The Pharmacy Guild of Australia

2 April 2013

Submission to the Review of Pharmaceutical Benefit Scheme Medicines Used to Treat Asthma in Children

1. Terms of Reference

The Terms of Reference for the Review are to:

1. Review the evidence on the efficacy and safety of single ingredient and combination product use of inhaled long acting beta2 agonist (LABA) in children not previously considered by the Pharmaceutical Benefits Advisory Committee (PBAC) in making recommendations to the Minister.

2. Review the Drug Utilisation Sub-Committee report on utilisation of combination inhaled cortico-steroid (ICS)/LABA considered by PBAC and supplement this analysis with any additional data and clinical information sources available in Australia.

3. Identify areas of prescribing for childhood asthma in Australia where clinical practice is inconsistent with clinical guidelines; and if there is evidence that supports this practice.

4. Identify and review recent (past five years) healthcare professional and consumer education in the area of medication management in children with asthma.

5. Identify effective interventions that have resulted in improvement of prescribing and quality use of medicines in the context of childhood asthma using overseas or Australian literature.

2. Background

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the Review of Pharmaceutical Benefits Scheme (PBS) Medicines Used to Treat Asthma in Children prepared by the Department of Health and Ageing.

The Guild is the national peak pharmacy organisation representing community pharmacy. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

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Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy.[1] The Guild highlights that Australia's 5,200 community pharmacies operate in a highly regulated environment to provide the highest quality of care in delivering cost-effective, safely dispensed medicines under the PBS.

Community pharmacy also maintains a high standard of patient care with the Quality Care Pharmacy Program (QCPP) which is recognised as the Australian Standard for service provision within the community pharmacy sector. The QCPP is a quality assurance program aimed at raising the standards of pharmacy services, ensuring community pharmacies provide a uniform approach when delivering professional services and customer care. QCPP accreditation has been shown to support continuous improvement in the supply of medicines.[2]

As of 31 December 2012, approximately 98% of Australian community pharmacies were registered with QCPP and approximately 92% were accredited or in the process of becoming accredited.

Dispensing is a fundamental component of pharmacy practice. In addition to the labelling and supply of a product according to legal and regulatory requirements, it involves the interpretation and evaluation of the prescription, selection or preparation of a pharmaceutical product, and the provision of information to ensure safe and effective use of the product. Pharmacists must dispense accurately, reflect the prescriber's intentions and be consistent with the needs and safety of the consumer.[3]

3. Context

- Combination ICS/LABA inhalants subsidised on the PBS include:
    - Fluticasone + Salmeterol (Seretide™)
    - Budesonide + Eformoeterol (Symbicort™)

- Seretide is listed as a restricted benefit on the PBS for the following situations:
    - Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol and fluticasone
    - Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol and fluticasone

- Symbicort is listed as a restricted benefit on the PBS for the following situations:
    - Patients who had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformeterol and budesonide
    - Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformeterol and budesonide
    - For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids

- For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids
- For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroids and a long-acting beta-2 agonist

4. Comments

The Guild provides comment with respect to items 4 and 5 of the Terms of Reference for review:

4. Identify and review recent (past five years) healthcare professional and consumer education in the area of medication management in children with asthma.

5. Identify effective interventions that have resulted in improvement of prescribing and quality use of medicines in the context of childhood asthma using overseas or Australian literature.

There have been no education or intervention programs in recent years within the community pharmacy sector for medication management or QUM support *specifically* for children with asthma, however there are some training courses and pharmacy interventions within the broader context of asthma support or management, which could be applied to and/or adapted for children with asthma.

4 a) Pharmacy Asthma Management Service

The Pharmacy Asthma Management Service (PAMS) was piloted in 2009/2010 as part of the Fourth Community Pharmacy Agreement (Fourth Agreement). PAMS entailed the in-pharmacy provision of a series of patient (or carer) education sessions, medication review, assessment of asthma control and spirometry measurement for adults at risk of poor asthma control. Where appropriate, patients were referred to their GP for review.

PAMS was based on a randomised controlled trial[4] completed in 2006 in which the pharmacist asthma support service demonstrated a positive impact on asthma control, medication use, asthma quality of life, asthma knowledge and perceived control of asthma.

As part of the Fourth Agreement, PAMS was intended to be piloted in two stages, with stage 1 investigating the outcomes and benefits of 3 versus 4 consultations and stage 2 implementing the recommended service of 3 or 4 consultations (as determined from stage 1) more broadly from Australian community pharmacies. Due to timing issues within the Fourth Agreement, stage 2 did not eventuate.

The service involved a series of 3 or 4 consultations with a trained and credentialed pharmacist over a 6 month period. As part of the Fourth Agreement pilot program, patients had to be over 18 years of age. Patients were recruited using a questionnaire

for risk of poor asthma control and were usually identified while purchasing asthma medicines or targeted from dispensing histories.

The service demonstrated:

- improved asthma control
- improvement in inhaler technique
- increased ownership of written action plans
- improvement in medication profile
- improvement in asthma knowledge
- decline in perceived impact of asthma on quality of life
- enhanced perception of asthma control

As part of the service, pharmacists received a readiness payment of $500 to contribute to preparing the pharmacy for the provision of PAMS, a training subsidy of up to $1120 to cover costs for additional pharmacist training, and $100 per consultation. Similar positive changes were observed for both intervention types (i.e. 3-visit and 4-visit) and the programs evaluation report[5] indicated that in almost all health outcome measures, there was no significant difference between the 3-visit and 4-visit interventions.

The evidence for improved patient outcomes from this service is strong. While the service was specifically targeted as part of the pilot program to people with uncontrolled asthma over 18 years, it could potentially be adapted for application to children with asthma (refer to 6 c) below).

4 b) MedsCheck

A MedsCheck provides an in-pharmacy review of a consumer's medicines, focusing on education and self-management and aims to:

- identify problems that the consumer may be experiencing with their medicines
- help the consumer learn more about their medicines including how medicines affect medical conditions
- improve the effective use of medicines by consumers and
- educate consumers about how to best use and store their medicines

To be eligible for a MedsCheck, a consumer must:

- be a Medicare and/or DVA cardholder
- have not received a MedsCheck, Diabetes MedsCheck or HMR in the last 12 months;
- be living at home in a community setting
- be taking five or more prescription medicines
  or
  has had a recent significant medical event, defined as a recent event or new

diagnosis that has the potential to impact on the consumer's medication adherence or knowledge of their medicine regimen and may increase the risk of medication misadventure

MedsChecks are conducted by pharmacists within a community pharmacy setting and while not mandatory, it is recommended that with patient (or carer) consent, pharmacists provide the patient's GP with a summary of issues or recommendations.

Pharmacists are paid $60 for a MedsCheck service and patients are limited to one MedsCheck service per year.

4 c) Clinical Interventions

Under the Clinical Intervention element of the Fifth Agreement's Pharmacy Practice Incentive (PPI) Program, community pharmacies are eligible for modest incentive payments to encourage pharmacists to document appropriate clinical interventions in a consistent manner. A clinical intervention is a professional activity undertaken by a pharmacist directed towards improving the quality use of medicines by patients (or carers). It may result in a recommendation for a change in the patient's medication therapy, means of administration and/or medication-taking behaviour.[6]

A Clinical Intervention project investigated under the Fourth Agreement's Research and Development Program demonstrated a higher rate of documented clinical interventions when there was an active prompt. Understandably, the project also demonstrated that a pharmacy's documented intervention rate was significantly influenced by the workload in the pharmacy, where a higher workload was associated with a decrease in the intervention documentation rate. Similarly, individual pharmacists' intervention documentation rate was influenced by their experience, knowledge and training.[7]

4 d) Asthma Training

A review of the Guild's CPD accreditation database found that there were a number (approx. 8) education activities provided on the topic of asthma since 2011, by Guild State and Territory Branches, the Guild Academy and by the National Asthma Council. The National Asthma Council held a "Primary Care Asthma Update" accredited initially in 2011 and reaccredited in 2012. One of the topics covered was paediatric asthma. Others included how pharmacists can use PPIs/5CPA incentives in relation to asthma eg Disease State Management, Clinical Interventions.

The Guild's Training Academy has provided some generic training for pharmacists in asthma care, such as 'Asthma: Talking to a pharmacist helps'. This training was sponsored by GlaxoSmithKline and taught:

- the physiology, symptoms and triggers of asthma
- how asthma is classified
- how asthma is managed
- medicines that help manage asthma, including; relievers, preventers and symptom controllers what people with asthma think about asthma symptoms

- what pharmacists can do to help

With appropriate funding, the Guild's Academy could develop and/or deliver pharmacist training specifically covering asthma care for children.

4 e) Pharmacist prescribing

With Health Workforce Australia (HWA) in the process of concluding its review into non-medical prescribing in Australia, there is the potential for pharmacists to take on an enhanced role in patient care as an authorised prescriber in a similar manner to that seen in overseas countries such as New Zealand, the UK and USA. Overseas studies comparing non-medical prescribing to standard medical care show prescribing by non-medical health professionals is no worse than prescribing by medical practitioners in terms of benefits and safety.[8]

There are a number of non-medical prescribing models ranging from 'Independent Prescribing' in which the licenced prescriber has sole and full responsibility for patient assessment, diagnosis and clinical management, to 'Protocol Prescribing' in which the prescribing authority is delegated from an independent prescriber (usually medical practitioner) to a dependent prescriber who strictly follows an agreed protocol. The models perhaps most likely where pharmacists can play an enhanced role that uses their specialised training are[9]:

- **Supplementary Prescribing** – a voluntary partnership between an independent prescriber through an agreed patient-specific clinical management plan implemented with the patient's (or carer's) consent.
- **Collaborative Prescribing** – involving the medical practitioner diagnosing and making the initial treatment decision for the patient and the non-medical prescriber selecting, initiating, monitoring, modifying and continuing or discontinuing pharmacotherapy as appropriate to achieve agreed patient outcomes.

5. Discussion

Current remuneration for dispensing prescriptions in Australia is focused more towards volume dispensing rather than the extent of pharmaceutical care to the patient. As a result, community pharmacists typically contact the prescriber on issues relating to legal aspects of prescribing, clarification of items and safety issues such as incorrect dosing or medication interactions. The introduction of incentives such as those offered under the Fifth Agreement's PPI Program is encouraging pharmacists to extend their roles through more clinical interventions with prescribers. However, there are a number of variables that influence the uptake and success of clinical interventions, including:

- Workload – there are no controls as to when a patient presents a prescription at a pharmacy. Typically, at busier times, the pharmacist is less likely to perform more complex interventions and will limit themselves to the perfunctory duties associated with dispensing such as review of legal and safety elements.
- Duty pharmacist – it has been shown that the level of clinical intervention varies according to the dispensing pharmacist's experience, training and knowledge.
- Prescriber attitude – while a pharmacist may highlight a prescribing anomaly with the prescriber, prescription changes are dependent on the prescriber accepting

the pharmacist's advice and/or recommendation. This is largely dependent on the prescriber's experience, training and knowledge as well as inter-professional relationship with the pharmacist.

- Pharmacist-prescriber relationship – except for legal, clarification or safety issues, many pharmacists are often reticent to discuss changing prescribing patterns with a prescriber with whom they do not have a close working relationship.

Pharmacists that have been specifically trained, and in some instances credentialed for specific services (e.g. HMR, PAMS), are often better equipped and experienced to discuss collaborative care arrangements for specific patients as well as more general prescribing pattern recommendations.

There have been a number of studies in Australia and overseas which have shown that pharmacist involvement as an active member of the health care team leads to improved patient health care.[10,11] However, the Guild maintains that it is essential to include the community pharmacist as an active team member and would encourage arrangements that facilitate involvement of community pharmacists as part of a patient's multi-disciplinary health support team.

Regarding asthma care for children, a European study in 2008[12] showed that less than half of all children in the study prescribed asthma medication had a registered diagnosis of asthma. The study also showed that the three parties having most significance on prescribing of asthma medication in children were the patient, family and GP and that there was a higher variance in prescribing between GPs for children below the age of six compared to older children. This was attributed mainly to diagnostic complexities especially in preschool children with asthmatic symptoms.

6. Recommendations

Community pharmacists have the capacity and ability to play a greater role in supporting improved QUM initiatives for children with asthma. The Guild puts forward the following recommendations, for future consideration:

6 a) Targeted pharmacist training as part of the Clinical Interventions priority area of the PPI Program

The Guild recommends developing a *multi-disciplinary* training module about asthma in children that highlights current areas of best-practice, for example those of interest to this review. Such training should be provided to pharmacists and prescribers, particularly GPs, along with recommendations on how pharmacists and GPs could better work together to enhance the care of children with asthma. Such training should include specific guidance on how community pharmacists could review prescriptions and provide recommendations on when and how to engage with prescribers to discuss potential prescribing inconsistencies with best-practice care guidelines.

The costs for this proposal would be minimal and relate primarily to the development and delivery of a targeted training module. Once developed, the training module could be made available to groups such as the Guild Academy for delivery. Pharmacists and other health care professionals would be eligible for relevant continual professional development (CPD) points and community

pharmacies would continue to be incentivised to conduct interventions as part of the PPI program. Medicare Locals could be utilised to support targeted implementation.

6 b) Asthma focussed MedsCheck program

Consideration could be given to developing and implementing a specialised medicine use review program for patients with asthma, including children, based on experience gained through the Medscheck and Diabetes Medscheck Program under the 5CPA . The evaluation of these 5CPA Programs would need to be taken into account in developing this service.

6 c) Develop and implement a modified Pharmacy Asthma Management Service (PAMS) for Children

As PAMS involved the training and credentialing of a community pharmacist to provide a targeted asthma support service for adults with uncontrolled asthma, there is the potential to review and modify the service for pharmacists to be more actively engaged as a member of the asthma primary health care team for newly-diagnosed children with asthma.

Pharmacists and GPs can be trained with a view to GPs referring a newly diagnosed or suspected child with asthma to a PAMS pharmacist for disease state support information/support and medication device training, followed by ongoing monitoring with feedback to the GP who would be responsible for the coordination and general oversight of patient care. The PAMS pharmacist could assist the GP in confirmation of diagnosis along with therapy recommendations consistent with best-practice guidelines. The PAMS pharmacist could then continue to monitor the child in the following few months, with referral to the GP with appropriate recommendations for identified issues or if the asthma remains poorly controlled. The GP can review the child at semi-regular intervals (e.g. 6-monthly), assured that the PAMS pharmacist is monitoring their patient in the interim and will bring any issues to their attention. This service could be enhanced further should the PAMS pharmacist have the capacity to take on a collaborative or supplementary prescribing role.

Such a service would need a costing-study based on suspected patient numbers and anticipated number of pharmacies to be engaged. In addition, it would be recommended to include an evaluation of such a service to ensure desired outcomes are being achieved and assess the cost-effectiveness of the service. There is the potential that the trained PAMS pharmacist could be of assistance for other asthma care initiatives within the community pharmacy setting which could make the development and implementation of the initiative more cost-effective.

7. Conclusion

The Guild has highlighted a number of options which could utilise the skills and expertise of community pharmacists to better provide asthma care for children that is consistent with best-practice recommendations. Key to these proposals is training and resourcing prescribers and pharmacists and promoting greater collaboration between the individual professional groups. Community pharmacists are well placed to work with GPs to support and monitor children with asthma, referring those with issues or uncontrolled asthma back to the GP for review.

Reference Sources:

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