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BMJ Recommends Pulling Avandia: EU to Review Safety

GlaxoSmithKline's diabetes drug Avandia should be pulled from sale because of concerns about heart risks, British drug regulators said on Monday ahead of a special European meeting on the drug's safety.

The strong line from safety experts in the drugmaker's home market is a fresh blow to a medicine that was once Glaxo's second biggest seller but has become a liability since being linked to increased heart attack risk in 2007.

The Medicines and Healthcare products Regulatory Agency (MHRA) said it believed the risks of Avandia, known generically as rosiglitazone, outweighed its benefits and that "it no longer has a place on the UK market."

Spokesman Stephen Hallworth said the MHRA had put forward its position "robustly" to the European Medicines Agency (EMA) and would highlight its concerns again at a special meeting on the drug's future this week.

The EMA -- the decentralised European body responsible for licensing Avandia in 2000 -- will hold an extraordinary expert meeting on September 8 to review the drug's safety before finalising its position at its next scheduled meeting on September 20 to 23. London-based EMA said the additional meeting was necessary because of the complexity of the data being assessed.

The British Medical Journal (BMJ) and some leading doctors attacked the tardy response, calling for Avandia to be pulled off the market immediately and saying it should never have been licensed in the first place. British regulators' concerns about Avandia came to light following a BMJ investigation that found out the Commission on Human Medicines -- an independent working group advising UK ministers -- had recommended the withdrawal of Avandia in July.

A MHRA letter sent to doctors on July 26 merely advised them to "consider alternative treatments where appropriate."

Dr Deborah Cohen, who led the BMJ investigation, said letter was not clear enough, and the MHRA should have informed doctors of the commission's full opinion.

"Medicine is all about benefits versus risks," she said in a telephone interview. "And if a group of experts in drug safety believes the risks outweigh the benefits, that's an important message that would inform doctors when they're prescribing."

The BMJ's editor, Dr Fiona Godlee, told Reuters: "The time has now come for this drug to be withdrawn from the market."

Avandia used to be Glaxo's second-biggest drug, selling $3 billion (1.9 billion pounds) in 2006 until health concerns emerged. Its sales plunged to $1.2 billion in 2009, or some 2.7 percent of group sales, as many doctors switched to Takeda's rival drug Actos.

In the United States, health advisers recommended to regulators on July 14 that Avandia should be allowed to stay on the market but with additional warnings.

The Food and Drug Administration is expected to make a final decision on Avandia later this month and the agency usually follows recommendations from its advisory committees. Glaxo said an extensive research programme showed Avandia was safe and effective when used appropriately according to its labelling.

The drugmaker has faced a slew of lawsuits in the U.S. but tried to put the issue behind it in July by taking a record legal charge of 1.57 billion pounds, partly to settle the bulk of the Avandia claims. Britain's Department of Health said in a statement it was aware of concerns about Avandia, but advised patients not to stop taking their medication without talking to a doctor.

"MHRA has issued guidance to all healthcare professionals with clear warnings about the associated risks for some patients," it said. "Ministers have not been asked to make any decisions about the licence of Avandia in the UK." (source: Reuters)

Published on : Mon, 6 Sep 2010