The Pharmacy Guild of Australia

POLICY

Medicines Access Programs (MAP)

Also referred to as Compassionate Use Programs, Expanded Access Programs, Product Familiarisation Programs, Cost-Share Programs, and Early Access Programs. This policy does not apply to products used as part of a registered clinical trial approved by the relevant Human Research Ethics Committee (HREC).

Position

The Pharmacy Guild of Australia supports the early access to life saving medicines for all Australian's when provided in accordance with all relevant policies, procedures, codes of conduct outlined by regulatory bodies such as the Therapeutic Goods Administration (TGA).

The Guild recognises that availability of these early access programs such as MAP provide a mechanism for patients with a clinical need to access medicines that might otherwise be out of their financial reach because the medicines are not listed on the Pharmaceutical Benefits Scheme (PBS).

Patient and prescriber involvement

The Guild notes:

- The prescriber should only prescribe those medicines for which there is an approved clinical indication.
- If an application for PBS listing has been made then the medicine should only be prescribed as part of the MAP, consistent with the requested PBS restriction.
- Patients should only be commenced if there is a guarantee by the sponsor that supply of medicine will continue for as long as the patient requires it or until it is subsidised by the PBS. The patients should not be put at risk if the program is ceased or PBS-listing does not eventuate. This is consistent with Council of Australian Therapeutic Advisory Groups guidelines.[1]
- Patients and carers should be provided with all the necessary and relevant information about the medicine and the program.

[1] http://www.catag.org.au/wp-content/uploads/2012/08/OKA10428-CATAG-Guiding-Principles-for-Australian-Hospitals-FINAL-pdf.pdf

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Community pharmacy involvement in MAP

- Pharmacies should be provided with all the necessary information about the medicine so that they can provide appropriate counselling to the patient and assist in pharmacovigilance, monitoring any side effects or interactions.
- Where a community pharmacy is involved in a MAP it should store, manage, dispense and maintain records for these medicines as they would any other medicines. This will ensure interactions can be managed, monitored or the product packed in a patient's Dose Administration Aid (DAA) if used.
- Due to the above professional activities required of a MAP, community pharmacies should be adequately remunerated for the work involved.
- A community pharmacy has the right to decline involvement in a MAP on moral and/or ethical grounds.
- Ideally, an agreement should be formed between the sponsor and the Guild for community pharmacy involvement in MAP. This could include details on supply and remuneration arrangements to community pharmacies, a standardised process for monitoring pharmacovigilance and recording (e.g. GuildCare).

Background

Medicines Access Programs

MAPs can go by a number of different names such as compassionate use, expanded access, product familiarisation, cost-share, early access programs but all have the same principle that patients can get access to a medicine that is subsidised by the sponsor.

These programs provide patients with access to medicines that may not yet be registered in Australia or may be registered with the TGA but not yet subsidised under the PBS. MAPs allow patients to access the medicine before registration or subsidy and differ from the Special Access Scheme (SAS).

Medicines Australia

The Medicines Australia Code of Conduct[2] makes the following points with regards to Product Familiarisation Programs (PFPs):

- Companies must ensure that all Product Familiarisation Programs (PFP) have the aim of allowing the medical profession to evaluate and become familiar with a product.
- A company will make available on request the rationale for a PFP without delay, but in any event in no longer than 10 working days from the date of the request.
- Companies must not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.
- PFPs must involve patients being treated for approved indications of the product.
- The company must provide a patient information document to be given to the patient by the healthcare professional which explains that the product will be provided under a PFP for a fixed period, after which it may only be available on a private prescription if it is not reimbursed under the PBS at that time.
- PFPs may be initiated at any time following the approval of the product for registration; or the approval of new indications. Only one PFP may be conducted for a particular indication.

[2] https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf

- The enrolment period for patients into the PFP must not exceed six months. However, at the expiry of the enrolment period, companies may extend the period of enrolment where there is a strong clinical and/or equity rational for such an extension. The length of time each patient may receive treatment under a PFP should be determined by the clinical rationale.
- Only starter packs may be supplied free of charge to prescribers for these programs for use by a patient. Trade packs may only be supplied free of charge for a PFP if the product is dispensed through a pharmacy or other authorised dispensary or dispenser.
- A PFP will allow an individual healthcare professional to enrol a maximum of 10 patients in the program.
- No formal protocol is required for PFPs where individual patient data is not collected. Aggregated data on a healthcare professional's experience with the product may be collected under a PFP where there is no formal protocol. A PFP may be set up in a manner that enables the rigorous collection of individual patient data under a formal protocol. The protocol should be reviewed within the company to ensure that patient data collection complies with all relevant guidelines and legislation, particularly with respect to patient consent and data de-identification.
- Suspected adverse drug reactions reported during the PFP must be reported to the TGA in accordance with the current TGA Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines.

Council of Australian Therapeutic Advisory Groups (CATAG)

The CATAG has developed the "Managing Medicines Access Programs" documents with provides some principles for the governance of Medicines Access Programs in Australian Hospitals. The Guiding Principles are:

1. The management and oversight of all MAP should be delegated to a drug and therapeutics committee (DTC) or equivalent.
2. Appropriate advice regarding the supply of medicines within a MAP should be provided to patients.
3. Prescribers should comply with DTC requirements when participating in a MAP.
4. A formal agreement should exist between pharmaceutical companies and hospital or health service organisations when participating in a MAP.
5. Responsibilities of all parties involved in the provision of the MAP should be assigned and clear.

Related Policies

N/A

Authority

Endorsed:

National Council – January 2018

Reviewed:

Policy and Regulation Sub-Committee – December 2016
Pharmacy Viability Committee – December 2016