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Drug Injury Watch

Prescription Drug Side Effects News and Information from Attorney Tom Lamb

Health Canada Issues Ketek MedEffect Alert In Early September 2007

Thursday, September 06, 2007

Antibiotic Ketek Restricted To Certain Types Of Pneumonia; No Longer Used For Sinusitis, Bronchitis, Tonsillitis, Pharyngitis

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On September 5, 2007 Health Canada issued by email a MedEffect alert about Ketek which included this summary:

Sanofi-aventis Canada, Inc. is informing Canadians that the antibiotic Ketek (telithromycin), should no longer be used to treat sinusitis, bronchitis, tonsillitis or pharyngitis. Ketek can still be used to treat certain types of pneumonia.

More information about these restrictions imposed on Ketek in Canada are set forth in the accompanying "[PUBLIC COMMUNICATION Health Canada Endorsed Important](#)

[Safety Information on KETEK \(telithromycin\)" and the the so-called "Dear Doctor" letter sent to health care professionals by Sanofi-aventis Canada Inc. on August 30, 2007.](#)

From this Canadian Ketek Dear Doctor letter we get this more in-depth information about this change in indications for Ketek in Canada:

Upon review of the available safety information, including reported cases of severe liver injury, Health Canada has determined that the benefit-risk profile for KETEK® no longer supports its use for the treatment of acute exacerbation of chronic bronchitis (AECB), acute bacterial sinusitis (ABS) or tonsillitis/pharyngitis. These indications will be removed from the label.

KETEK® continues to be indicated only for the treatment of community-acquired pneumonia (CAP) of mild to moderate severity due to *Streptococcus pneumoniae*, (including multi-drug resistant isolates [MDRSP]), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae* (Chlamydia) *pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Staphylococcus aureus* for patients 18 years old and older.

In view of the following developments regarding Ketek in the U.S., however, this action by Health Canada and Sanofi-aventis Canada seems relatively late:

- ▶ [In December 2006 an FDA advisory panel recommended the use of Ketek should be restricted](#) to treatment of community-acquired pneumonia, only, and should no longer be used as treatment for acute bacterial exacerbation of chronic bronchitis nor acute bacterial sinusitis;
- ▶ [In February 2007 we learned that the FDA was going to heed this recommendation](#) by its advisory panel when the agency issued a bulletin entitled "FDA Announces Label and Indication Changes for the Antibiotic Ketek"; and,
- ▶ [In March 2007 Sanofi-Aventis sent a "Dear Doctor" letter in the U.S](#) regarding these prescribing and treatment changes that were being made for Ketek due to its association with severe liver injury.

Meanwhile, several product liability lawsuits regarding cases of serious liver injury allegedly caused by Ketek have been filed in various courts, here, during 2007. We are not aware of any Ketek lawsuits filed in Canada but that is not to say that there are not any, there.

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