Avandia Recall Decision In Europe To Be Announced On Or About September 23, 2010

Will This September 2010 EMA Committee Meeting Result In A Consensus, Unlike July 2010 FDA Avandia Panel Voting

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 22, 2010; see http://bit.ly/bcgdEC)

UPDATE: FDA Keeps Diabetes Pill on Market; Europe Suspends Sales (9/23/10, Wall Street Journal)

The Committee for Medicinal Products for Human Use (CHMP), which has been meeting at the headquarters of the European Medicines Agency (EMA) in London since September 20, 2010, is expected to announce tomorrow, September 23, whether GlaxoSmithKline's diabetes drug Avandia (rosiglitazone) should be recalled in Europe due to its links with heart attacks.

From this September 20 article by *Reuters* reporter Ben Hirschler, "EU agency meets to weigh fate of Glaxo's Avandia", we get some indication about why it is likely there will be a decision to recall Avandia in Europe:

> Some European government safety experts, including those in Britain, argue that the risks of Avandia outweigh its benefits and the medicine no longer has a place on the market.
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> As a result, the drug, once Glaxo's second-biggest seller, is now more likely to be withdrawn in Europe than the United States, where concerns about the drug were first raised, industry analysts believe....
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> Pressure has increased for the European watchdog to pull the drug after British regulators said two weeks ago they had requested it be removed from sale.
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> Under European rules, national agencies such as Britain's Medicines and Healthcare products Regulatory Agency (MHRA) must comply with the European consensus, since Avandia was licensed centrally by the EU body in 2000.
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> "Once the committee has reached a verdict, even if it is by a majority, and it has been endorsed by the European Commission, then it is binding throughout Europe," the EMA spokeswoman said.

At a July 2010 FDA Advisory Committee the voting was split on how to deal with the conclusion that Avandia posed a serious heart attack risk to patients -- with just less than half calling for an Avandia recall while slightly more than half thought that more restrictions put on prescribing doctors would be sufficient.

We will let you know the EMA decision about an Avandia recall as soon as we get the news.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com