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NEWS

MPs call for Commons committee to examine cost to NHS of missing data

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The government should demand that the £500m (€620m; $810m) it spent in 2009 on stockpiling oseltamivir (Tamiflu) be given back if it was found that the manufacturer withheld trial data that showed it to be no more effective than placebo, say MPs.

Researchers from the Cochrane Collaboration have claimed that the manufacturer, Roche, has conducted over 123 clinical trials but that at least 60% of these are unpublished, which means that they cannot properly assess the effectiveness or risks of oseltamivir.

Roche agreed in 2009 to make key trial data on oseltamivir available to independent scrutiny, and the *BMJ* is running an open data campaign (bmj.com/tamiflu) to persuade the company to fulfil its promise.

However, so far Roche has offered only to set up a multiparty advisory board to review what type of analysis of data on oseltamivir would be useful to researchers—an offer that the Cochrane group has rejected.[1]

Six MPs have now asked the parliamentary Public Accounts Committee to conduct an inquiry into the waste of NHS resources caused by trial data being concealed—not just data on drugs but also those on medical appliances and implants.

The MPs said that the committee could provide "vital insight" into the level of waste from the concealment of clinical trial data and would hold manufacturers and regulators to account.

The MPs' letter, which is addressed to Margaret Hodge, chairwoman of the Public Accounts Committee, says, "It could be that the previous government spent 0.5% of the entire 2009 NHS budget on a drug which the manufacturers were aware was no better than a placebo. Without all the clinical trial data, we cannot draw firm conclusions, but it surely cannot be right for a pharmaceutical company to receive £500m of taxpayers' money if it withholds information about its own products.

"In the event that your committee finds Roche has deliberately concealed evidence which shows Tamiflu to be simply a placebo with side effects, you might wish to consider a recommendation that the government seeks repayment of the £500m cost."

The letter is signed by the Conservative MPs Sarah Wollaston, David Davis, and Adam Afriyie, Labour's Barbara Keeley and Valerie Vaz, and the Liberal Democrat Julian Huppert.

It also points out the failings in the regulation of implants and devices, which are often approved with manufacturers deciding what trial data to provide, leading to inappropriate use, morbidity, and high revision rates.[2]

The letter says, "There are failings at every level, from ethics committees which allow trials to proceed without insisting on data being published, to organisations like the National Institute for Clinical Excellence and the European Medicines Agency which do not insist on receiving all the evidence—and then making it available to all interested medical researchers—before granting regulatory approval for drugs, appliances and implants.

"Sharing information can be a very powerful way to protect patients, because then 'many eyes' can be brought to bear on what are often complex questions. Problems with Rosiglitazone, Tamiflu, Vioxx, and many devices were spotted by the global community of independent academics, rather than by individual countries' regulators acting behind closed doors."

1 Kmietowicz Z. Cochrane group rejects Roche's offer of "advisory board" to discuss analysis of oseltamivir data. *BMJ* 2012;345:e8072.
2 Cohen D. EU approval system leaves door open for dangerous devices. *BMJ* 2012;345:e7173.

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