Tamiflu review shows desperate need for full clinical trials data transparency

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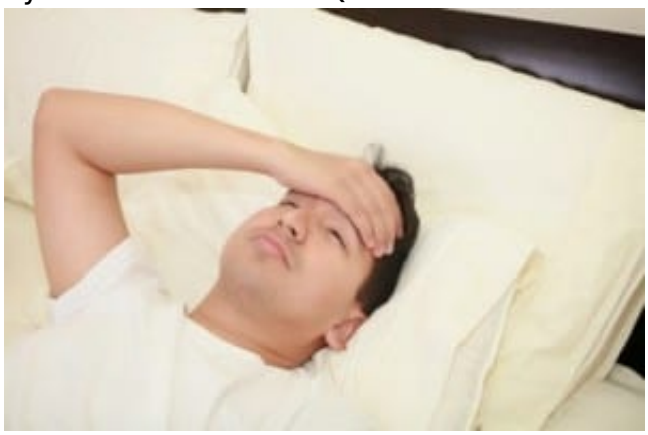

Today, the British Medical Journal published the Cochrane Collaboration's updated systematic review on Tamiflu (oseltamivir).

The inclusion in the review of clinical study reports (CSRs)—comprehensive documents prepared by the pharmaceutical industry for regulatory processes—has been crucial to uncovering the true effects of the drug.

Despite the fact that governments around the world spent billions of dollars stockpiling Tamiflu, based on overly-optimistic claims by the drug's maker, Roche, and on the advice of the World Health Organization, complete evidence from clinical trial data shows that the drug's benefits were overestimated and its potential harms were downplayed. The Cochrane authors say, in fact, that there is no strong evidence that Tamiflu is effective in reducing complications from influenza (such as pneumonia), or reducing hospitalisation rates.

Furthermore, the comparison between the complete unpublished trial records and journal publications shows that a number of adverse events, such as psychiatric side effects, were mentioned in the CSRs, but omitted—even denied—in journal publications. This serves as a further example of the extent to which reporting bias, a common practice in biomedical research, puts people at greater risk of harm.

Encouragingly, the passing of the Clinical Trials Regulation by the European Parliament last week shows that significant advances in clinical trials transparency are being made in Europe. Clearly, the case of Tamiflu illustrates that mandatory public disclosure of all clinical trial data is needed to protect people's health and to avoid wasting public healthcare spending on ineffective treatments. The current system of drug evaluation and regulation must be vastly improved.

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