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# Public 'misled' by drug trial claims

**By Michelle Roberts** Health reporter, BBC News



Drugs need to undergo extensive testing in trials before approval

Doctors and patients are being misled about the effectiveness of some drugs because negative trial results are not published, experts have warned.

Writing in the British Medical Journal, they say that pharmaceutical companies should be forced to publish all data, not just positive findings.

The German team give the example of the antidepressant reboxetine, saying publications have failed to show the drug in a true light.

Pfizer maintains its drug is effective.

Reboxetine (Edronax), made by Pfizer, is used in many European countries, including the UK.

But its rejection by US drug regulators raised doubts about its effectiveness, and led some to hunt for missing data.

This is not the first time a large drug company has come under fire about its published drug trial data.

## **Trial information**

Pharmaceutical giant GlaxoSmithKline (GSK) was criticised for failing to raise the alarm on the risk of suicidal behaviour associated with its antidepressant Seroxat.

GSK rejected claims that it improperly withheld drug trial information.

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### **"Start Quote**

Our findings underline the urgent need for mandatory publication of trial data"

End Quote The research authors

But GSK has also been forced to defend itself over allegations about hiding negative data regarding another of its drugs, Avandia, which is used to treat diabetes.

Now researchers from The German Institute for Quality and Efficiency in Health Care say there is unpublished trial data for Pfizer's antidepressant reboxetine that should be made public because it could change views about the drug.

Dr Beate Wieseler and colleagues carried out their own assessment of reboxetine, looking at the results of 13 trials, including eight previously unpublished trials from the manufacturer Pfizer.

They found the drug was no better than a placebo in terms of remission and response rates. And its benefit was inferior when compared with other similar antidepressants.

Furthermore, a higher rate of patients had side effects with reboxetine than with placebo. And more stopped taking the drug because of side effects compared with those taking a placebo or a different antidepressant.

## **Biased picture**

The researchers said there has been a publication bias and this had overestimated the benefit of reboxetine and underestimated potential harm. And, they said, it was a widespread problem that applied to many of the drugs in use today.

"Our findings underline the urgent need for mandatory publication of trial data," they say in the **BMJ**.

They warn that the lack of all information means policy makers are unable to make informed decisions.

In the US, it is already a requirement that all data - both positive and negative - is published. The UK is also striving to achieve this.

The UK's regulator, the MHRA, said: "There is a European initiative to provide public access to the results of clinical trials. The currently planned timeline is that this information could become available in late 2011/early 2012."

A spokeswoman for Pfizer said: "In the UK, Pfizer's reboxetine is licensed for the acute treatment of depressive illness/major depression and for maintaining the clinical improvement in patients initially responding to treatment.

"This medicine presents an effective treatment option to clinicians for the use in patients suffering from these conditions.

"Pfizer discloses the results of its clinical trials to regulatory authorities all around the world. These regulatory authorities carefully balance the risks and

benefits of each medication, and reflect all important safety and efficacy information in the approved product labelling.

"Pfizer will review the meta-analysis relating to reboxetine published in the British Medical Journal on 13th October 2010 in detail and will provide further comment after completing the review."

Others lay at least some of the blame with the medical journals that publish drug trial data.

In response, the BMJ has promised to devote an entire issue to the topic next year.

BMJ Editors Dr Fiona Godlee and Dr Elizabeth Loder said: "It is time to demonstrate a shared commitment to set the record straight."