

Formulary notes for the List of Approved Medicines



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Introduction

Queensland Health is committed to the safe, rational and cost-effective use of therapeutic substances to benefit patients of its institutions and supports quality use of medicine principles.

To achieve this goal, Queensland Health believes that a statewide approach to the availability of therapeutic substances will limit duplication of effort and resources and support equity of access. This is accomplished through the oversight of the Queensland Health Medicines Advisory Committee (QHMAC) which creates, maintains and reviews a statewide list of therapeutic substances available in Queensland Health institutions and gives guidelines and general restrictions for the substances' appropriate usage.

The LAM is the official formulary for all medicines and pharmaceutical preparations approved for use in Queensland public hospitals and institutions.

Hospital and Health Services (HHS) or local hospital medicines committees, where they exist, should address local policy issues.

QHMAC has made the therapeutic cost-effectiveness of medicines its prime consideration when selecting items for inclusion on the LAM.

Formulary notes

Generic listing of medicines

Medicines on the LAM are listed in alphabetical order using the generic (chemical) names. Medicines should, in general, be prescribed using their generic names and will be dispensed accordingly.

PBS items

The LAM is intended to provide prescribers with a one-stop reference by combining the Queensland Health List of Approved Medicines (LAM) for use in Queensland public hospitals with links to Pharmaceutical Benefits Scheme (PBS) listings, if relevant. Also, for further information, the Queensland Health PBS business rules can be accessed on the Queensland Health intranet.

Restrictions

The aim of restrictions is to encourage safe and cost-effective medicine prescribing and usage in Queensland Health institutions. This is achieved by:

- controlling availability of new medicines until there is a satisfactory amount of experience gained with their efficacy and toxicity
- limiting the availability of expensive items to treat specific diseases which cannot be managed by other more economical and well-established medicines.

Medical officers (and other authorised prescribers) in Queensland public hospitals and institutions are requested to comply with the LAM when prescribing medicines and to adhere to LAM restrictions.

Restrictions, where applied, may include the following term:

- ‘specialist staff’ or ‘specialist staff and country medical superintendents’
 - to be prescribed by these senior medical staff, and clinicians working under their supervision
- ‘on the advice of an infectious diseases physician or a clinical microbiologist only’
 - in order to minimise the development of resistance to certain antibiotics
- ‘for use in accord with PBS Section 100’ or ‘for use as per the PBS indications’
 - to be prescribed in line with Section 100 (e.g. Highly Specialised Drugs Program), or Section 85 (general schedule) PBS indications
- ‘not a Queensland hospitals formulary medicine’
 - guidelines for medical superintendents/executive directors of medical services (EDMSs) to consider individual patient approvals (IPAs) for specific medicines are provided on the LAM internet home page.

Applications for medicine availability

General information

Requests to QHMAC should be made through a hospital or HHS medicines committee using either the standard or minor LAM submission form. Where a hospital or HHS medicines committee does not exist, requests should be made through the QHMAC secretariat after consultation with the local hospital medical superintendent/EDMS and the director of pharmacy.

Requests from pharmaceutical manufacturers or their agents will not be considered by the committee. Requests from Queensland Health clinical staff involved with medicine usage will be considered.

Medicines not approved for marketing where there is a specific clinical need

In general, medicines which do not have marketing approval from the Commonwealth Therapeutic Goods Administration (TGA) will not be considered for inclusion on the LAM. There are a few exceptions—a statement is included in the LAM restriction to indicate if the medicine is not TGA approved (unlicensed) for any use in Australia. For information relating to off-label use of medicines, see QHMAC’s statement on page 12 of this document.

Deletion of medicines from the List of Approved Medicines

The committee considers it important that medical staff draw attention to any medicines which they consider not to have proven efficacy or safety or which have been superseded by new medicines.

Notes for staff submitting applications to the Queensland Health Medicines Advisory Committee

Requests can be processed more quickly if the appropriate submission form is completed. Guidelines to assist clinicians, titled Guide for requesting changes to the Queensland Health List of Approved Medicines (LAM) can be accessed via the LAM webpage.

In the majority of instances, the standard LAM submission form (six pages) would need to be completed. The abridged minor LAM submission form (two pages) should only be used for requests which do not require evidence of safety or efficacy—contact the QHMAC secretariat. Electronic copies of the standard submission form can be obtained on the LAM webpage or in hardcopy from your local pharmacy department.

Importantly, standard LAM submissions should include:

1. best available evidence of efficacy and safety. It is important that applications provide a balanced assessment of the medicine and not consist only of materials provided by the pharmaceutical manufacturer
2. comparisons with alternative medicines including cost comparisons and evidence from published studies of head to head trials
3. estimates of the numbers of patients and cost impact at hospital and statewide levels, where possible.

Where alternatives are available on the LAM consideration should be given to:

- providing evidence that new medicines are at least equally efficacious, more cost-effective or less toxic than existing medicines
- avoiding unnecessary duplication of medicines on the LAM.

Applications may be directed to:

Postal address: QHMAC Secretariat

Medication Services Queensland

GPO Box 48

BRISBANE QLD 4001

Email: QHMAC-Secretariat@health.qld.gov.au

Individual patient needs

Where an individual patient's clinical needs can only be met through the use of a medicine which is not on the LAM, approval may be given by the local medicines committee or medical superintendent. Where relevant specialist expertise does not exist locally to support this process, QHMAC or other relevant specialists may be used as a reference point. Relevant special access approvals must be obtained for use of non-LAM medicines. Medicines initiated in this way will become an ongoing charge on the patient's local hospital.

The provision of medicines for use in clinical trials

It is expected that the medicines for use in clinical trials will be supplied free of charge by the pharmaceutical manufacturers for the duration of the trials. It is desirable that, in considering applications for clinical trials involving pharmaceuticals, the institutional ethics committees consider potential future financial implications. Specific policy guidelines for familiarisation drugs are included later in this introductory section.

Medicine ordering policy

Except in emergency or in circumstances with prior approval from the director of Medication Services Queensland, hospitals should purchase all pharmaceuticals and dental products through the Central Pharmacy, Health Support Queensland.

Unless appropriately approved, only medicines listed on the LAM should be ordered.

Ordering procedures are described on subsequent pages.

Policies relating to medicine use

A number of policy statements have been developed by QHMAC and subsequently endorsed by Queensland Health. These are included on the following pages. Others can be accessed on the Medication Services Queensland home page via the Queensland Health intranet.

Policy statements

Policy on unnecessary duplication of medicines on Queensland Health List of Approved Medicines

It has been accepted that the following policy will be applied in consideration for availability of new medicines.

It is not accepted that making all marketed medicines available through Queensland public hospitals and institutions would contribute to good medical practice or quality use of medicines, nor is it economically feasible.

A range of effective medicines are made available including representatives from important treatment groups. For many groups (e.g. beta blockers, ACE inhibitors), only a selection are made available. These, however, are available through all Queensland public hospitals.

When a patient is admitted on a medicine that is not listed on the LAM and a different medicine in the same therapeutic group is available there are options of:

- changing the patient to the medicine available on the LAM
- continuing therapy with the patient's own medicine which has been brought with them
- obtaining approval from the medical superintendent/EDMS for purchase of the non-LAM medicine (only if there are compelling reasons for not following either of the first two points).

Policy guidelines for familiarisation medicines

These guidelines provide the framework under which policies on familiarisation medicines may be developed by individual hospitals while maintaining consistency across the state.

Definition

Familiarisation medicines are marketed medicines which are not included on the LAM for use in Queensland public hospitals and are supplied to hospitals free of charge. This usually includes medicine samples and supplies for post-marketing studies. Some of the principles applied to familiarisation medicines may also be appropriate to apply to some Special Access Scheme (SAS) medicines.

General principles

Medicine familiarisation programs have become an issue in relation to the supply of pharmaceutical products in Queensland public hospitals. They can create considerable difficulties in terms of patient expectations and budgeting implications.

Queensland Health accepts that it is reasonable practice for senior medical staff to gain familiarity with new medicines to gain an understanding of their place in therapy. However, it is not the intent of this policy to promote or encourage the expansion of familiarisation schemes.

The use of familiarisation medicines should not interfere with usual practices, including existing tender arrangements. Familiarisation medicines should not be initiated with the expectation that they are a long-term solution to a particular problem.

Policy guidelines

The acceptance of familiarisation medicines by hospitals should only be undertaken in accordance with a policy which incorporates the following points:

- Evidence of substantial, actual or potential clinical efficacy is provided.
- Approval has been given by the appropriate hospital body (e.g. medicines committee, medical superintendent/EDMS, or in some cases, ethics committee) to use the medicine on an individual patient basis or in a group of patients.
- The number of patients for which the medicine will be indicated is small.
- Familiarisation medicines are stored, managed and dispensed through the hospital pharmacy in accordance with procedures applicable to other medicines.
- The hospital is not placed under any direct or implied obligation to the pharmaceutical company as a result of agreeing to accept and supply familiarisation medicines.
- The length of time that the familiarisation arrangement will apply is stipulated and held to. It would be usual that a request to consider the inclusion of the medicine on LAM would be made to QHMAC during this time.
- A contingency plan is agreed upon with the pharmaceutical company in the event of a medicine not receiving approval for inclusion on LAM. This may be a commitment from the pharmaceutical company to continue to support the patient by providing the medicine free of charge.

Advice to patients

Patients must be made fully aware of the status of these medicines. Patients should receive written advice that:

- the medicine is a new medicine which is not generally available in the public hospital system
- any ongoing supply is likely to be from the originating hospital and the medicine is not likely to be available from other hospitals
- after the appropriate period of review, on-going supply of the medicine cannot be guaranteed, and patients may need to be transferred to another agent or obtain the medicine privately and meet any associated costs.

Guideline statements on the use of cancer chemotherapy

- Chemotherapy should be provided through a multidisciplinary team in which doctors, nurses and pharmacists work to approved written guidelines.
- Parenteral cancer chemotherapy should be administered by specially trained nurses.
- Junior doctors should only administer cancer chemotherapy in exceptional circumstances.
- A specialist pharmacist should check prescriptions ensuring they are compatible with the appropriate guidelines.

Preparation of pharmaceuticals in hospital pharmacy departments

In general, preparations available on the LAM will have been commercially prepared or prepared in the Central Pharmacy facilities following the principles of good manufacturing practice. The extent of preparation in pharmacy departments should be minimal except for immediate pre-use reconstitutions etc.

In 1993, standards for the preparation of pharmaceuticals in Australian hospital pharmacy departments were sponsored by the National Coordinating Committee on Therapeutic Goods. This adopts a quality management approach to hospital pharmacy preparation procedures. These standards should be followed if preparation is undertaken. The current standards are published in the Journal of Pharmacy Practice and Research, 2010, vol. 40 no. 2, pp. 133–144.

Medicine ordering procedure

Except in emergency or in circumstances with prior approval from the director, Medication Services Queensland, hospitals should purchase all pharmaceuticals and dental products through the Central Pharmacy, Health Support Queensland.

Unless appropriately approved, only medicines listed in the LAM should be ordered.

Delays in receiving the goods will be reduced if the following procedures are observed:

Orders are to be sent by iPharmacy as a store transfer request, email, fax or post.

Postal address:	Director of Pharmacy Central Pharmacy PO Box 232 INALA QLD 4077
Phone:	(07) 3120 8500
Fax:	(07) 3120 8561
Email:	CentralPharmacy@health.qld.gov.au
On call service:	Telephone: (07) 3646 8111
Website:	https://qheps.health.qld.gov.au/central-pharmacy

Hospitals or clinics using email to send orders must have prior approval from the director of Central Pharmacy.

Requests for:

- Routine orders:
 - must reach Central Pharmacy no later than 2 pm to be ready for same day dispatch by 5 pm.

- Urgent orders:
 - requiring same day or overnight dispatch must also reach Central Pharmacy by 2 pm where practicable, however every effort will be made by Central Pharmacy to supply urgent orders received after this time, should the requirement be patient critical.
- iPharmacy or email urgent requests that require immediate processing:
 - hospitals should follow up with a phone call after the request is sent: 3120 8500.
- Urgent overnight orders:
 - are delivered next business day. Should a Saturday or public holiday delivery be required, order should be marked 'urgent overnight—Saturday delivery'

Urgent orders should be kept to an absolute minimum both in terms of number of orders and items per order, since such orders may incur significant additional freight and associated costs.

Restricted items

To avoid unnecessary delays in the dispatch of medicines which carry some restrictions, hospitals which do not have relevant specialist staff are requested to advise when ordering such medicines, the purpose for which a particular medicine is required and by whom it was prescribed and, if necessary, patient identification.

Special access scheme items (SAS)

When ordering unregistered items through the SAS, Central Pharmacy requires either a fully completed SAS Category A or C notification, or a Category B approval issued by the TGA or a completed SAS Emergency Stock Ordering Form. Orders and correspondence for SAS products should be directed to CentralPharmacy_SAS@health.qld.gov.au. For more information about the SAS ordering process please visit: <https://qheps.health.qld.gov.au/central-pharmacy/products/special-access-scheme>

Order detail

Adequate information regarding strengths, pack size, quantities and the corresponding Central Pharmacy stock code is essential for non iPharmacy orders.

For iPharmacy orders, quantities should be in the standard pack unit of measure.

For manually prepared orders such as handwritten, spreadsheet and email based orders, quantities should be in packs for tablets and capsules. For injectables and other items, the hospital must clearly indicate whether the quantities are based on individual units or packs.

For example, if 20 injections of promethazine 25mg/1mL are required, order in the following manner:

- 2 x pk10 promethazine 25mg/1mL inj.

or

- 20 promethazine 25mg/1mL inj.

Where appropriate, hospitals should order in outer pack or shipper quantities to facilitate handling.

Non-pharmaceutical items—e.g. surgical requisites, needles, syringes, dressings, etc.—are not listed in the LAM. Such items are not to be included in orders to the Central Pharmacy.

Dispatch and receipt

Routine orders—will be dispatched by normal road or air transport depending on **client-specific logistics**.

Urgent orders—will be sent by air freight or other appropriate transport.

On receipt, all goods should be thoroughly checked against the packing note and any credit/return claims made within **seven business days**.

Returns

All return/credit requests must be made via Central Pharmacy's online request form located at: <https://qheps.health.qld.gov.au/central-pharmacy/order-issues>

Only items granted an approved return authorisation (RA) number will be permitted for return to Central Pharmacy or credit supplied. Central Pharmacy will organise the pick-up for any items approved for return, no unauthorised deliveries will be accepted. Items approved for return must be packaged in a manner that maintains the manufacturer's approved storage conditions.

Please note: financial responsibility for returned items remains with the sending hospital/pharmacy until received at Central Pharmacy in saleable condition maintaining manufacturer's storage conditions.

For more information, please consult Central Pharmacy's "Goods Return Policy" located online at: <https://qheps.health.qld.gov.au/central-pharmacy/order-issues>

Expired items for destruction should not be returned to Central Pharmacy. To reduce medicine wastage, if an item (particularly an expensive item) is unlikely to be used before its expiry, please complete the online return request specified above to see if the item can be returned for use elsewhere within the state.

Attention to these guidelines for ordering procedures and the return of goods will contribute to the efficiency of supply and use.

Redistribution of stock

If stock is supplied from hospitals to other hospitals or institutions, adequate records must be maintained to allow sites supplied to be identified in the event of a product recall.

Off-label use of medicines

The off-label use of medicines is defined as circumstances where a medicine is used in ways other than as specified in the product information which has been approved by the Therapeutic Goods Administration (TGA). Examples include when a medicine is prescribed or administered for another indication, at a different dose, via an alternate route of administration, or for a specific patient group outside the registered use. Prescribing off-label is unavoidable and very common. Off-label use does not apply to a medicine which is not licensed in Australia, or to a TGA registered medicine whose formulation is modified.

The Council of Australian Therapeutic Advisory Groups (CATAG) has published Rethinking medicines decision-making in Australian hospitals: guiding principles for the quality use of off-label medicines. This document aims to provide a consistent framework for decision-making for off-label use, and outlines a careful and responsible approach to be applied when medicines are used off-label in 'routine', 'exceptional', 'conditional' or 'research' circumstances.

QHMAC agrees, 'in principle', with the CATAG guiding principles. QHMAC supports the view that "routine" use is justified where there is high quality evidence supporting the safe, efficacious and cost-effective use of the medicine off-label and an overall favourable harm-benefit ratio. In those circumstances, the usual process for consent to therapy, should apply and no additional measures are required. QHMAC members consider that, where robust evidence or gold standard clinical guidelines support use, which is off-label in Australia but may be well established practice in Australia or other first world countries, this use could be considered 'routine use'.

QHMAC concurs with the CATAG guiding principles in that, where the evidence for a medicine's use is limited, unclear or controversial, it is necessary to obtain informed patient consent (and, where possible, it should be written consent) and all details should be clearly documented in the patients' medical notes. In those cases monitoring use, outcomes and adverse events should be assured. The approach which should be adopted in these cases (i.e. exceptional, conditional and research use) is outlined in the CATAG guiding principles.

QHMAC recommends the flowchart (Figure 1 of the CATAG guiding principles) as an aid to ensuring the delivery of quality use of off-label medicines in Queensland public hospitals and the associated processes required.

CATAG's guiding principles recognise that, for some TGA registered medicines, commercial considerations can act as a barrier to TGA registration being sought for other, well evidenced indications and uses; and off-label use, in itself is not illegal or unethical. On occasions, QHMAC knowingly recommends LAM restrictions which specify an off-label use. These recommendations take safety, efficacy and cost-effectiveness into account and are made on the basis that QHMAC considers use is supported by reasonable quality evidence and there is an acceptable risk benefit profile in the specific patient group. Wherever identified, off-label LAM restrictions include the disclaimer:

When medicines are used in ways other than as specified in the TGA approved product information, documentation and evaluation should be undertaken with reference to QHMAC's advice in the LAM formulary notes and the CATAG guiding principles for the quality use of off-label medicines (www.catag.org.au).