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Dear [redacted]

Corticosteroids for the treatment of chronic Asthma in adults and children aged 12 years and over

Thank you for the opportunity to respond to the appeal made by TEVA to the final appraisal determination (FAD) for the above technology appraisal. As is noted in your response to the appellant, the point they raise is of a technical and discrete nature. TEVA have not challenged the recommendations made in the guidance section of the FAD.

The appellants specifically refer to two paragraphs in the evidence section, 4.2.5 and 4.2.6 both of which relate to the methodology used in the assessment report, specifically the use of averages (weighted and unweighted means) to express the costs of each inhaled corticosteroid drug.

While acknowledging that these sections of the FAD could have been written differently, the Appraisal Committee reject the notion that the use of weighted and unweighted means to reflect the cost of the different drugs amounts to perversity in their decision making. These paragraphs are not 'obviously and unarguably wrong', but are a reflection of the way in which the economic analysis provided by the assessment group was presented to the Committee

and as such appear in the 'evidence' section of the FAD. The Committee was fully aware of the derivation of these weighted and unweighted averages and the fact that any method of averaging may conceal individual variation between products. The Committee fully appreciated this when making their non-specific recommendations in sections 1.1 and 1.3 of the Guidance that 'the least costly product that is suitable for the person is recommended'.

Although the Committee does not accept that paragraphs 4.2.5 and 4.2.6 are factually inaccurate, it is proposed that the appeal by TEVA should be handled as a request for factual correction and these sections of the FAD be revised to make it clear that the conclusions drawn relate to averages and that due consideration should be given to the cost of individual products when interpreting the guidance. A suggestion for revised text of these paragraphs is given below.

4.2.5 At the lower end of the low-dose range (400 micrograms beclometasone dipropionate equivalent per day), the cheapest ICS drug is beclometasone dipropionate with an average cost of £65 per year (mean cost including all available inhalers containing beclometasone dipropionate). When CFC-containing products are excluded from this average, the cost increases but beclometasone dipropionate remains the cheapest ICS drug on average (mean cost £79 per year). Excluding CFC-containing products has no effect on the mean costs of fluticasone propionate, mometasone furoate or ciclesonide because these are available only as CFC-free products. At the upper end of the low-dose range (800 micrograms beclometasone dipropionate equivalent per day), beclometasone dipropionate is the cheapest drug with a mean cost of £130 per year. When CFC-containing products are excluded, beclometasone diproprionate remains the cheapest drug according to the unweighted mean cost, but fluticasone propionate becomes the cheapest if a weighted mean is considered (that is an average calculated by weighting each product according to market share in terms of quantity of doses sold). The weighted and unweighted mean costs for each drug conceal variation

in the costs of individual generic or branded inhalers and the cheapest product may not be a product containing the corticosteroid drug that was cheapest on average.

4.2.6 In the high-dose range (800–2000 micrograms beclometasone dipropionate equivalent per day), only four ICSs were compared because ciclesonide is not licensed for use at an equivalent dose. The cheapest drug is beclometasone dipropionate with an average cost of £198 per year (unweighted mean of all available inhalers). When CFC-containing products are excluded, When CFC-containing products are excluded, beclometasone diproprionate remains the cheapest drug according to the unweighted mean, but fluticasone propionate becomes the cheapest if a weighted mean is considered. The weighted and unweighted mean costs for each drug conceal variation in the costs of individual generic or branded inhalers and the cheapest product may not be a product containing the corticosteroid drug that was cheapest on average.

I hope this approach and improved clarity in the description of the evidence as presented to the Committee is acceptable to the appeal panel. If so, a revised FAD containing this new wording will be put forward to the Institute's Guidance Executive

Yours sincerely,

Professor David Barnett
Chair, Technology Appraisals Committee