

Outgoing Glaxo Head Says Drugs Should be Tested Sooner, Better

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Outgoing head of GlaxoSmithKline (GSK) Jean-Pierre Garnier says he does not foresee the US Food and Drug Administration (FDA) softening its position on drug approvals. Garnier is stepping down at the company's annual meeting next week. "This is not a pendulum," he says, "society wants to avoid risk. We have to tease out rare side effects earlier."

Garnier added that the FDA has raised the bar and companies must adapt by shifting drug development priorities and conducting trials on targeted sub-populations to better realize rare side effects prior to regulatory submission. Other senior industry personnel suggest the U.S. election has strongly impacted the FDA's position on new drugs and Garnier believes "the market will get reconstituted" with a new focus on so-called "progressive blockbusters," which will ultimately reduce drug development costs by eliminating false negative results sooner.

But with the Pharmaceutical Price Regulation Scheme re-negotiations still ongoing in the United Kingdom, where GSK is based, and warnings of a shift away from the country for pharma research and development, Garnier says, "We want to compete on the basis of innovation. The translation of policies has to take account of those needs. As long as they do, we'll be very happy to continue to stay ... but you cannot handicap us."

Garnier, who will assume another healthcare role after he steps down as chief executive next week confessed to the Financial Times that there are things he wishes he had done differently, including earlier release of data for GSK's beleaguered diabetes drug Avandia (rosiglitazone), but that overall he has "no regrets."

In April, the FDA issued a warning to GlaxoSmithKline for not reporting safety results on Avandia. Avandia received the prominent, "Black Box" warning label last year and the FDA said that between 2001 and 2007 GlaxoSmithKline neglected to update the agency on over 10 ongoing studies of Avandia, as required by regulations. The FDA acknowledges that information from those studies was included and disclosed in other notices to the government; however, the FDA categorizes the omissions as "serious," saying that the omissions "may be symptomatic of underlying post-market reporting failures."

Last November, Avandia received a Black Box warning, which is the most serious labeling warning that a drug can carry. Black Box warnings are posted on medications as a means to alert doctors and patients that the drug could increase the risk of heart attacks, although in the case of Avandia, that evidence is currently not conclusive. The labeling change to the Black Box followed several high-profile congressional hearings where the FDA and Glaxo were criticized for not disclosing the drug's potential risks earlier. A spokeswoman for Glaxo said the FDA had all safety studies on Avandia before it added the Black Box warning last year, adding that Glaxo is working with the FDA to resolve the issues.

Glaxo agreed to the FDA's demand for a major study that will directly review Avandia's heart effects. The study is not expected to be complete until 2014.