Generic fluticasone-salmeterol as effective as brand-name version, study finds

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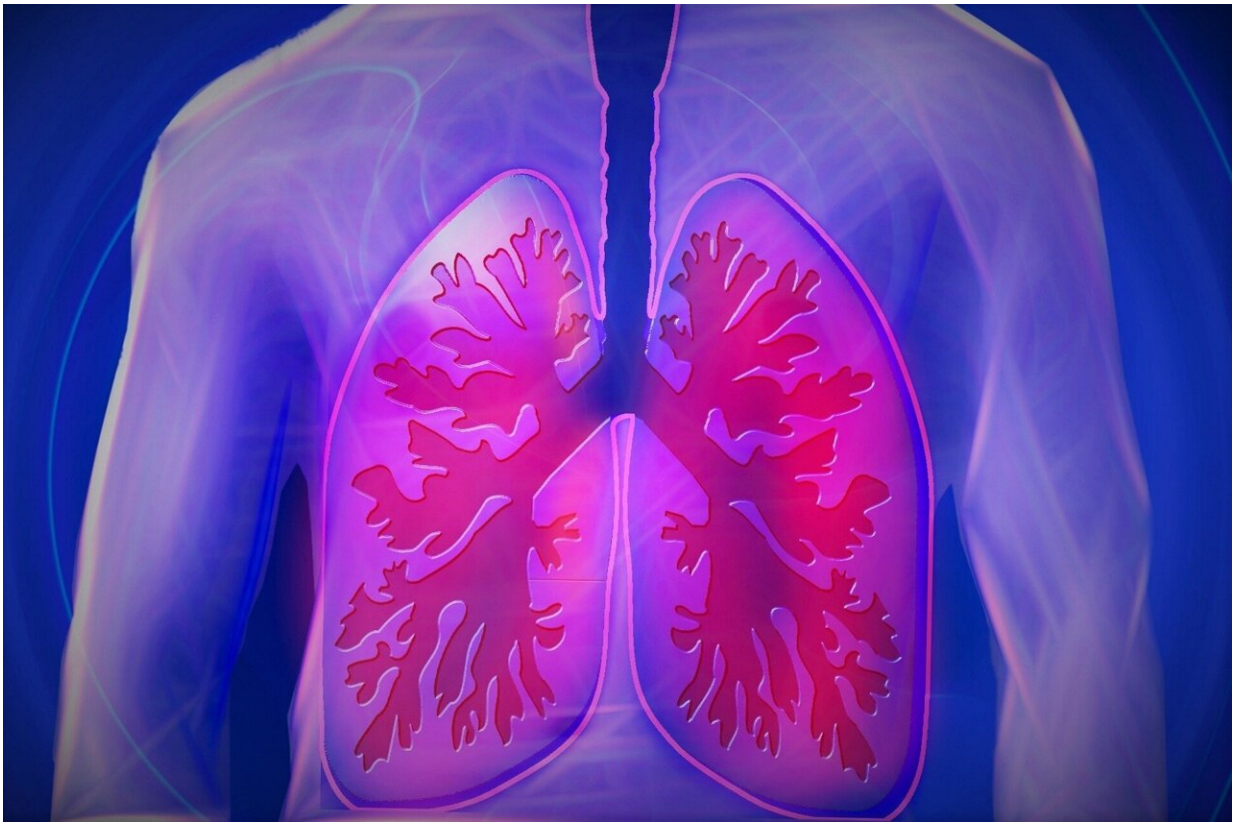

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A propensity score-matched cohort study of patients treated for chronic obstructive pulmonary disease (COPD) in routine practice found that the use of generic and brand-name fluticasone–salmeterol was associated

with similar outcomes. The findings are published in *Annals of Internal Medicine*.

In 2019, the U.S. Food and Drug Administration (FDA) approved the first generic maintenance inhaler for asthma and COPD. The inhaler, Wixela Inhub (fluticasone–salmeterol; Viatris), is a substitutable version of the dry powder inhaler Advair Diskus (fluticasone–salmeterol; GlaxoSmithKline).

When approving complex generic products like inhalers, the FDA applies a special "weight-of-evidence" approach. In this case, manufacturers were required to perform a randomized controlled trial in patients with asthma but not COPD, although the product received approval for both indications.

Researchers from Brigham and Women's Hospital and Harvard Medical School conducted a propensity score–matched cohort study of 10,012 matched pairs using either generic or brand-name fluticasone–salmeterol for COPD. The authors found that compared with brand-name use, generic use was associated with a nearly identical incidence of first moderate or severe COPD exacerbation. They also report that use of generic fluticasone-salmeterol was associated with similar rates of first pneumonia hospitalization as the brand-name reference drug.

According to the authors, their study adds important new data supporting the clinical equivalence of generic and brand-name fluticasone–salmeterol in a group of patients who were not included in clinical trials leading to generic version approval.

More information: William B. Feldman et al, Comparative Effectiveness and Safety of Generic Versus Brand-Name Fluticasone–Salmeterol to Treat Chronic Obstructive Pulmonary Disease, *Annals of Internal Medicine* (2023). DOI: 10.7326/M23-0615

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