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Release all Tamiflu data as promised, argue researchers

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There can be no debate about Tamiflu whilst Roche does not keep its promise to release "full study reports" about the drug, argue senior researchers from the Cochrane group today.

The latest correspondence is posted online today as part of the BMJ's open data campaign, aimed at persuading Roche to honour the promise it made almost three years ago to make key Tamiflu trial data available for independent scrutiny.

Last week, Donald MacLean, Life Cycle Leader for Tamiflu, wrote to Professor Chris Del Mar in his capacity as coordinating editor of the Cochrane Acute Respiratory Infections Group, concerning "our debate on Tamiflu data."

The Cochrane researchers say they object to Roche's suggestion that there is a debate on Tamiflu data. "There is no debate nor can there be any debate about the data whilst you do not honour your promise," they say. "The only reason we keep asking Roche to keep its promise, rather than simply getting the data from the European Medicines Agency directly, is because Roche has not supplied all of the data to the European regulator."

Roche's letter also mentions "disagreements" over the type of analyses the Cochrane team wish to do, but the researchers point out that their methods and analyses have been public for nearly two years and "follow Cochrane procedure" and state that they are not aware of any specific

concerns from Roche.

Roche's letter goes on to say that, in order to reach "an amicable resolution" Roche plans to set up "a multi-party advisory board to review the totality of Tamiflu data" …. which they believe is "a sensible, fair and transparent way of addressing this public debate."

But the Cochrane team argue that Roche's offer is merely a belated attempt at turning the clock back, and call on the company to expand its data sharing pledges "to become compatible with current regulatory norms."

They say: "The European Medicines Agency and the EU Ombudsman have made abundantly clear that there is no reason for anonymised clinical data to be withheld from public scrutiny once a marketing authorisation has been obtained for a pharmaceutical. Why should Roche not - at the minimum - meet this standard?"

In summary, they say, "we ask to you to honour your promise of three years ago and make public full clinical study reports in your possession."

Provided by British Medical Journal

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