

GSK fights compensation claims from UK patients who took rosiglitazone

Clare Dyer

BMJ

GlaxoSmithKline, the UK based multinational that makes the antidiabetes drug rosiglitazone (marketed as Avandia), is fighting compensation claims from UK patients who allege that the drug harmed them, even though the company has already paid billions of dollars to settle tens of thousands of similar claims in the United States.

Rosiglitazone, and the drug in combination with metformin (Avandamet), were withdrawn from the market in Europe in 2010 after studies showed that it could raise the risk of heart attack.¹ When it was taken off the European market it is thought that around 90 000 patients in the United Kingdom were taking it, and it is still in use in the US, although not for patients with heart problems.

By February 2012 GSK had settled more than 25 000 lawsuits brought on behalf of US users of the drug, but the company has been fighting litigation in the UK, said the solicitor Daniel Slade, who has launched proceedings in the UK for four claimants and has another 20 or so possible claims.

"They [GSK] dispute the allegations brought by our clients," said Slade, a partner in the Manchester firm Express Solicitors. "They don't admit the extent to which people are suffering. They say they don't believe it was caused by the drug or by their negligence or that the product was defective."

In the US, as well as settling lawsuits on behalf of patients allegedly harmed by the drug, GSK agreed in 2011 to pay \$3bn (£2bn; €2.2bn) in fines and civil settlements with US federal and state governments, after pleading guilty to promoting two antidepressants for unapproved uses and failing to report safety data about rosiglitazone to the Food and Drug Administration. The case, which investigated 10 drugs, was said by the US authorities to be "unprecedented in both size and scope."²

Concerns about side effects of rosiglitazone came to light in 2007 when the researchers Steven Nissen and Kathy Wolski published a meta-analysis of GSK's studies of the drug in the *New England Journal of Medicine*.³ Their study claimed that the drug was "associated with a significant increase in the risk of myocardial infarction" when compared with placebo or other antidiabetes regimens.

Claimants face an uphill struggle in successfully suing drug companies in the UK, where legal processes and funding arrangements for civil claims are much less friendly to claimants than in other countries.

Slade called on GSK to reach a compromise with his clients, who have a "no win, no fee" agreement with their lawyers, "sooner rather than later."

A spokesman for GSK said, "We have every sympathy for people with health complications associated with diabetes and those who care for them. However, respecting the UK court process, we are unable to comment on ongoing legal cases. We continue to believe that the company acted appropriately and responsibly in its management of Avandia."

He said that it was "wrong" to suggest that the company had hidden or concealed data on safety.

- 1 Cohen D. European regulatory body recommends suspension of rosiglitazone. *BMJ* 2010;341:c5291.
- 2 Hawkes N. GlaxoSmithKline pays \$3bn to settle dispute over rosiglitazone and other drugs. *BMJ* 2011;343:d7234.
- 3 Nissen S, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med* 2007;356:2457-71.

Cite this as: *BMJ* 2013;346:f695

© BMJ Publishing Group Ltd 2013