Tamiflu® (oseltamivir) – First-Time Generic

- On August 3, 2016, the FDA approved Natco Pharma's AB-rated generic version of Roche's Tamiflu (oseltamivir) oral capsules, for the treatment of acute, uncomplicated illness due to influenza A and B infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours, and for prophylaxis of influenza A and B in patients 1 year and older.
    - Tamiflu is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices.
    - Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (eg, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Tamiflu.
    - Tamiflu is not recommended for patients with end-stage renal disease not undergoing dialysis
- Based on a settlement agreement, Natco Pharma's partner, Alvogen, will be able to market generic Tamiflu before the expiration of the pediatric exclusivity period of February 23, 2017. Generic Tamiflu will be available as 30 mg, 45 mg, and 75 mg capsules.
    - Brand Tamiflu is also available as an oral suspension.
- According to IMS Health, Tamiflu oral capsules had U.S. sales of approximately $403 million for 12 months ending in December 2015.