Novartis breached code after doctors say it "invented" a disease

Annabel Ferriman *BMJ*

The drug company Novartis Pharmaceuticals UK has been found to be in breach of the industry's advertising code in promoting its drug nateglinide (Starlix).

A GP complained to the Prescription Medicines Code of Practice Authority, a body set up by the Association of the British Pharmaceutical Industry in 1993 to police its advertising rules, after he attended a meeting on diabetes and coronary heart disease. The meeting was organised by Lanarkshire health care committee and sponsored by Novartis.

At this meeting, a speaker used a large study—known as the DECODE study (Diabetes Epidemiology: Collaborative Analysis of Diagnostic Criteria in Europe)—to suggest that if doctors treating diabetes could reduce the high concentrations of sugar in their patients' blood after a meal, they could reduce their mortality. He produced literature from Novartis to support his contention. The literature pointed out that the company's drug nateglinide reduced glucose levels after meals and thereby implied that it could reduce mortality.

Dr Robert Flowerdew, who practises in Douglas, Lanarkshire, and a colleague, wrote to the authority saying: "The DECODE study does not investigate whether reducing post-prandial glucose concentrations reduces mortality in diabetics. In fact, it does not look into the treatment of diabetes, but is an investigation into the diagnosis of diabetes in an unscreened population."

He went on: "Should drug companies be allowed to indiscriminately use notable papers, which practitioners have often heard of, but not always read, in support of their products, thus gold stamping them?"

The code of practice authority upheld Dr Flowerdew's complaint. It said: "The panel considered that … [the company's literature] by linking PPG [post-prandial glucose] spikes to an increased risk of death and stating that Starlix managed PPG spikes implied that Starlix reduced cardiovascular risk and mortality.

"There was no evidence to show that this was so. The panel considered that [the literature] gave a misleading impression of the effect of Starlix on cardiovascular mortality and risk. A breach of the Code was ruled."

The authority said that the DECODE study was a meta-analysis from 13 prospective European cohort studies looking at the relation between glucose tolerance and mortality. It compared the oral glucose tolerance test with fasting glucose levels as diagnostic tools for diabetes. The study concluded that the first test was more sensitive than the second.

"The meeting used the DECODE study as evidence to change clinical practice ie manage post-prandial glucose levels in diabetic patients. The DECODE study did not investigate whether reducing post-prandial glucose concentrations reduced mortality," the authority said.

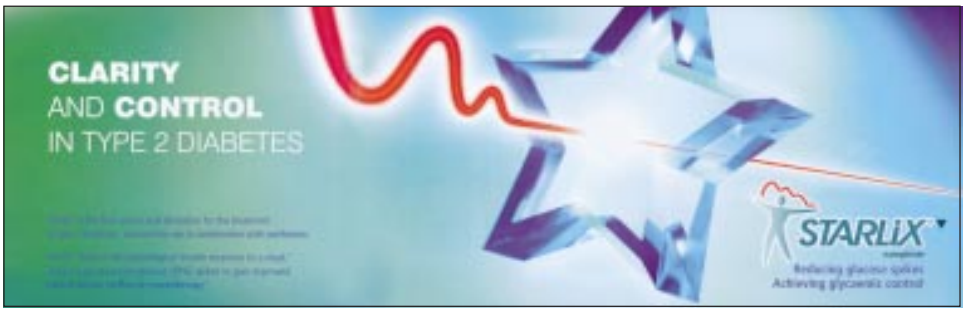
In its defence, Novartis told the authority: "It was not Novartis's intention to mislead the reader or suggest that by reducing the post-prandial glucose spikes, Starlix could also reduce the risk of mortality in diabetes. Indeed, this was not stated . . . It was, however, suggested that, by including a reference to mortality in a promotional piece for Starlix, even though no direct link was made to Starlix, the reader might mistakenly think Starlix could reduce mortality risk.

"Thus, in order to clarify this and avoid any potential for confusion, the Starlix promotional material had now been either amended or discontinued accordingly."

Dr Flowerdew thought that Novartis's behaviour was another example of a drug company inventing a disease so that it could come up with a product to cure it, the theme of an article in the *BMJ* (2002;324:886-91).

In a letter to the *BMJ* he wrote: "Novartis have invented a disease, high post-prandial glucose concentrations in diabetic patients, and come up with a product, nateglinide, a short acting beta-cell stimulant to be taken with meals, reducing post-prandial glucose spikes, and by inference, reducing mortality in diabetic patients. Nateglinide costs about four times more than gliclazide."

He told the *BMJ* that since the authority had imposed no penalty on the company for issuing misleading literature, there was no deterrence to using such practices in future. □



Dr Robert Flowerdew claimed that Novartis invented a disease, "high post-prandial glucose concentrations in diabetics," and then produced a drug—nateglinide (Starlix)—to cure it

Congress criticises drugs industry for misleading advertising

Scott Gottlieb *New York*

Some companies have disseminated misleading advertisements for prescription drugs, even after being cited for violations, a report issued by the US Congress says.

Congressional investigators, from the independent General Accounting Office, also said that drug advertising seemed to produce a major increase in the use of prescription drugs. The study estimated that at least 8.5 million Americans each year request and receive prescriptions for specific drugs after seeing or hearing advertisements for those products.

Among the drugs cited in the report for misleading advertisements were Flonase (fluticasone propionate), an allergy drug produced by A&H (Allen and Hanbury's), and Actonel (risedronate sodium), a drug for osteoporosis, made by Procter and Gamble.

Senator Susan Collins, a Maine Republican who was one of five members of Congress who requested the study, said: "The evidence suggests that consumers are paying a lot of attention to these ads, so it's imperative that they be accurate. If the increase in utilisation is based on false claims, that's very troubling."

The report rejected a claim by critics of the pharmaceutical industry that drug companies spent more on advertising than on research and development. The report found that drug makers spent much more on research. Last year, it said, companies spent $30.3bn (£19.3bn; 30.1bn) on research and development and $19.1bn on all promotional activities, including $2.7bn for advertising aimed at consumers.

Typically, when the Food and Drug Administration finds that a drug advertisement is so inaccurate, misleading, or incomplete that it violates federal law and regulations, the agency writes a letter instructing the manufacturer to halt the advertisements.

From August 1997 to August 2002 the agency issued 88 letters accusing drug companies of advertising violations—44 for broadcast advertisements, 35 for print advertisements, and nine that cited both types of advertisement.

In many cases, the agency said, companies overstated the effectiveness or minimised the risks of the drug. □