Dear Secretary

Please see further information below that was requested for clarification at the Senate Finance and Public Administration Legislation Committee hearing for the Inquiry into Pharmaceutical Transparency Bill on the topic of GSK's $3 billion civil settlement with the US Government.

The matters we have resolved in the settlement with the US Government do not reflect the company we are today. As mentioned yesterday these offences were isolated to the United States and originated in a different era for the company and GSK expresses regret and reiterates that the company learnt much from its mistakes.

Times change, societal expectations evolve. We are committed to continually re-examine how we conduct our business to ensure that our values are reflected in our practices, and that our practices are aligned with the expectations of those we serve.

Under the terms of the settlement, GSK pleaded guilty to misdemeanor violations of the Federal Food, Drug, and Cosmetic Act related to the marketing of Paxil for pediatric use and Wellbutrin for certain uses, and failure to include information about the initiation or status of certain Avandia studies in Periodic and Annual Reports submitted to the FDA.

The civil settlement agreement contained many allegations that were either inaccurate or incomplete, that selectively told only parts of the story, and that draw unwarranted conclusions from disputed facts. The civil settlement is not an admission of any liability or wrongdoing in the selling and marketing of Avandia.

With respect to the criminal plea, GSK admits that it did not include information about the initiation or status of certain Avandia studies in Periodic and Annual Reports submitted to the FDA. More specifically:

- In the 2001 Periodic Report, GSK did not indicate that Study 211 and RECORD had been initiated.
- In Annual Reports between 2001 and 2007, GSK did not include a status report on certain post marketing studies involving Avandia. Some of the studies that were omitted from certain of the Annual Reports included Study 211, RECORD, and APPROACH.
- In the 2007 Annual Report, GSK did not provide a status report for the ADOPT study.

RECORD, STUDY 211, ADOPT and APPROACH were all disclosed to the FDA in other reports and notifications. These inadvertent omissions from certain reports did not compromise the timely reporting of adverse events to the FDA from these studies, and as FDA spokeswoman Susan Cruzan confirmed, did not change the FDA's evaluation of the safety data for Avandia.

Kind regards

Lisa

Lisa Maguire
Associate Director Corporate Affairs and Patient Advocacy

GlaxoSmithKline Australia