**Title:** The occurrence of pneumonia in COPD patients treated with salmeterol xinafoate 50mcg/fluticasone propionate 250mcg (SFC250) – Interim report of post-marketing surveillance in Japan

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**Body:** Design: This was a non-interventional, observational, post-marketing surveillance conducted in Japan in a clinical practice setting. Method: Patients with COPD who were new users of SFC250 were enrolled. This report focuses on whether there is an association of COPD treatment with ICS and pneumonia as suggested in the literature. The history of pneumonia in 1 year prior to and after starting SFC250 was collected retrospectively and prospectively along with additional safety information. Result: 1,420 case cards were collected as of 31st October 2011, and 1,358 patients were eligible for safety evaluation. 78.4% were 65 years or older. 246 adverse drug reactions (ADRs) were reported in 181 patients. Most frequently reported ADRs were clinical bacterial pneumonia 4.9%, dysphonia 3.2%, bronchitis 1.2% and pneumonia (other) 0.8%. In 1,350 patients who were treated with SFC250 for any duration, diagnosis of pneumonia was reported as an adverse event in 8.4% of patients in the prior year, and 8.4% after starting SFC250. For the 922 patients were treated with SFC250 for 1 year, the diagnosis of pneumonia was made in 8.7% and 7.3% of patients in the year prior to and after starting SFC250, respectively. Pneumonia was more frequent in patients who had a hospitalization, lower BMI, longer duration of COPD, ex-smoker, severe COPD and patients with complication. The trend was the same in the year prior to and post SFC250. Conclusions: In clinical practice setting, the frequency of pneumonia was comparable before and after starting SFC250.