Leunase</u>	<u>Methotrexate</u>	<u>Ledertrexate, Methoblastin, Methotrexate, Injection BP, Methotrexate DBL, Methotrexate Ebrewa</u>
<u>Cyclophosphamide</u>	<u>Cycloblastin, Endoxan</u>	<u>Mitozantrone</u>	<u>Novantrone, Mitozantrone, Onkotrone</u>
<u>Cytarabine</u>	<u>Cytarabine</u>	<u>Oxaliplatin</u>	<u>Eloxatin, (DBL) Oxaliplatin</u>
<u>Dacarbazine</u>	<u>Dacarbazine</u>	<u>Paclitaxel</u>	<u>Anzatax, Paclitaxel, Ebewe, Taxol</u>
<u>Dactinomycin</u>	<u>Cosmegen</u>	<u>Pemetrexed</u>	<u>Alinta</u>
<u>Dasatinib</u>	<u>Sprycel</u>	<u>Procarbazine</u>	<u>Natulan</u>
<u>Daunorubicin</u>	<u>Daunorubicin Dauno Xome</u>	<u>Raltitrexed Toumufex</u>	<u>Paclitaxel</u>
<u>Docetaxel</u>	<u>Taxotere</u>	<u>Raltitrexed</u>	<u>Tomudex</u>
<u>Doxorubicin</u>	<u>Adriamycin, Doxorubicin</u>	<u>Rutuximab</u>	<u>Mabthera</u>
<u>Doxorubicin liposomal</u>	<u>Caelyx</u>	<u>Temozolomide</u>	<u>Temodal</u>
<u>Epirubicin</u>	<u>Parmorubicin, Epirubicin</u>	<u>Teniposide</u>	<u>Vumon</u>
<u>Etoposide Phosphate</u>	<u>Etopophos</u>	<u>Thioguanine</u>	<u>Lanvis</u>
<u>Etoposide</u>	<u>Etoposide, Vepesid</u>	<u>Thiotepa</u>	<u>Thiotepa</u>
<u>Fluorouracil</u>	<u>Efudix, Fluorouracil, Injection BP, Fluouracil Ebewe</u>	<u>Topotecan</u>	<u>Hycamtin</u>
<u>Fludarabine</u>	<u>Fludara</u>	<u>Trastuzumab</u>	<u>Herceptin</u>
<u>Fotemustine</u>	<u>Muphoran</u>	<u>Vinblastine</u>	<u>Velbe, Vinblastine</u>
<u>Ganciclovir</u>	<u>Cymevene Vitrasert</u>	<u>Vincristine</u>	<u>Oncovin, Vincristine</u>
<u>Gemcitabine</u>	<u>Gemzar</u>	<u>Vinorelbine</u>	<u>Navelbine, Vinorelbine</u>