

Patient Interest Groups
Submission of Evidence Template

Product to which this submission relates	ASMANEX (Mometasone)
Date of SMC meeting (if known)	

NB Not all sections on this form are required to be completed.

Disclaimer: *The comments contained in this document are not those of the company (licence holder), nor of SMC and are the responsibility of the submitting group.*

Should you have any queries regarding the completion of this form,
please contact the SMC secretariat:

Telephone: 0141 225 6989/6997

Section 1 – General Information

Submitting Organisation

Please provide an overview of the organisation making the submission, including the aims of the organisation and an outline of membership.

Asthma UK Scotland is an integral part of Asthma UK.

The charity's vision is

control over asthma today, freedom from asthma tomorrow.

Our mission is to improve the health and well-being of people with asthma by building and sharing expertise about asthma.

We do this thorough:

Funding research through grants and fellowships, and driving the research agenda for the UK

Providing information, advice and support to people with asthma and those who care for them

Influencing public policy that affects the lives of people with asthma and those who care for them.

The current membership of Asthma UK is approximately 17,000.

Number of People Affected by this Disease

Although SMC has access to epidemiological data, you may wish to provide information on the number of people who are affected by the disease.

According to the Scottish Health Survey (1998), 400,400 people in Scotland have asthma.

This equates to around 1 in 15 adults and 1 in nine children in Scotland affected by the condition. It is the commonest long-term condition in children in the UK.

User Perspective

Please provide an outline of user needs, preferences or experiences in relation to the use of existing medication/treatments.

Patients' experiences differ, but based on Asthma UK sponsored research and personal communication from people with asthma, we would make the following points:

1. There is, as yet, no permanent cure for asthma: the aim of treatment is to reduce the symptoms in order to improve quality of life. People with asthma are remarkably tolerant of

their condition and many have low expectations of what can be achieved with a combination of i) correct medication in an effective dose; ii) a device they can use efficiently; and iii) good asthma care.

2. Most people with asthma have to live with a regular, often twice/thrice daily, treatment regimen even when their symptoms are mild to moderate. This regimen may include the use of two or more inhalers twice or three times a day. Since some medications are only effective if they are taken routinely, even when no symptoms are present, it is easy to see why compliance is less than perfect in many people with asthma. Users would prefer a regimen that was equally/more effective in reducing wheeze, cough, breathlessness and chest tightness but less obtrusive, required less frequent administration and was quick/simple to take.

3. Asthma varies in severity both between individuals and within the same individual over time, necessitating a flexible treatment regimen. However, unless the person with asthma has received sufficient education, including some degree of self-management skills, a change in either medication, dose or delivery device is dependent upon regular contact with a healthcare professional, preferably one with a recognised qualification in asthma management. It is, therefore, helpful if the same medication can be taken in variable doses as daily need dictates rather than having to take a different or additional medication, possibly contained with a different type of delivery

4. Common treatments fall mainly into those for symptom relief and those for prevention of attacks. People with asthma frequently refer to their treatment by reference to the colour of the delivery device e.g. blue for relievers and brown for preventers rather either the brand or generic name. This adherence to colour coding is helpful.

5. There are a large range of delivery devices available and some medications are only available in one particular delivery device. Even a change in dose for the same prescription can result in the need to change devices. Therefore, people with asthma could find themselves prescribed one medicine in a metered dose inhaler, another in a acuhaler and another in a turbohaler. This is more common than one would wish, particular when the person with asthma has been seen by a number of healthcare professionals rather than consistently by one prescriber. Good asthma management attempts to minimise this but, as we know from a number of studies and conversations with people with asthma and their carers, the quality of asthma management is patchy and unpredictable. Offering a range of medicines within a choice of delivery devices means the person with asthma can become familiar with one device.

6. Not only does device diversity require additional time by the healthcare professional in teaching inhaler technique (assuming the healthcare professional has the training necessary to provide this) but can in itself lead to poor technique e.g. the slow, deep inspiration necessary to attain good lower lung deposition using a mdi is very different from the short, sharp inspiration needed with a dry powder device and the duration of recommended breath-holding can be unattainable. A medicine that can be delivered effectively with minimal inspiratory volume would be helpful, particularly in the elderly and children.

7. Many devices require a degree of co-ordination the lack of which results in reduced efficacy. Whilst this is frequently the co-ordination needed to activate the device at the same time as breathing it may also be in relation to eye-hand co-ordination. This is further complicated by problems such as arthritis and the elderly often find fingertip sensitivity is insufficient to manipulate small capsules, sometimes in blister peel packs, that need to be inserted prior to inspiration. Small fingers, elderly fingers and arthritic fingers find great difficulties manipulating devices. A combination of the above all result in many patients having extremely poor inhaler technique and this wastes NHS resources as well as failing to achieve the potential therapeutic results. GPs are encouraged to prescribe mdis which are frequently the cheapest means of administration if one disregards the fact that much of the medication is wasted! . A device that is simple to use, and requires neither good co-ordination, manual dexterity or inspiratory volume would be of help.

8. The problem of variety in delivery devices is further complicated by the need to use large volume spacers. The fit between mdi and spacer is not universal. Spacers are now acknowledged as equal to/better than nebulisers in an emergency. However, although the individual owns a spacer which, in the past, was compatible with the mdi they were prescribed, subsequent changes in medication and device may not have been married to the need to change existing spacer and, as a result, when an emergency arises the discovery that the spacer cannot be used merely exacerbates the problem. This can set up a vicious circle of hyperventilation and bronchoconstriction. Greater compatibility between devices and spacers would be helpful.

9. As stated in 7 above, some devices require greater inspiratory volume than the person possesses, particularly during an acute attack but they may also produce reflex coughing due to cold aerosol particles being deposited at speed at the back of the throat. This coughing reduces the amount of medication reaching its target. The coughing itself, particularly when the atmosphere is cold or dusty, worsens the asthma and related distress. A medication that can be delivered minus this effect would be helpful.

10. Since it is difficult to anticipate the last dose of an inhaler, resulting in no medication being available when needed, some inhalers have a counter demonstrating either the number of doses taken or the number remaining. This frequently requires a magnifying glass to see! Those devices where an audible click is heard on activation may be unsuitable for those with anything less than perfect hearing. A device that makes it clear when the amount of active ingredient is getting low and when a dose has successfully been administered would be helpful.

11. The introduction of long-acting beta 2 agonists has meant that sleep disturbance may be reduced since people with moderate to severe asthma are frequently woken at night when their last dose of short-acting bronchodilator has worn off. Of late, combined reliever/preventer medications have been made available, reducing the need for more than one medicine/device to be taken. These developments have contributed to improved quality of life.

12. However, NHS patients are more likely to be prescribed the cheaper though equally effective medications and metered dose inhalers are normally the first option unless clearly contraindicated. This means that fee-paying patients are likely to be called upon firstly, to pay

for three separate medicines/devices e.g. short-acting emergency reliever, long-acting reliever, and an inhaled steroid rather than one of the more expensive reliever/preventer combined medications, or, secondly, to be called upon to pay for a second prescription for a device other than a mdi when they have proved they are unable to use this type of device. Whilst acknowledging that combination medications reduce the flexibility of variable dose per single active ingredient, anything that reduces the need for more than one device is helpful to people with asthma.

13. Most medicines have potential side effects. The use of inhaled rather than oral medications has reduced these but they are still a significant factor. People with asthma complain of the taste of some of the inhaled medications. There is a recognised risk of dysphonia and oral candidiasis if the mouth is not rinsed out immediately afterwards and/or a large volume spacer used. Despite being armed with both the knowledge and good intentions many people with asthma do not rinse their mouths or gargle after inhalation. Many asthmatics say they can recognise other asthmatics not by their breathing but by their voice! A medicine that has no taste or a pleasant taste would be particularly useful with children and one that does not carry oropharyngeal/laryngeal side effect would be useful.

14. Some medications used to relieve bronchospasm, particularly in the elderly who not infrequently have an element of COPD complicating the picture, may increase urine retention, hesitancy on micturition and constipation sufficient to deter the individual from continuing to take the medication. This coupled with covert and unintentional ageism that still exists in the minds of some healthcare professionals can lead to a breakdown in the patient/professional partnership, the former being seen as non-compliant. Elderly people with asthma not infrequently suffer from other health-related problems and may be on a cocktail of medicines all with their own side-effects therefore what we need are asthma medicines with minimal side-effects/preferably none!

15. Whilst any improvement in asthma symptoms are welcome, improvement can also lead to complacency and failure to adhere to the necessary discipline of a treatment regime or attend for monitoring by a healthcare professional. This can result in sudden, potentially fatal, worsening of asthma. It is well known that people with asthma are frequently slow to seek emergency help and even those few who have been instructed in how to self-manage an emergency are frequently loathe to take effective doses of reliever for fear of adverse reactions. Low risk of overdose is important.

16. Even when timely intervention by healthcare professionals is sought, the response-time can be critical, particularly so in remote and rural locations during adverse weather. This may result in the person with asthma needing to self-medicate for a lengthy period of time using maximum doses of reliever until medical/paramedical help arrives. This is a frightening situation for both the sufferer and those around him/her. The public still holds the belief that nebulisers deliver more effective therapy and an increasing number of people are purchasing home nebulisers which are marketed without full explanation of what type of medicine can be used with them. During an emergency, the sufferer should ideally monitor his/her peak flow and this involves yet another device that, this time, requires him/her to blow rather than inhale. Therefore, the quicker the response time from inspiration to bronchodilation the better.

Section 2 – Product Specific Details

Potential Impact

Please provide an outline of the potential impact upon the lives of patients/carers in relation to the product to be assessed.

- Asmanex is a corticosteroid - a 'preventer' treatment (closely related to fluticasone)
- It has been compared to other preventers and appears to be as effective when taken twice daily
- Other studies comparing Asmanex twice daily with a double dose once daily show it to be equally effective
- It is still not approved for use in the US by the FDA. We have not been able to find out why but the manufacturers have decided to re-submit with a different user profile to overcome the problem.

Perceived Advantages/Disadvantages

Please provide an outline of the perceived advantages or disadvantages in relation to this product or its mode of delivery.

The main treatment-related determinants in compliance include:

- Expectation of benefit
- Fear of side effects
- Ease of use
- Multiple medications
- Multiple daily dose
-

Asmanex makes little impact on most of these:

- **Expectation of benefit.** It is not significantly better than most of the existing alternatives. The benefits of preventer inhalers are not appreciated or understood by many people with asthma (Needs Of People With Asthma Study & Focus Groups)
- **Fear of side effects.** Long-term use of cortico-steroid is widely perceived by people with asthma (NOPWA) to be harmful. There is some evidence to suggest it has less of a suppressive effect on they hypothalamus/adrenal system in adults.
- **Ease of use.** It is an inhaled powder. The considerable problems with these are well documented. The delivery device is not significantly better.
- **Multiple medications.** An Asmanex combination therapy is planned but not yet available.
- **Multiple daily dose.** Once a day rather than twice a day.

Wider Implications

Please provide any further details in relation to the wider implications for patients or carers (eg reduced hospitalisation, reduced time off work, quality of life issues).

Asmanex is reported to provide a lasting improvement in quality of life (J Asthma. 2003 Jun)

Asmanex could contribute to patient choice and has the moderate advantage to some people with asthma of requiring only one dose a day.