

Basel, 09 December 2009

Roche comments to recent media reports about Tamiflu

Roche stands behind the robustness and integrity of its data supporting the efficacy and safety of Tamiflu and the conduct of our clinical trials and publication policies. Tamiflu has been commercially available for 10 years and used by around 68 million people worldwide. The Cochrane Group was wrong to exclude the data.

Tamiflu is playing a pivotal role in responding to pandemic (H1N1) 2009. According to US government data published last month, the only intervention that was shown to make a difference to the clinical outcome in hospitalised patients was treatment with antivirals within the first two days of symptoms appearing. Around 90% of those people were given Tamiflu¹.

The issue at the heart of the Cochrane review team's questions is that Roche was unable to provide them the underlying data without signing a confidentiality agreement. **However, patients who enrolled in these Tamiflu clinical trials did so under the condition that Roche securely stored their information, did not disclose the identity of patients and maintained the confidentiality of their information.** By signing a confidentiality agreement, the Cochrane Group could have had access to the data.

All study reports cited in the Kaiser (2003) and Nicholson (2000) publications were submitted for independent analysis to the regulatory authorities' bodies, who gave their approval for the use of Tamiflu, including the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

Reference

1. Jain *et al.* Hospitalized Patients with 2009 H1N1 Influenza in the United States, April-June 2009. *N Engl J Med.* 2009;361:1991-3.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

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