

Management and governance of individual patient approvals for medicines and other therapeutic goods

Purpose

This document has been developed to guide Hospital and Health Services (HHSs) to manage, in a consistent way, individual patient approvals (IPAs) for access to medicines for indications which are not included on the Queensland Health List of Approved Medicines (LAM). A robust process, managed by HHS medicines committees, must be in place to ensure that access to medicines is equitable across the state, medication usage is evidence based, patient safety is assured and financial sustainability is maintained.

Scope

This guideline shall apply to the processes undertaken when Queensland Health (QH) clinicians wish to prescribe, for QH public patients, medicines which are not included on the LAM. This includes prescribing items that are not listed on the LAM, despite being included on the Pharmaceutical Benefits Scheme (PBS), and prescribing LAM medicines for other than the LAM indications.

It does not include all considerations associated with off-label use of medicines. (Refer to *Appendix E* for further guidance).

Background

QH's limited formulary reduces unnecessary duplication of medicines. Refer to *Appendix D* for details on how it applies to enteral nutrition products, PBS medicines and all inpatient and outpatient prescribing.

Principles

Governance and management

All applications for IPA are the responsibility of HHS medicines committees. The QHMAC secretariat will support communication between these committees and Queensland Health Medicines Advisory Committee (QHMAC), to promote consistent statewide processes. (Refer flowchart *Appendix A*).

Initiation and continuity of therapy

All QH clinicians should comply with the LAM when prescribing for patients of Queensland public hospitals and institutions.

When a clinical need to **initiate** a non-LAM medicine/indication is identified, IPA must be sought from the HHS medicines committee.

When a requirement is identified to **continue** an inpatient on a non-LAM therapy, and when the patient's own medicine cannot be used, approval must also be obtained through a robust mechanism, with oversight by the HHS medicines committee as decided locally (*Use of Patient's own Medicines* guideline is available on the Queensland Health intranet).

Where an IPA has been approved at a referral hospital for a patient resident elsewhere, responsibility for ongoing supply rests with the HHS in which the patient resides. Full details can be found in Schedule 1, Section 9 of the service agreements between the Department of Health and the HHSs, available at <https://www.health.qld.gov.au/system-governance/health-system/managing/agreements-deeds>

Approval periods and extension of approvals

IPAs must be granted for a defined and limited period of time. Ongoing approval must only be considered after the prescriber has provided a report on the response to treatment using objective outcome measures.

Emphasis is on the prescriber taking responsibility for the ongoing monitoring of the patient's response, with appropriate cessation of treatment in the event of side effects or lack of efficacy.

If new information emerges relating to the efficacy, cost (including PBS subsidy status) or LAM listing of a medicine, the HHS medicines committee can reserve the right to review relevant IPAs.

Outpatient approvals

The Queensland public hospital system is not an alternate funding mechanism for community patients. Private community patients are not to be referred to QH facilities solely with the intent to gain access to non-PBS subsidised medicines.

An IPA for use by an outpatient must take into account the total cost impact on QH, including all associated costs such as the load on outpatient clinics and resources required to dispense the medication, and ensure that processes are in place at the patient's local hospital to ensure continuity of supply and regular review of the ongoing need for the medicine.

Follow up must occur in a QH facility and include documentation of response to therapy and side effects recorded in the patient's QH medical file.

External advice

The committee may identify circumstances where external consultation could be sought.

Expert Support

A range of expert advisers are to be identified to provide support to sites without expert or fully resourced medicines committees and for the occasions where an HHS committee does not have expertise in a specific area of practice. External expert advice (such as an on-call clinical pharmacologist, nominated senior specialist or another medicines committee) should be sought as required.

High cost medicines which are not listed on the LAM

High cost medicines are those with either a high unit cost or with a high volume of use resulting in an overall high cost. Advice from another HHS high cost medicines committee could be sought when the anticipated cost of treatment is, for example, >\$10,000 per patient per year/course, or \$100,000 per hospital per year.

Processes are also to be identified to review and share information on medicine committee approvals of high cost non-LAM items.

Urgent and out-of-session approvals

Circumstances where urgent approvals (i.e. after hours) are requested so that medicines can be commenced immediately will be uncommon and must not include occasions where prescribers have not planned ahead. Urgent approvals will only be given in life threatening circumstances where delaying treatment would lead to significant patient mortality/morbidity.

The HHS committee may establish a mechanism for approvals to be granted out-of-session, where it is agreed that a decision cannot wait until the next meeting of the medicines committee (e.g. delegation of this role to the medical superintendent or another medicines committee delegate). However, for high cost medicines, decisions must be delayed (unless urgent) until the next meeting of the appropriate committee.

Details of these urgent and out-of-session applications and approvals must be forwarded immediately to the HHS medicines committee to be recorded and tracked to inform future decisions and approvals.

Delegation to approve out-of-session requests

Delegations should be minimised to allow the resources of HHS medicines committees to be targeted at assessing applications that are considered to be high risk or high cost. Where delegations are used, they must be approved by the medicines committee for a discrete period of time and be minuted accordingly.

All delegations must be made in writing and outline the scope, and identify suitable thresholds to initiate progressing to the full medicines committee, or to QHMAC. The committee should produce consensus guidelines for the delegate to follow in the future for that particular medicine for the particular indication.

Delegated approvals must always be recorded and reported to the medicines committee and are generally not the mechanism to put in place local “blanket approvals”. Where guidelines have not yet been put in place by the committee, delegates must justify their decision making to the medicines committee next time the committee meets.

Committees may choose to have mechanisms in place to streamline “minor” approvals. They may decide that some approvals are suitably delegated to the local medical superintendent, a head of department (including director of pharmacy) or local hospital specialist. For instance, the HHS committee may agree that the local medical superintendent (or another delegate) give individual patient approval where clinical justification exists for items under a certain value e.g. \$1,000 per patient or \$10,000 per annum—refer *Appendix B*.

Patient group (“blanket”) approvals

Patient group approvals are strongly discouraged. Their use can cause disruption to the management of patients when transferred between health care facilities, leading to financial, clinical and administrative issues at the receiving hospital, and they do not reflect the QH intent of equity of access. For these reasons, HHSs are encouraged to forward submissions for patient group approvals to QHMAC for consideration.

If QHMAC does not endorse the addition of an item to the LAM or does not endorse its use in the proposed patient group, HHS medicines committees must review the evidence to support a need for current patients to continue on the medication, and carefully consider the initiation of any new patients on the item.

Decisions should be made locally, and statewide, to identify trigger levels where IPA applications should no longer be managed locally. At the stage where their large volume or broad impact is significant, these should be forwarded to QHMAC. IPA trigger levels at a single site may be a proportion of drug budget and are likely to vary between facilities. (Refer flowchart *Appendix A*). If QHMAC does not subsequently endorse this use, HHS committees should review and reconsider these local IPAs.

Processes

Applications for IPAs

All applications to HHS medicines committees for initiation of non-LAM therapy for individual patients must present evidence of efficacy, safety and cost compared to alternate therapies on the LAM. Applications are to be made on an individual patient approval request form (available through local hospital pharmacy departments).

When IPA has been granted

Record keeping and review

Suitable records of approvals must be kept. Review of clinical progress and reporting of outcomes is essential to ensure learnings are shared and processes are rigorous. In addition, this reporting provides a mechanism for ceasing the provision of funded medicine if there is a lack of benefit or if detriment is occurring. Some elements of these records may currently be maintained in systems such as iPharmacy. (Refer *Appendix C*).

Funding

Where an IPA has been granted for initiation of a non-LAM medicine, the local hospital will be responsible for providing ongoing supplies, providing the initiating hospital has forwarded documentary evidence of the IPA approval. The financial impact on small sites must be borne in mind when patients are transferred back to their local hospital and measures should be put in place to assist this transition in patient care.

Advice of approval

The initiating hospital’s pharmacy (or dietetics) department must be provided with the signed IPA approval prior to the prescription being presented for initial supply of the non-LAM

medicine. Where applicable, the patient’s local hospital must also be contacted and the relevant documentation forwarded to ensure patient therapy can be continued. (Refer Appendix C).

Appeals

There must be an avenue of appeal for unsuccessful applicants within each HHS, as decided locally.

When IPAs are strongly discouraged

- If QHMAC has considered the medicine for the requested indication and rejected its addition to the LAM for the relevant patient group and where the applicant cannot identify strong grounds for a clinical need in a particular patient (access to all QHMAC recommendations is available on the Queensland Health intranet–search for “QHMAC meeting outcomes”)
- If the Pharmaceutical Benefits Advisory Committee has considered the medicine / indication / patient group and does not recommend Commonwealth funding
- If a case does not meet the criteria of a Commonwealth funded access program for the proposed indication (e.g. Highly Specialised Drugs Program or the PBS)
- When required for initiation of therapy, where a clinically similar item or one in the same therapeutic group is included on the LAM
- If a clinical need is identified for a medicine with the potential for widespread use in Queensland public hospitals or a number of local individual approvals have already been given (in these cases, a submission should be made to QHMAC to request addition to the LAM).

Approval

Original version approved by: **Consensus of the Queensland Health Medicines Collaborative, March 2010.**

Subsequent versions endorsed by QHMAC.

Definitions

Term	Definition / explanation / details
Individual patient approval (IPA)	The mechanism in Queensland Health public hospitals which allows a local approval to be given for patient access to medicines that are not included on the LAM for the required indication.
Queensland Health List of Approved Medicines (LAM)	The restricted list of medicines, and the indications for use, which the Queensland Health Medicines Advisory Committee has recommended for statewide prescribing in Queensland public hospitals and institutions.

Term	Definition / explanation / details
Medical superintendent	Refers to the executive director of medical services, clinical chief executive officer, country medical superintendent or other medical officer who has the authority or been given the delegation to make clinical decisions to approve, or not to approve, the use of non-LAM medicines.
Medicine	For the purpose of this document “medicine” refers to pharmaceuticals and other therapeutic substances including intravenous fluids and nutritional items.
Non-LAM medicine	Medicines or indications not included on the LAM. Note: Many items which are listed on the Pharmaceutical Benefits Scheme (PBS) are non-LAM medicines.
Pharmaceutical Benefits Scheme (PBS)	Operates within Queensland Health public hospitals and institutions through the PBS Access Program (Queensland Health PBS Business Rules are available on the Queensland Health intranet). This program allows Commonwealth subsidy for PBS medicines for Queensland Health outpatients, oncology day therapy patients and patients on discharge.
Queensland Health Medicines Advisory Committee (QHMAC)	The statewide based advisory committee which makes recommendations on additions and changes to the LAM. Recommendations which are approved by the committee sponsor, acting on behalf of the Director-General of Queensland Health, are then included in the LAM and form Queensland Health guidelines.
Standing offer arrangement (SOA)	SOAs are in place for a number of therapeutic groups. (Refer to Appendix D).

Related Documents

- Queensland Health List of Approved Medicines (LAM)
- Individual Patient Approval request form—contact your local hospital pharmacy department
- Use of patient’s own medicines guideline – available on the QH intranet

Further Information

For information please contact - QHMAC Secretariat, Medication Services Queensland, Chief Medical Officer and Healthcare Regulation Branch. Email: QHMAC-Secretariat@health.qld.gov.au

Appendices

Appendix A: Flowchart—governance of individual patient approvals (IPAs)

Appendix B: Risk and delegation

Appendix C: Records, review and advice

Appendix D: Background

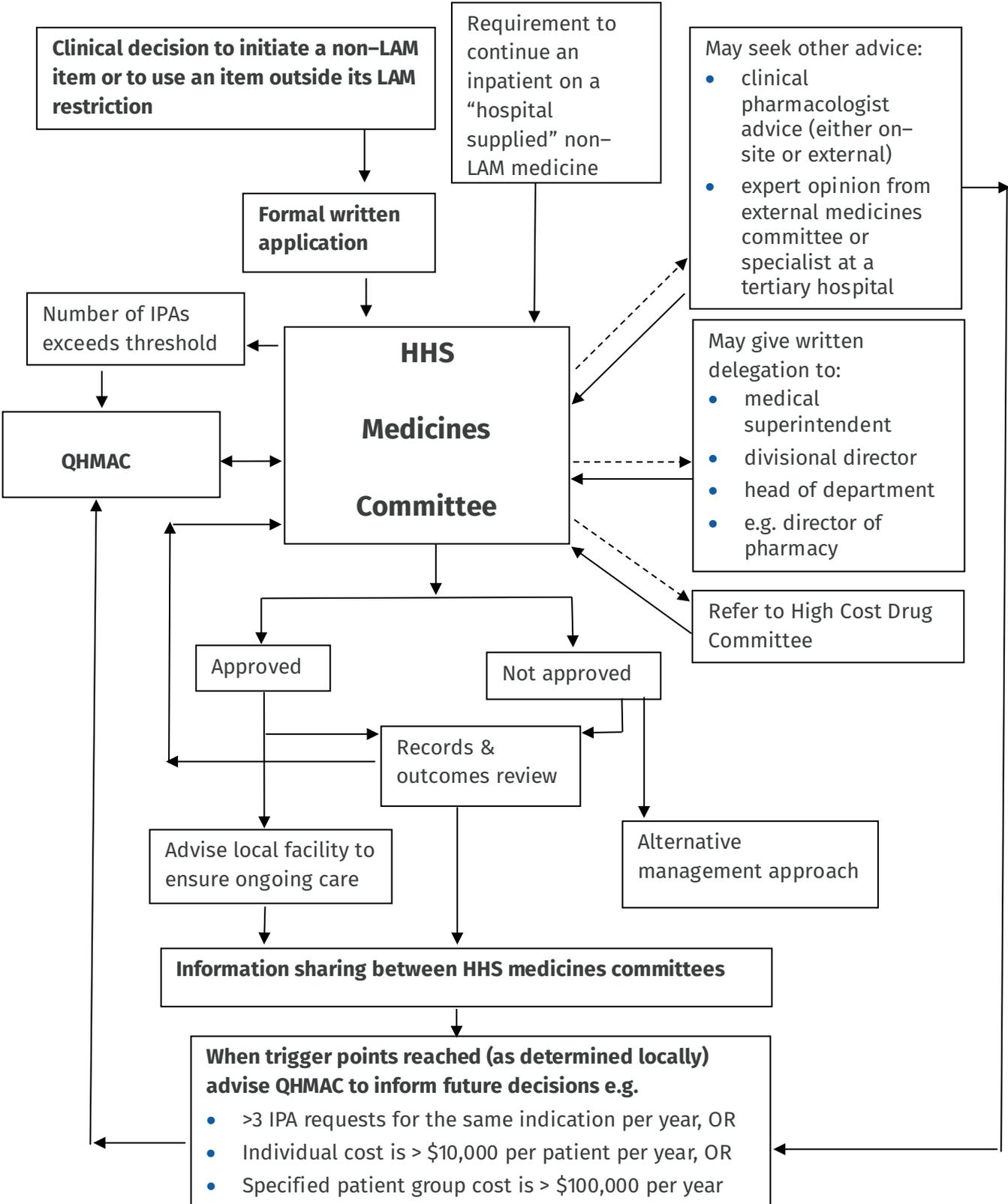
Appendix E: Off-label use of medicines

Version Control

Version	Amendments	Author/s	Date
	Draft in consultation	QHMAC-Secretariat	June 2009 – June 2010
1.3	Updated on QHMAC Nutritional Subcommittee (NUSCO) advice with reference to nutritional items.	QHMAC-Secretariat	May 2011
1.4	Included note at page 12 of 15 about revised version of statewide IPA request form (App 6)	QHMAC-Secretariat	May 2011
2.0	Changed appendices names and detached statewide IPA request form–made IPA request form a stand-alone interactive document.	QHMAC-Secretariat	June 2011
3.0	Web linked details updated, and format changes made in line with QH editorial style guide. Deletion of definitions as these are now included in document body text. Addition of <i>Appendix E: Off-label use of medicines</i> .	QHMAC-Secretariat	February 2016
4.0	Revised box in <i>Appendix A</i> . Interactive stand-alone IPA request form no longer on web. Directors of Pharmacy are developing and sharing documents for this purpose.	QHMAC-Secretariat	May 2016
5.0	Document reformatted for new LAM interface.	QHMAC-Secretariat	June 2016
6.0	Amended to reflect current arrangement as defined in the “QH guideline: Inter-hospital management of the supply of medicines” (May 2016).	QHMAC-Secretariat	September 2017
7.0	Reformatted onto new QH template; under ‘Initiation and continuation of therapy’ included details on HHS responsibilities re ongoing supplies.	QHMAC-Secretariat	October 2021

Governance of individual patient approvals (IPAs) Appendix A

(refer to guideline for full details)



Risk

Risk level relates to:

- risk to the patient of experiencing serious side effects
- level of experience with use of a particular medicine (i.e. length of time in market)
- level of experience with the use of a medicine to treat a particular indication or patient group (e.g. the elderly).

The level of risk diminishes as the level of familiarity and the volume of evidence grows for the use of a medicine in a particular indication.

If IPAs for particular low risk and low cost medicines become common, then the medicines should be considered for either formulary listing or drafting of standardised reporting criteria and approval periods.

Delegation of approvals

Delegations should take into account the relevant expertise and level of financial delegation of the delegate. However, it is generally preferable to nominate an individual member of the medicines committee who is independent of the particular area so that a balanced and objective decision can be made. External advice may need to be sought. Although the director of pharmacy may be delegated to approve non-LAM presentations of LAM PBS medicines for inpatient use, the director of cardiology would not always be delegated to consider approval requests for cardiovascular medicines, unless this was previously agreed for specific circumstances or medicines.

Taking into account cost, anticipated benefit and whether an approval is for an inpatient, for extended use as an outpatient, or for a one-off supply, the HHS medicines committee might choose to delegate approvals to an individual in the following circumstances:

- a) medicines for which QHMAC has provided guidance notes for IPA approval (refer to 'LAM' home page on the Queensland Health intranet)
- b) medicines for which cost effectiveness is likely and QHMAC has recommended that access to the medicine (for the requested indication or the specific patient group) is most suitably obtained through IPA (refer to QHMAC meeting outcomes, available on the Queensland Health intranet)
- c) to allow continuation of an inpatient's PBS medicine, when all other options to use the patient's own medicines have been exhausted, and it is clinically imperative that therapy is not changed
- d) use of a non-LAM form, strength or presentation of a LAM medicine, or a variant (e.g. flavour) of an enteral nutrition tender item, which is required for patient therapy
- e) as a short-term measure where no other option yet exists (refer to section on Delegation to approve out-of-session requests)

Such delegations should be intended to streamline patient care and should not constitute local "patient group" or "blanket" approvals for items QHMAC has not been asked to consider,

or has rejected, for addition to the LAM. These delegations would not usually be suitable on initiation of therapy or when it is clinically appropriate to use a LAM item.

Records, review and advice Appendix C

Record keeping

All approvals, including verbal or telephone, require suitable record keeping which should include a tracking number or other identifier. In the case of urgent approvals, this may be done retrospectively.

The record may be in electronic form (e.g. may be maintained in iPharmacy) and should include patient details (name, UR number, telephone, address) and details of treatment (including length of approval). It is preferable to include brief clinical details and rationale for approval.

Review and reporting

Review and reporting is critical for clinical governance and audit—at the local and state levels.

All individual patient approvals should be tracked and measured locally. Patient outcomes and usage data should be reported to share learnings and inform future decisions.

All approvals (including those made by the Committee or its delegate) should be recorded, collated and subject to peer review. Regular reports should be provided to the HHS medicines committee or hospital executive, as decided locally.

Reports are essential to allow extension of approval past the end of the approval period.

Specific recording and monitoring of prescribing against the agreed protocol may be undertaken and Drug Utilisation Evaluations should be conducted at regular intervals.

Approvals, non-approvals and treatment outcomes should be shared with other HHSs to allow collation of n=1 events to provide more meaningful and useful data statewide.

Some IPA approvals may have the potential to be progressed to QHMAC for review and/or to the relevant pharmaceutical company for input or feedback.

Circulation of advice

The specialist initiating therapy must:

- a) arrange for the Pharmacy (or dietetics) department at the initiating hospital to be advised of the IPA approval and relevant details. To allow timely supply and dispensing, this must be done prior to the patient presenting at pharmacy with the prescription.
- b) take appropriate steps to ensure that the patient's local hospital has been contacted and that documentary evidence of the IPA approval has been provided to ensure safe and sustainable continuation of the patient's therapy by the local hospital. Also, that there is a process in place for regular review of the on-going need for therapy.

Unnecessary duplication of medicines

Queensland Health believes that a state-wide approach to the availability of therapeutic substances in Queensland public hospitals limits duplication of effort and resources and facilitates equity of access to medicines across the State. Queensland Health policy on unnecessary duplication of medicines states that “it is not accepted that making all marketed medicines available would contribute to good medical practice or quality use of medicines, nor is it economically feasible”.

Hence only a limited selection of medicines, particularly when there is wide representation in a therapeutic group, are included on the LAM. (For example, there is a limited number of LAM listed angiotensin converting enzyme inhibitors.) Decisions to limit the number of LAM items in a therapeutic group is based on clinical need and cost effectiveness. Items considered to have limited or insignificant clinical advantages over LAM therapies are often not listed on the LAM.

Generic prescribing and QH Standing Offer Arrangements (SOAs)

Medicines are generically listed on the LAM and generic prescribing is essential to ensure quality use of medicines. QH enters into SOAs with pharmaceutical companies to obtain the most competitive prices for therapeutic goods. These arrangements, also referred to as “tenders”, often result in only one brand of a particular generic medicine being available in QH hospitals. To maintain the integrity of the tender process, alternate brands of medicine must not be used without individual patient approval.

Nutritional products

All enteral, and many parenteral, nutrition products used in Queensland public hospitals and clinics are assessed by QHMAC, with advice from the Nutritional Subcommittee (NUSCO) of the Dietitian Nutritionist Strategic Coalition.

Products deemed by the committee to be efficacious and cost effective, and required by QH clients, are included in the LAM (refer to Nutritional Products document on the LAM homepage on the Queensland Health intranet). Not all variations of nutritional supplements are available and, as they are usually subject to tender arrangements, a selection of brands and flavours are available. Items which are not on the LAM or the current tender require a local approval.

The Pharmaceutical Benefits Scheme (PBS)

While QHMAC takes into account the PBS status of medicines when making a recommendation for inclusion on the LAM, the Committee does not include all PBS items on the LAM. Doctors prescribing in QH hospitals and institutions are required by the PBS Business Rules to limit all prescribing to items on the LAM, and must request individual patient approval to prescribe non-LAM items, including those that are PBS listed. QH clinicians are not to prescribe non-LAM PBS medicines for public patients without appropriate approval being granted—despite the location at which the prescription is dispensed.

Off-label use of medicines

Appendix E

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).