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**Title:** No age effect on systemic exposure to beclometasone and formoterol after pressurized metered dose inhalation in paediatric, adolescent and adult asthma

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**Body:** INTRODUCTION: The systemic exposure of orally inhaled drugs may differ in relation to the age of patients. A pMDI fixed dose combination of beclometasone dipropionate and formoterol fumarate (BDP/FF) is marketed in adult asthma (100µgBDP/6µgFF per actuation) and currently under development in adolescents and children at doses of 100µgBDP/6µgFF and 50µgBDP/6µgFF, respectively. OBJECTIVE: To compare the systemic exposures ( $AUC_{0-t}$ ) of FF and B17MP (active metabolite of BDP) after single dose administration of BDP/FF in three different age groups of the asthma population (children, 5-11yrs, adolescents, 12-17yrs and adults, >18 yrs). METHODS: The pharmacokinetic profiles of FF and B17MP were evaluated over 8h from three independent studies, each performed on a different age group. Children (n=20), adolescents (n=29) and adults (n=24) received a single dose of BDP/FF (children: 200µg/24µg, adolescents and adults: 400µg/24µg) via the pMDI with AeroChamberPlus™ spacer device. RESULTS:  $AUC_{0-t}$  of B17MP and FF after dose administration in adolescents were equivalent to adults; 90% confidence intervals (CI) fell within the 80-125% range. Exposure in children in comparison to adolescents was equivalent for FF while it was halved for B17MP (90%CI=41-56%). CONCLUSIONS: The exposure to B17MP and FF correlates with the dose independently of patient age. In children, the administration of a low dose assures lower systemic levels of B17MP compared that in older patients. Due to the concern about growth reduction with corticosteroids, the reduction of BDP dosage for children seems a wise and safe approach.