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Response to the GEMA Executive Committee☆

Respuesta al Comité ejecutivo de GEMA

Dear Editor,

We thank the GEMA Executive Committee for their comments on our letter on discrepancies in the classification of inhaled glucocorticoids (IGC) between the GEMA and GINA classifications.[1] As they point out, clinical practice guideline recommendations must be based on solid evidence, something that is lacking in this particular area. GEMA's positioning is therefore in line with the indications of the Summary of Product Characteristics and the therapeutic positioning report recently published by the AEMPS.[2]

In their argument in favor of classifying a dose of 100 μg/24 h fluticasone furoate (FF) as medium, they cite the 2 papers that constitute the few references that compare ICGs in terms of equipotency. In the Bateman study,[3] different doses of FF versus fluticasone propionate (FP) 100 μg/12 h (low dose) were compared over a period of 8 weeks. The dose of FF 100 μg/24 h was not inferior that of FP 100 μg/12 h in terms of FEV_1, and did not produce a significant decrease in cortisol. The study of Busse et al.,[4] specifically designed to assess safety at 52 weeks, showed that urinary cortisol values for FF 100 μg/24 h were normal for 90% of patients at baseline. Throughout the study, urinary cortisol at all visits was normal in 72% of cases, low in 10%, and high in 17%.

GEMA positioning on the medium dose is consistent with most clinical practice guidelines. However, an example of the difficulty that persists in establishing the exact equipotent dose of FF is that the UK guidelines (SIGN 158),[5] published by the British Thoracic Society (BTS), use 3 categories (low, medium and high dose) to classify ICG. Specifically, they situate FF/vilanterol 100 μg/24 h in the medium dose section, while simultaneously including it in half of the low-dose step. The BTS standpoint is a very good reflection of the limitations we still encounter in establishing the exact equipotent dose of FF.

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