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Title: Equivalence of an innovative multidose salmeterol/fluticasone dry powder inhaler vs comparator in paediatric asthma

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Body: This study evaluated efficacy and safety of an innovative dry powder inhaler (DPI – Sandoz) vs Seretide™ Accuhaler™ (GSK) containing 50 µg salmeterol and 100 µg fluticasone per actuation. A double-blind, double-dummy, multicentre, randomized, 2-arm parallel group study in children with persistent moderate asthma with a 2-week washout period and 12 weeks of active treatment; twice daily inhalation of a single actuation from an active and placebo device. The innovative DPI and Seretide™ Accuhaler™ gave comparable results in children (6–11 years) across all endpoints.

Children aged 6–11 years	Innovative DPI	Seretide™ Accuhaler™
Change in FEV_1 from baseline at endpoint		
Mean baseline FEV_1, L	1.377	1.402
Mean absolute change in FEV_1	0.476	0.463
Adjusted mean for relative change, %	35.2	34.0
FEV_1 treatment difference*,% (95% CI)		
Per protocol set (n = 96 and 98)	1.2 (-3.9; 6.3)	
Full analysis set (n = 99 and 102)	0.7 (-4.3; 5.7)	
Serial FEV_1 assessments post-dose at endpoint		
Median time to maximum FEV_1, mins	119.5	121.0
$FEV_1AUC_{0-4}/4$ vs pre-inhalation FEV_1	1.041	1.054
Treatment difference*, % (95% CI)		
Per protocol set (n = 96 and 98)	0.988 (0.972; 1.004)	
Full analysis set (n = 99 and 102)	0.989 (0.973; 1.005)	

*ANCOVA - analysis of covariance

The incidence of adverse events with a suspected drug relationship was very low and comparable between treatments.