Reviewer's report

**Title:** Long-Term Safety of Mometasone Furoate Administered via a Dry Powder Inhaler in Children: Results of an Open-Label Study Comparing Mometasone Furoate With Beclomethasone Dipropionate in Children With Persistent Asthma

**Version:** 1  **Date:** 16 March 2009

**Reviewer:** Olof Selroos

**Reviewer's report:**

The authors, who were not involved in the planning of the study, present safety data of a 52-week study performed almost 10 years ago. The study had two doses of mometasone (MF) twice as high as the FDA approved dose for children (100 µg once daily): 200 µg once daily and 100 µg bid and as a reference BDP 100 µg bid was used – the CFC pMDI not available any more.

The design is traditional, the assessments, too.

**Major compulsory revisions:**

There is no mentioning about what happened with patients experiencing asthma worsening. Were they discontinued? What type of treatment was allowed and for how long could additional treatment be given to permit the patients to stay in the study? This should be clearly described and the number of patients at baseline, week 26 and week 52 in the study reported. Without this information it is impossible to state that the report is dealing with a 52-week study.

According to Figure 2 the probability of continuing in the study after 160-200 days was only 40-50%. How many children were in the study for 52 weeks? This is important to know when looking upon adverse events (Table 2).

Unfortunately ACTH-stimulated cortisol was not measured at baseline and after 52 weeks (or when children discontinued). This should have been done. An explanation needs to be added to the discussion.

There are a few further details that needs to be added.

1. This was a randomized study. I guess that it was bad luck that the number of 4-5 years old children in the BDP group is almost twice as many as in the MF-DPI 200 µg AM dose group?

2. The urinary corticol values corrected for creatinine show very wide SD values (Figure 3B). It is necessary to describe how many children had values below the reference range at each time point: baseline, week 26 and week 52. I also suggest to include the 26-week values in the figure.
3. Page 5, first para. “Patients who were unable to use the MF-DPI device or peak flow meter were excluded”. The number of patients excluded should be mentioned.

4. Page 8, second para. Plasma mometasone was not detectable in the majority of patients. Add when these measurements were performed and give a figure instead of the nonspecific term “majority”.

5. Page 9, first para. Reference is made to the study by Todd et al with the statement……children receicving high doses of other ICSs. It is important to state that the Todd study found that it was almost exclusively high doses of fluticasone propionate causing adrenal crisis.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

During the last five years I have received fees from AstraZeneca and Schering-plough for writing medical manuscripts and report