

Stakeholder Forum Summary

Post-Market Review of PBS Medicines Used to Treat Asthma in Children Department of Health, 18 November 2013

Disclaimer: This document is intended to provide a broad summary of the views expressed by stakeholders who attended the Forum. No attempt was made to reach consensus and for this reason the document may contain conflicting statements. Only information provided at the Forum has been included. Statements should be considered as views or opinions, not as medical advice, as they may not be supported by clinical evidence. The views expressed may not reflect the views of the Department.

PURPOSE AND CONTEXT

The aim of the Forum was for stakeholders to express their views, concerns and issues in the context of the Terms of Reference and in response to the six focus questions posed.

This Stakeholder Forum provided an opportunity for the Department to gather a range of stakeholder perspectives. These perspectives will inform the next draft Report for the Post-Market Review of Pharmaceutical Benefits Scheme (PBS) Medicines Used to Treat Asthma in Children.

Stakeholders were informed that the draft report will be published on the PBS website in 2014, for the final consultation phase prior to PBAC consideration of the report and any further consultation.

Prior to the meeting, attendees were provided with a background discussion paper that included information on the Review Terms of Reference, a table outlining asthma medicines, current PBS restrictions, a summary of the DUSC findings, key themes from the public submission process and the focus questions for the Forum. The Step Wise Approach to Asthma Treatment was also attached.

In order to assist the discussion a summary of the Drug Utilisation Sub-Committee (DUSC) findings on the utilisation of medicines to treat asthma in children was presented at the Forum. Stakeholders had an opportunity to ask questions about the medicines and findings.

SUMMARY OF STAKEHOLDER RESPONSES TO FOCUS QUESTIONS

Q1: In respect to the DUSC analysis which showed over 50% of children with asthma were prescribed a preventer medication. What are some possible explanations for this apparent high use of preventer medications?

- Some children being prescribed preventer medicine may not actually have asthma.
- The published data on numbers of children with asthma has limited reliability therefore estimates of use may have limited validity.
- When a person is diagnosed with asthma the specialist or General Practitioner (GP) must determine the appropriate class or type of asthma, the severity and frequency of episodes that the person is encountering and then determine where this person sits within the treatment algorithm. The question is how is this applied to children when the majority of asthma clinical trials do not include children, therefore there is limited published evidence on use of these medicines in children?
- The GP may perceive pressure from parents to alleviate the stress on the child and the family by quickly addressing asthma symptoms.
- Children may not be given a high enough dose of the reliever medication so that they remain symptomatic, which may lead to additional, unnecessary prescribing by their doctor. If a higher dose reliever was prescribed this may relieve the symptoms and prevent unnecessary escalation in prescribing.
- There are also time constraints on GPs who may have insufficient time to fully engage with their patient in the discussion of their asthma.
- Up to date Guidelines are required which reflect GP interaction with their patient, holistic management of asthma in children, differences in asthma management technique between adults and children.
- Education of health professionals and consumers needs to be given high priority and the challenges associated with asthma education are acknowledged.
- There is a lack of awareness among the clinical community about safety aspects of FDCs and possible risks to the child.
- Often parents have not been advised when to seek specialist intervention. A child's asthma situation may be escalated and then return back to the basic starting point.

Q2: What might the rationale be for initiating to a Fixed Dose Combination (FDC) of Long-Acting Beta₂-Agonists (LABA) and Inhaled Corticosteroid (ICS), without first trialling a corticosteroid? (Given that guidelines require that a patient be inadequately controlled on a corticosteroid before stepping up to a FDC).

- GPs may prescribe an appropriate medicine at first presentation but may not step the patient down in their treatment regime when necessary. It is possible that patients do not return for follow up.
- Cost is an issue for families and often children require several medicines, making a FDC a useful and cheaper option.
- Convenience of FDC is considered important to parents and GPs, and GP perception that FDC are more effective treatments.

- The issue of accuracy in asthma diagnosis, i.e. the classification of asthma by severity may be considered higher at the time of presentation.
- GPs consider that prescribing medicines to stop respiratory symptoms is a high priority and LABA's manage symptoms. They do not want to see harm come to a child.
- Patients are still confused over what is preventer and reliever medication, despite the education work that has been done in this area. GPs consider having a combination facilitates better health outcomes by readier acceptance of taking medicine.
- Pharmacists could be acknowledged as an alternate and readily accessible source of advice for asthma patients and families on available asthma medications. Asthma Australia is aware that patients can receive inadequate, or misunderstand, advice from their GP initially in relation to appropriate asthma medication.
- Of concern to parents and prescribers is the question over the impact of ICS on growth or other side effects.
- FDC is perceived as a newer and more advantageous medicine, particularly as less corticosteroid is used in an FDC.
- Industry promotes the appropriate use of their FDC products in adults. It does not promote the ICS monocomponent products.
- There is less information available in relation to paediatric asthma than there is for adult asthma. The Guidelines are always mentioned when discussing adult asthma.
- GP education needs to be increased, particularly their awareness of the Guidelines.
- Prescribing can also be influenced based on whether the patient is presenting during an acute attack or is in a more stable situation.
- Insufficient data is available on reasons for the prescription. Are these medicines are being prescribed for asthma or for another condition such as a post viral cough?
- Are FDCs being prescribed because GPs prefer a long-acting beta₂-agonist which is only used in an FDC, thinking it will lower the use of a short-acting beta₂-agonist (SABA)?

Q3: There have been concerns about the impact of corticosteroids on growth in children. How does this influence prescriber and consumer perceptions about using asthma medicines in children?

- Some families have considerable concerns on the impact of ICS on children, not only in relation to growth issues but also other side effects such as depression.
- It appeared that children were happier on FDC however parents do not know the long term effects of its usage. Parents do not follow up on this and expect that this information should come through their health care professional.
- The focus of asthma education interventions should be on the prescriber and not the dispenser.
- There are risks and benefits associated with corticosteroid usage. The prescribing behaviour is informed by Guidelines however with social (such as family circumstances) as well as clinical factors coming into the equation, on occasion prescribers choose to disregard these Guidelines.

- Parents also want their GP to resolve their child's problem immediately rather than taking into consideration any longer term issues. A longer term approach can mean multiple visits and medication changes.

Q4: What aspects of the current PBS restrictions can be improved to promote safe use of asthma medicines in children? For example montelukast is the only asthma preventer medicine with age requirements in the PBS restriction, and it had minimal dispensing outside these age requirements.

- A phone authority for FDC might be a way forward.
- Influencing prescriber behaviour is difficult to achieve. Montelukast has an Authority and this restriction enables more appropriate usage. However the costs to government associated with the listing of a medicine as an Authority was appreciated, including the resources required to respond to enquiries. This may have a significant impact in rural and remote areas where access is an issue. There is also the potential for under-treatment because of the disincentive associated with the Authority. An Authority may be the only way to ensure that a medicine is used appropriately. Prescribers would be actively required to use the appropriate treatments as specified in the Guidelines.
- An appropriate specialist needs to offer this advice on what asthma medicines are age appropriate for children. There needs to be explicit age criteria in these restricted medicines. There are very few asthma medicines that should be used in children under the age of five. A FDC should be within these restrictions and prescribed according to the type of asthma that a person or child presents with.
- It must be acknowledged that GPs and specialists are now dealing with a society of informed consumers and they should be providing high quality paediatric specific information in simple, lay language and providing answers to any questions to ensure the patient/carer/family understands what this information means for them.

Q5: Some public submissions noted that there has been a lack of recent paediatric education for the management of asthma. What kind of education initiatives would improve the quality use of asthma medicines in children? And how do we ensure the best impact of this education?

- Currently education for paediatric asthma is inadequate. There was a time when paediatric asthma education was provided however GPs were inundated with this. A multifaceted approach is what is now needed with a range of stakeholders and settings. Schools and childcare settings are particularly important for childhood asthma education. Asthma Australia noted that they do undertake a comprehensive approach in schools to the point that now most children cannot be taken on school camps if they do not have an asthma care plan in place.
- A multifaceted approach to childhood asthma education is essential.
- The education of health professionals needs to be complemented by consumer campaigns.
- Asthma Australia and the National Asthma Council of Australia require funding to provide paediatric asthma education, including for pre and post evaluation. Ms Whorlow stated that the timing is now very good to establish this education component as new Guidelines will be launched in March 2014.

- Educational materials achieved through shared decision making and involving NPS will also be launched in conjunction with release of the National Asthma Council guidelines next year.
- Recipients of education material need to be consulted on what works best for them.

Q6: What patient relevant outcomes from the use of asthma medications are important to children and carers?

- If children receive the appropriate asthma medication they will not miss school.
- Quality of life will be improved.
- Children are able to maintain their sporting activities without interruption.
- Ease of use of medication is important.
- Some concern over the steroid load.
- The financial impact in using preventers, relievers, spacers, carer's leave.
- The stigma associated with a sick child.
- The impact on the family.
- What patient factors does the GP consider when prescribing asthma medications for children?
- How does the GP balance patient expectations with regulatory requirements?
- If patient outcomes and the Guidelines do not align, then the GP will always address patient outcomes.
- GPs have minimal time available with their patient to provide education on managing the condition. Usually they are looking for the "quick fix".

ADDITIONAL PERSPECTIVES OF STAKEHOLDERS

Note: The division of the comments in this section into categories is intended to provide readers with an understanding of stakeholders' backgrounds. Some views may have been expressed by single or multiple stakeholders and the division does not indicate either consensus or disagreement from other attendees.

Clinicians, Health Professionals, and Health Professional Peak Bodies

- An undefined proportion of asthma medicines are being used for children who have not been diagnosed with asthma.
- Use of FDCs has been associated with non-responsiveness to treatments and tolerances to reliever medication which makes treating asthma attacks difficult.
- Perception of greater risk is associated with older established treatments. Inadequate information is available on the side effect profile of FDCs. If asthma medicines are used in their appropriate dosages then positive effects are seen.
- With an Authority it is important to understand that different products and dosages have different licence indications. Introduction of an authority on the lowest dose form of a product (consistent with a paediatric indication) could potentially lead to a paradoxical increase in prescribing of "off label" higher doses in order to avoid the restriction.

- A multifaceted approach to asthma intervention is required. Education needs to involve clinical education in relation to diagnosis and type of asthma. Similar issues arise in other classes of medicines for children and educations should be broader than for asthma alone.
- Education programs should be offered to patients and their families at a time when they are most receptive to hearing and taking in the advice and information, usually the follow-up phases and not during the acute phase.
- Insufficient numbers of Paediatric Respiratory Specialists are available and therefore these people are only accessed for the most severe asthma cases.
- AIHW report indicates that hospital admissions for asthma in children have fallen by 35% and in adults by 45% and PBS expenditure on asthma medicine has risen but not as significantly as other medicines on the PBS.
- If an FDC is being used inappropriately then an Authority may be beneficial in stopping this prescribing behaviour. Can an FDC be used for children regardless of age?
- Children with intermittent asthma are being prescribed FDCs. If the prescribers are using the Step Wise Approach the implementation of the last level should be at Authority level. Paediatric Respiratory Specialists consider that this would improve the rational delivery of asthma medication in children.
- Concerns associated with steroid use and growth in children. Commissioned research would be valuable in this area.
- Two questions should be considered when discussing appropriate prescribing of FDCs; should an Authority be used or should the patient be stabilised on a single product first?

Consumers and Consumer Peak Bodies

- The reasoning behind use of concessional holders for the data collection was queried, with the response from the Department being that as some asthma medicines are under the co-payment, concessional data was used for the Review as a way to cover them. It is assumed that this concessional cohort will be representative of the entire cohort.
- Consumers held concerns associated with treatments prescribed for asthma which may be associated with potential harm to children.
- Health professionals may not follow asthma guidelines. If they choose not to they must clearly explain to the patient and their family why they are choosing not to.
- People in rural and remote area lack of access to GPs and paediatric specialists.
- Consumers acknowledged the financial burden of asthma medicines on a family.
- Importance of colour in identification of medicines. It was suggested that all same dose forms should be the same colour.
- With global marketing colour coding of asthma puffers has become very confusing. The National Asthma Council of Australia does provide a chart which defines asthma medicines.
- The needs of people from non-English speaking backgrounds need to be accounted for by a GP in their consultation with the patient and their family. Asthma care plan's need to be provided in writing.
- Are asthma care plans being used? This will assist the family/school/childcare staff/sporting coaches to oversee the child's asthma medication and care.

- Children can be involved in the management of their asthma. When GP, specialist and family work well together, the family receives all of the education that they need to effectively manage the asthma.
- There is a need for more targeted education programs for parents of children with asthma.
- Consumers need to be supported by better dialogue between themselves and their health professional.
- Medicare Locals may have a role in the asthma education space, particularly in rural and remote areas.

Industry and Industry Peak Bodies

- GPs are highly educated in relation to addressing general asthma but less so for paediatric asthma and the clinical community is not as aware of FDC treatment of asthma in children.
- Messages in asthma treatment are correct but may not be communicated correctly, which is closely linked to lower levels of health literacy in the population.
- The Pharmacist has a critical role in supporting people with asthma.
- PBS restrictions requiring stabilisation on monocomponents prior to initiation on the FDC are often ignored and a more practical solution should be available.
- PBS restrictions should align with guidelines and have a greater level of adherence.
- The National Asthma Council of Australia has new Guidelines to be launched in March 2014.
- From the 2011 Asthma Australia Survey, cost was the fourth most important issue for consumers and a considerable barrier. Reliever medicines are generally cheaper than other asthma medicines.
- Colour coding of asthma puffers should be a role for the National Prescribing Service (NPS).