

# PHARMACOVIGILANCE CENTER SAFETY COMMUNICATION

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## Single-ingredient long-acting beta-agonist use in the Military Health System (MHS)

Long-acting beta-agonists (LABAs) are a class of drugs used to treat patients with asthma or chronic obstructive pulmonary disease (COPD). Because data show that LABA use has been associated with increased risk of hospitalizations, intubations, and death from asthma, the Food and Drug Administration (FDA) released a safety communication on February 18, 2010<sup>1</sup> followed by a label change to all LABA products (finalized June 2, 2010)<sup>2</sup> stating that single-ingredient LABA use is contraindicated in **asthma** patients. LABAs should only be used in conjunction with a long-term asthma controller medication (LTACM), usually an inhaled corticosteroid (ICS). The FDA recommends that LABAs be prescribed in a product that combines the LABA with an ICS. The label changes apply to treatment of asthma **but not COPD**. This communication describes results from an observational study using MHS administrative claims to determine the proportion of LABA dispensed as single-ingredient. The specialty of the provider that prescribed the LABA was evaluated, where possible.

The Army Pharmacovigilance Center (PVC) evaluated the proportion of LABAs that were dispensed as single-ingredients to asthma patients within the MHS before and after the label change. Administrative data from patient interactions with the MHS,

including diagnostic codes, procedure codes, and prescription information, were used to select asthma patients (International Classification of Disease, 9<sup>th</sup> revision [ICD-9] code 493.xx in the year before the LABA) who filled a LABA from 01JAN2006 to 30SEP2011. Patients ages 65 and older or those with codes for COPD (491.xx, 492.xx, 496.xx) were excluded to limit the evaluation to LABA prescribed for asthma rather than for COPD. Prescriptions dispensed within MTF outpatient clinics were linked to the patient medical encounter at the time the LABA was written to determine the prescriber specialty. The LABA prescriptions considered in our evaluation were only included if the patient was continuously eligible for enrollment in the MHS, was not outside the continental US (OCONUS), and was not deployed for the 365 days prior to their LABA. These inclusion criteria improved the likelihood of capturing asthma patients while excluding COPD patients. Single-ingredient LABA was defined as any LABA dispensed to a patient who did not have an overlapping ICS prescription based on dispensed pharmacy administrative records. This measure may

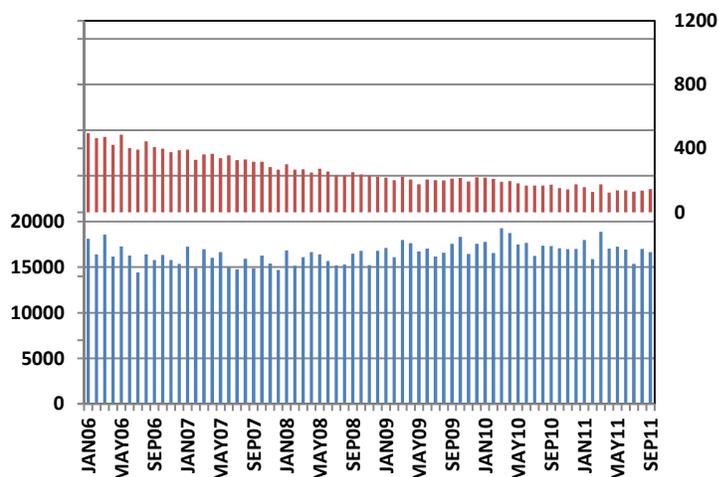


Figure 1. Total (blue) and single-ingredient (red) LABA dispensations among asthma patients in the MHS; 01JAN2006-30SEP2011

have overestimated the frequency of single-ingredient LABA if patients did not use ICS prescriptions as prescribed.

LABA use in patients with asthma has remained consistent during the period from 01JAN2006-30SEP2011 at about 17,000 prescriptions filled per month. The overall percent of single-ingredient LABAs per all LABAs dispensed to patients with asthma was very low (1.6%) and appeared to improve over time (**Figure 1**). The average percent of LABAs that were single ingredient from JUL-SEP of 2006 was 2.7% while it was only 0.8% from JUL-SEP 2011. Within MTF outpatient clinics, LABAs were most commonly prescribed by General Medicine providers (83%). Only 9% of LABAs dispensed as the result of an MTF outpatient encounter were prescribed by an allergy, immunology, or pulmonology specialist. Other specialists wrote 4% of prescriptions filled during the time period. When LABAs were dispensed as single-ingredients from a prescription written during an MTF outpatient encounter, the prescriber most commonly had a General Medicine specialty (83%). The vast majority of LABAs were dispensed in a combination inhaler with an ICS (97%), most commonly Advair (88%).

In summary, LABAs are frequently prescribed within the MHS and use has remained consistent over time. The proportion of LABAs that are dispensed as single ingredients is very low and has decreased over time. General Medicine providers wrote the majority of LABA prescriptions filled as the result of an MTF outpatient visit. Among the few LABAs that were dispensed as single-ingredients in MTF outpatient clinics, most were written by General Medicine providers. The PVC continues to monitor use of LABA within

the MHS to ensure the safety of our service members and their families.

## HOW ARE WE DOING?

**GOOD** compliance with labeled guidelines with respect to single-ingredient prescribing of LABAs.

## References:

1. Food and Drug Administration. FDA drug safety communication: new safety requirements for long-acting inhaled asthma medications called Long-Acting Beta-Agonists (LABAs). 2010; <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200776.htm>. Accessed June 28, 2011.
2. Food and Drug Administration. FDA drug safety communication: drug labels now contain updated recommendations on the appropriate use of long-acting inhaled asthma medications called Long-Acting Beta-Agonists (LABAs). 2010; <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213836.htm>. Accessed June 28, 2011.

### Prepared by:

Tamra E Meyer, PhD, MPH  
Epidemiologist  
Army Pharmacovigilance Center  
703-681-5884

### Approved by:

Trinka Coster, COL, MC, USA  
Director, Army Pharmacovigilance Center  
703-681-5860

### Written:

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