CLENIL® MODULITE®▼

Beclometasone dipropionate (BDP)

Prophylactic management of mild, moderate or severe asthma in children

Corticosteroids for the treatment of chronic asthma in children under the age of 12 years

Response to the assessment report produced by the Peninsula Technology Assessment group and Southampton Health Technology Assessments Centre

28 February 2007

Trinity-Chiesi Pharmaceuticals Ltd

Having had the opportunity to review the assessment reports, *Inhaled corticosteroids and long-acting beta$_2$-agonists for the treatment of chronic asthma in adults and children under the age of 12 years: Systematic review and economic analysis*, carried out on behalf of NICE, we would like to draw the Appraisal Committee's attention to the following points regarding Clenil® Modulite® (beclometasone dipropionate, Trinity-Chiesi Pharmaceuticals Ltd, UK).

Clenil® Modulite® should be included in the list of BDP products currently available in the UK (page 16).

Interestingly, unlike section 7 of the adult assessment report, there is at least some mention of the service impact, in terms of therapeutic reviews and monitoring, associated with switching from CFC-containing to CFC-free BDP products. There should be more consistency between the two reports over this issue. Although short-term, this will affect a large number of patients whose asthma is controlled by BDP alone, so the impact of the switch should be properly assessed.

Overall, although the scope of the report is aimed at inter- and intra-class comparisons, there are important product and service impact differences within the BDP group that need to be given more attention.

In addition, specific comments on section 6.7, the review of the submission by Trinity-Chiesi Pharmaceuticals Ltd, are as follows.

The comparison of the costs of switching from Becotide® to either Clenil® Modulite® or alternative dry powder inhaler (DPI) options was made because clinical equivalence between Becotide® and Clenil® Modulite® has been shown in trials. The assessment report states that a more appropriate comparator, such as budesonide (BUD) or fluticasone propionate (FP), should have been used instead of Becotide®. However, this largely misses the point of the economic analysis, which was not to compare Clenil® Modulite® directly with Becotide®, but to state that for patients switching from their current BDP product to an alternative BDP product licensed in children, it would be less costly and potentially more cost-effective (if we assume clinical equivalence between all BDP products) to switch to Clenil® Modulite® rather

than to other BDP options (that is, DPI products such as Asmabec® or Becodisks®). It would make no difference to this argument if we had used BUD or FP as the current ICS and explored which was the cheapest BDP product licensed in children to switch to – it would still be Clenil® Modulite®, as in Table 27 (page 150). We feel this should be recognised in the report, instead of the bland statement that an incorrect comparator was used.

The fact that Clenil® Modulite® is the cheapest CFC-free BDP product at 400 µg/day is recognised in Figure 10 (page 166). It is of lower cost here than the cheapest BUD and FP products; therefore, the net cost impact of switching to Clenil® Modulite® would have been a cost saving if we had used BUD or FP as a comparator and assumed equal efficacy.

The assessment report claims that the correct patient population has not been identified, as the main trial used recruited children aged six to 16 years (page 151). In fact, the correct patient population *was* used in our submission – a subgroup analysis of children under the age of 12 years was performed.