

Prime minister gives backing to more transparent drug trial data

Adrian O'Dowd

London

David Cameron has added his support to efforts to ensure much greater availability of data from drug companies' trials.

However, a leading expert has criticised Cameron for not making more of a commitment on forcing companies to publish all their clinical data.

The issue of drug companies not submitting all trial data was raised in the House of Commons on 5 December by Richard Bacon, the Conservative MP for South Norfolk.

The *BMJ's* open data campaign (bmj.com/tamiflu) is aimed at securing appropriate and necessary independent scrutiny of data from clinical trials after the failure of the drug company Roche to fulfil its promise made in 2009 to release full clinical trial reports on oseltamivir (Tamiflu).

Bacon said in the Commons, "Three years ago, the NHS spent £500m on Tamiflu without having seen all of the data on effectiveness or safety.

"Given that far from being an isolated case it is normal for the drugs industry to have almost complete control over the evidence base upon which crucial public decisions are made, will the prime minister ask Roche to make available the full clinical study reports on Tamiflu so that doctors, patients, and tax payers are not misled?"

Cameron gave no such commitment but acknowledged that there should be more transparency in trial data in the interests of patients.

"My honourable friend raises an important issue not only because of the cost to the taxpayer but also because of possible overstatement of benefits to patients," he said.

"There does need to be more transparency in these clinical trials' data. We are committed to make sure that happens, and so the European Medicines Agency's work is supported on this, from next year there will be a legal requirement to publish summary reports from clinical trials."

However, Tom Jefferson, an independent epidemiologist with the research organisation the Cochrane Collaboration and the first author of the Cochrane review of neuraminidase inhibitors for preventing and treating flu,¹ said that he was disappointed with the prime minister's response.

"The reason we have a stockpiled drug surrounded by uncertainty, as the prime minister acknowledges, is precisely because for over a decade we have been subjected to summaries of the evidence," said Jefferson.

"Our work shows that summaries are not good enough and nothing but the full picture will suffice."

Sarah Wollaston, a GP and the Conservative MP for Totnes, also supports full publication of trial data but said that the prime minister was not in a position to force drug companies to do so at this stage.

"Today I wasn't expecting the prime minister to suddenly announce that Roche would have to hand over the data, but he did give a very clear statement of supporting open data," said Wollaston.

"Mentioning this subject during prime minister's question time is about keeping the pressure up and keeping it on the agenda. From my point of view Tamiflu is just one example. There is a systematic problem here.

"We are hoping that the Public Accounts Committee will look at this. I think we need to attack this from as many angles as possible. If it means that the public accounts committee look at it purely from the angle of an astonishing waste of public money, then good."

1 Jefferson T, Jones MA, Doshi P, Del Mar CB, Heneghan CJ, Hama R, et al. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Cochrane Database Sys Rev* 2012;(1):CD008965.

Cite this as: *BMJ* 2012;345:e8333

© BMJ Publishing Group Ltd 2012