Drug regulators are protecting profits over patients, warn researchers

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Medicines regulators are protecting drug company profits rather than the lives and welfare of patients by withholding unpublished trial data, argue researchers in the British Medical Journal today.

They call for full access to full trial reports (published and unpublished) to allow the true benefits and harms of treatments to be independently assessed by the scientific community.

Despite the existence of hundreds of thousands of clinical trials, doctors are unable to choose the best treatments for their patients because research results are being reported selectively, write Professor Peter Gøtzsche and Dr Anders Jørgensen from the Nordic Cochrane Centre in Denmark.

Selective reporting can have disastrous consequences. For example, Rofecoxib (Vioxx) has probably caused about 100,000 unnecessary heart attacks in the USA alone, while anti-arrhythmic drugs have probably caused the premature death of about 50,000 Americans each year in the 1980s.

This must be remedied, they say, and they describe a three-year struggle to access unpublished trial reports for two anti-obesity drugs, submitted by the manufacturers to the European Medicines Agency (EMA) for marketing approval in the European Union.

"The information was important for patients because anti-obesity pills

are controversial," say the authors. "People have died from cardiac and pulmonary complications or have experienced psychiatric disturbances, including suicidal events, and most of the drugs have been de-registered for safety reasons."

But the EMA refused access, arguing that this would undermine commercial interests and that there was no overriding public interest in disclosure. They also cited the administrative burden involved and the worthlessness of the data after they had edited them.

The authors appealed to the European ombudsman, who criticised the EMA's refusal to grant access. But only after the ombudsman accused EMA of maladministration, did it agree to widen public access to documents.

"There is something fundamentally wrong with our priorities in healthcare if commercial success depends on withholding data that are important for rational decision making by doctors and patients," say Gøtzsche and Jørgensen.

Provided by British Medical Journal