Correspondence

Telithromycin and Myasthenia Gravis

Str—We would like to provide clarification and some additional information regarding the editor’s comment [1] accompanying the Reuters news item on telithromycin (Ketek; Aventis) [2]. The Reuters news item reported accurately that Aventis in Germany (and in other countries where telithromycin has been launched) recently issued a warning to health care professionals advising them of the potential for exacerbation of myasthenia gravis (MG) in patients with pre-existing MG who were receiving telithromycin. This provider notification resulted from a review of the Aventis drug safety database, which initially revealed 8 cases of MG exacerbation in patients taking telithromycin for treatment of respiratory tract infection. Aventis proactively revised the core prescribing information for telithromycin to include a precautionary statement about the use of telithromycin in patients with MG, on the basis of findings from active pharmacovigilance and postmarketing drug surveillance.

The editor [1] acknowledged that MG exacerbations have also been reported in association with other classes of antibiotics, including β-lactams, fluoroquinolones, and aminoglycosides [3], as well as with other classes of medications [4]. For clarification, it is important to note that preclinical studies performed to date have not shown an effect of telithromycin on neuromuscular junction transmission at concentrations of up to 100 times the therapeutic free-drug concentration.

The precaution is specific to patients with MG; the overall safety profile of telithromycin remains unchanged. Telithromycin is not recommended for patients with MG, unless other therapeutic alternatives are available. If no other therapeutic alternatives are available, patients with MG who are receiving telithromycin must be monitored closely.

Telithromycin was first launched in Germany in 2001 and is now available in the European Union and other parts of the world, including Latin America; telithromycin was recently approved for use in Canada. To date, >4,000,000 courses of telithromycin have been prescribed worldwide.

Following the positive recommendation from their Anti-Infectives Division Advisory Committee, the US Food and Drug Administration (FDA) issued a second approvable letter for telithromycin in January 2003, in which additional analyses and information but no clinical studies were requested before marketing approval (information can be found at the FDA Web site [5]). Aventis has now provided the requested information to the FDA and is currently working to secure approval of telithromycin and to bring the benefits of telithromycin to US patients as soon as possible.

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Cardiac Dysrhythmia following Smallpox Vaccination

Str—The growing threat of bioterrorism has led to the reintroduction of smallpox vaccination programs [1]. The potential dermatologic and neurologic adverse events associated with the vaccine have raised significant concerns among health care professionals and vaccine recipients [1, 2]. In the past, cardiac complications, predominantly myocarditis and pericarditis, have been rare occurrences [3–5].

However, since the recent vaccination program has been undertaken, there have been reports of adverse cardiac events following the administration of the vaccine, including myocarditis, pericarditis, dysrhythmias, angina, and myocardial infarctions [4]. Whether there is a direct correlation between vaccination and cardiac adverse events remains unclear. We describe a woman who developed symptomatic trigeminy after receiving the smallpox vaccine.

A 29-year-old Asian female health care professional presented to the hospital for evaluation of recurrent palpitations. The onset of palpitations occurred 10 days after receiving the smallpox vaccine (she had previously received smallpox vaccine as a child). There were no associated cardiac symptoms, nor was there a history of cardiac disease. Findings of a physical examination were normal. Results of electrocardiography and thyroid function tests were normal, and serum electrolyte levels...