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Title: Comparison of the in vitro performance of originator and generic drug-combination dry powder inhalers

Naomi 31473 Teekamp n.teekamp@rug.nl MD [1], Paul 31474 Hagedoorn p.hagedoorn@rug.nl MD [1], Bernard G. 31475 Huijbers b.g.huijbers@rug.nl MD [1], Doetie 31476 Gjaltema d.gjaltema@rug.nl MD [1], Henderik W. 31477 Frijlink h.w.frijlink@rug.nl MD [1] and Anne H. 31495 de Boer a.h.de.boer@rug.nl MD [1]. [1] Department of Pharmaceutical Technology and Biopharmacy, University of Groningen, Groningen, Netherlands .

Body: Rationale: Efficacy of inhalation therapy is dependent on device performance and drug choice. To reach intended sites of action in the airways, inhaled drug particles must have optimal aerodynamic size distribution, adjusted to the delivery flow rate. For dry powder inhalers (DPIs), the critical factors are the inhaler resistance and the fine particle fraction (FPF) of the delivered dose. These can vary, depending on the device characteristics. However, because of different test conditions, the few studies available on the aerosol properties of different inhalers are often not comparable. Methods: In order to investigate different device properties, the in vitro performance of three combination inhalers (two originator, Symbicort® Turbuhaler® [S-TBH] and Seretide® Diskus® [S-D], and one generic, Rolenium® Elpenhaler® [R-E]) were compared at 2, 4 and 6 kPa, under the same test conditions. Results: Flow rates at 4 kPa varied between 59 L/min (S-TBH) and 69 L/min (R-E). Delivered doses and FPF (both as % of label claim) varied considerably more. At 4 kPa, the delivered doses of the inhaled corticosteroid (ICS) component were 95% (S-TBH), 87% (SD) and 85% (R-E). FPFs <5µm (and 1–3µm) for ICS were 51% (30%) for S-TBH, 23% (13%) for S-D and 16% (6%) for R-E. FPFs and delivered doses of the β-agonist components of S-TBH and S-D were slightly lower than the corresponding values for the ICS component, but not in the case of R-E. Conclusions: This study shows that different DPIs deliver significantly different FPFs (by a factor 2-3; S-TBH > S-D > R-E) with different flow rates at the same inhalation effort, which may have clinical implications in terms of drug distribution in the airways.