Pharmaceutical Benefits Advisory Committee Submission

Generic fluticasone propionate/salmeterol 500/50mcg dry powder inhaler

Medicine to which this submission relates
Generic fluticasone propionate/salmeterol 500/50mcg dry powder inhaler

Date of PBAC meeting:
November 2016

Please include any declarations you wish to make regarding the PBAC submission upon which you are commenting. If you have no declarations to make, please respond “nil”
Asthma Australia occasionally receives grants-in-aid from pharmaceutical companies however no funding is provided for advocacy and submission work.

What comments would you like the PBAC to take into account when it considers this submission? You may comment on any aspect of the drug, vaccine or medicinal product in question.

Asthma Australia and its member Foundations is supportive of the concept of generic medicines and the range of choice it provides to consumer's and the potential cost advantages associated at a consumer and government policy level. The following are considerations for the Pharmaceutical Benefits Advisory Committee (PBAC) regarding the listing of fluticasone propionate with salmeterol 500/50mcg (AirFluSal Forspiro).

Thorough examination of therapeutic equivalence of a medication and device is crucial and it is noted that equivalence between AirFluSal Forspiro and Seretide is evident with regards therapeutic value, device accuracy and safety. This would typically provide supporting evidence to allow substitution of the reference product (Seretide Accuhaler), however the majority of asthma and COPD medications present with an additional consideration due to the use of delivery device to administer the medication.

Prescribing practices
The reference product Seretide, a combination medication is currently available in three dosages within the dry powder device, accuhaler (50/100, 50/250, 50/500) allowing for stepped adjustment in treatment as per Australian best practice guidelines. A daily dose of >500mcg of Fluticasone Propionate is classified as a high dose and would only be suitable for a small percentage of the asthma population. For most patients, high doses of inhaled corticosteroids would only be used for short periods if at all and require stepped adjustment to lower doses in the future. The availability of a single 50/500 dose as AirFluSal does not allow for back-titration within the same device, therefore requiring an alternate device as changes in dosage are required. It would then only be suitable for patients who following medication review need to be maintained on the available dose and back titration is not achievable.

There is currently substantial concern regarding the high and inappropriate rate of combination medication prescribing in Australia. As the submission is related specifically to single and high dose combination medication, consideration must be given to whether the addition of another high dose combination therapy may in fact “normalise” or encourage the prescribing of combination therapy in patients whose condition does not warrant it. Accompanying medical practitioner education is essential to prevent unwarranted use.

For more information, contact your local Asthma Foundation: 1800 ASTHMA (1800 278 462) | asthmaaustralia.org.au
This dosage of combination therapy is not suitable for adolescents or children and as such the age restriction of 18 years and older is appropriate.

**Introduction of alternate delivery device**
The importance of correct delivery device technique has been well documented however research suggests that up to 90% of people use their devices incorrectly.\(^1\)\(^2\)
Incorrect use of asthma delivery devices can result in sub-therapeutic doses, leading to poorly controlled asthma, increased hospitalisations and a poorer quality of life.\(^3\) All contributing to health system, productivity and other financial costs.

Regardless of the type of inhaler device prescribed, patients are unlikely to use inhalers correctly unless they receive clear instruction, including a physical demonstration, and have their inhaler technique checked regularly.

Whilst this medication presents to be therapeutically equivalent, and would in theory be suitable for substitution for the reference product the issue that presents is that the medicine is delivered via a different device to what was prescribed or had previously been prescribed and instructed upon, and/or the reference produce specifically prescribed was for an intermediary approach through stepped adjustment of treatment.

It is understood that with "a flagging", substitution can occur unless the GP has indicated otherwise. The default on most GP prescribing software is to allow brand substitution unless the prescriber consciously indicates that "no brand substitution allowed" for each prescribing event. It is our experience that this does not regularly occur. Therefore if substitution (a-flagging) is applied to the reference product (Seretide 50/500 accuhaler) there is the potential for a patient to be substituted without the prior approval from the prescriber and the opportunity to provide adequate education and instruction on its use. In this circumstance it would then be the responsibility of the dispensing pharmacist to instruct the patient in the new device or arrange for the patient to return to the prescriber for device instruction at additional cost to the consumer and healthcare system.

Whilst both AirFluSal Forspiro and Seretide Accuhaler are dry powder inhalers; the mechanism and instructions for use are different, patients will need to be assessed for suitability and educated with respect to the differences in the mechanism of use for the new inhaler, preferably by the prescriber in the first instance and also the dispensing pharmacist.

It is suggested that in the instance of asthma and COPD medications, significant consideration be given as to whether a generic medication in a different device is suitable for substitution without the prescriber’s approval based on the potential for poor asthma outcomes.
It is also the responsibility of the sponsor to ensure there are ample placebo devices available in the market for primary health care and those in a position to provide asthma education to health professionals and people with asthma.
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Adherence to product
Adherence is a significant consideration in the introduction of a new medication and delivery device. Whilst funded by the manufacturing company, a recent study which showed that longer-term adherence to AirFluSal Forspiro was greater than for patients prescribed Seretide accuhaler.

The introduction of a device that could lead to improved patient outcomes through improved treatment adherence would be of benefit however this medication/device should be chosen based on the identified needs and ability of the patient to manage and use this device.

In conclusion, Asthma Australia supports the availability of medicines and devices that provide consumers with choice in their asthma management. A restricted benefit listing of Fluticasone/Salmeterol 500/50 (Airflusal Forspiro 500/50) for patients with asthma and COPD may provide consumer choice and be of benefit to people with asthma based on the therapeutic equivalency and as a potentially preferred device. The absence of additional dosages and potential device substitution is of concern and could potentially lead to adverse outcomes for people with asthma. This will be one of many generic medications to be introduced to the Australian market and as such it is imperative that an appropriate precedent is set based on the interests and outcomes for people with asthma and COPD.

The addition of any preventer medication to the Australian market must be considered a complementary approach with an additional focus on consumer asthma self-management education, provision of an asthma action plan, delivery device instruction and regular engagement with their medical practitioner.

How did you learn about this consumer submission process to be able to submit your comments today?

The PBAC submission was brought to the attention of Asthma Australia by Glaxosmithkline and AstraZeneca.

References


