Investigation questions motives behind post-marketing studies

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An investigation published by the *BMJ* today raises concern about the motives behind post-marketing studies of new treatments for diabetes and calls for better regulation to ensure "a proper balance" between the commercial and clinical functions of these studies.

Experts warn that these studies are fuelling "catastrophic health expenditure" in low income countries, and a former drug industry employee admits that many of these studies "had more marketing than science behind them."

In theory, post-marketing studies are primarily used to show that a new drug is safe and effective in the real world. But there are concerns that many of these studies are predominantly serving a marketing purpose – to promote new, more expensive treatments and influence the prescribing habits of physicians.

Concerned about the role and legitimacy of post-marketing studies for new insulins, Edwin Gale, Emeritus Professor of Diabetic Medicine at the University of Bristol, analysed their use by three main insulin manufacturers (Eli Lilly, Novo Nordisk and Sanofi-Aventis).

New analogue insulins can cost up to four times as much as conventional human insulin, but evidence shows that they offer little benefit to most people with type 2 diabetes.

Yet Professor Gale found that nearly 400,000 people worldwide have

been recruited into post-marketing studies of insulin analogues since 2005. One company recruited nearly 360,000 individuals. Most studies were carried out in middle or low income countries, had limited scientific value, and promoted wider use of more expensive insulins. Most patients are also likely to remain on the new insulins at the end of the studies.

It seems reasonable to ask whether a company would invest in such large scale activities without a good commercial rationale, writes Gale. Although physicians may participate in good faith, he says that "the patient or healthcare system pays for a more expensive agent instead of one that is cheaper and equally effective, and the public is offered misleading claims of comparative merit based on studies of limited scientific value."

In an accompanying article, John Yudkin, Emeritus Professor of Medicine at University College London argues that post-marketing studies "may be driving households into catastrophic health expenditure."

He points to Novo Nordisk's PREDICTIVE study, which paid doctors in 26 countries to start 47,565 people with diabetes on the company's insulin analogue, Levemir. Professor Yudkin calculates that in India, where 3,435 patients were enrolled in the study, and where patients must cover drug costs themselves, the annual cost of Levemir would be eight times more than a generic human insulin.

Novo Nordisk can be justifiably proud of some of their social responsibility initiatives over the past 10 years, he says, "but it now needs to reclaim the moral high ground."

In a third article, a former drug industry employee reveals that some post-marketing studies "had more marketing than science behind them" and

admits to "playing" with the data "to ensure that the benefits of the drug were emphasised and the disadvantages were minimised where possible."

Wishing to remain anonymous, the author describes other questionable practices, including the use of key opinion leaders to add credibility to the results and to influence decision makers and other prescribers.

"Allowing companies to focus more time and efforts on drug development, or increasing transparency by encouraging industry authors to disclose the fact that the research has commercial objectives (as long as these are balanced with scientific value) would definitely help to develop better drugs for patients," they conclude.

Provided by British Medical Journal

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