FDA places stringent restrictions on Avandia

By ACSH Staff — September 24, 2010

Following a split vote by an FDA advisory panel in July on whether Avandia was safe to stay on the market after evidence surfaced implicating the diabetes drug with an increased risk of heart attack, the FDA announced yesterday that it will place stringent restrictions on Avandia’s availability. Patients who wish to continue use of Avandia will have to enroll in a Risk Evaluation and Mitigation Strategy (REMS) program along with their doctors and pharmacists. Though the FDA did not formally withdraw approval for the drug, new prescriptions can only be written for patients who cannot take Actos, a diabetes drug in the same class made by Takeda that does not pose the same heart problems associated with Avandia.

Upon announcing the news, FDA Commissioner Dr. Margaret Hamburg said, “As FDA commissioner, my job would be infinitely easier if we had consensus and full scientific clarity.”

“Well everyone’s job would be infinitely easier if we all had consensus and full scientific clarity, but there’s no such thing — it seems to change by the month,” retorts ACSH's Dr. Gilbert Ross.

Also ruling on Avandia yesterday was the European Medicines Agency, which will be suspending sales of the drug over the next few months without formally withdrawing its approval.

Both agencies’ decisions seem to set a precedent for future drug regulatory approval: medicines will now have to improve the quality or length of a diabetic’s life rather than just control blood sugar levels. “Up until now, we’ve been blindly assuming that tight blood sugar control would improve health outcomes. It now appears that the future of the drug approval process may require more attention to real-world clinical parameters,” says Dr. Ross. “For example, rather than approving drugs that commonly use biomarkers such as lower cholesterol, companies will have to use clinical end points instead, such as a reduction in heart disease.”