GLAXOSMITHKLINE PLC
Form 6-K
September 23, 2010

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending September 2010

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

--

Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the
Securities Exchange Act of 1934.

Yes No x

--

Issued: Thursday 23 September 2010, London UK, LSE Announcement

GSK regulatory update on Avandia following EMA and FDA reviews

GlaxoSmithKline (GSK) confirms that following a review of Avandia® (rosiglitazone maleate) by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), each agency has today announced their individual regulatory decisions and the resulting actions.

In the European Union*, the EMA has suspended the marketing authorisation for all rosiglitazone-containing medicines (Avandia, Avandamet® and Avaglim®). As a result, physicians in Europe are being advised that affected patients need to be transitioned to alternative treatment options. The EMA has stated that the suspension will remain in place unless convincing data are provided that identify a group of patients in whom the benefits of the medicine outweigh its risks.

In the US, all rosiglitazone-containing medicines (Avandia, Avandamet and Avandaryl®) will remain available with additional safety labelling and restrictions for use. The FDA will also require a Risk Evaluation and Mitigation Strategy (REMS) programme with additional measures to ensure the safe use of the medicine.

Dr. Ellen Strahlman, GSK's Chief Medical Officer, said: "Our primary concern continues to be patients with type 2 diabetes and we are making every effort to ensure that physicians in Europe and the US have all the information they need to help them understand how these regulatory decisions affect them and their patients."

The company continues to believe that Avandia is an important treatment for patients with type 2 diabetes and is now working with the FDA and EMA to implement the required actions. GSK will also work closely with other regulatory agencies to comply with any decisions made by them regarding rosiglitazone-containing medicines. GSK will voluntarily cease promotion of Avandia in all the countries in which it operates and will continue to respond to requests for information and support from healthcare professionals and patients.

Regarding clinical trials, the FDA has imposed a new post-marketing requirement (PMR) for GSK to commission an independent re-adjudication of the endpoints reported in the large, prospective, randomised, controlled study, RECORD. GSK will provide its full support for this review. The FDA-required TIDE study has been placed on full clinical hold by the agency. TIDE is the only GSK-sponsored clinical trial using Avandia currently being conducted in the US and Europe. GSK in conjunction with the TIDE steering committee will communicate this decision to local regulatory agencies, ethics committees and institutional review boards (IRBS).

Financial Information

Total sales of Avandia products in the first half of 2010 were £321m (-18%); US £164m (-23%); Europe £72m (-17%); Emerging Markets £37m (-5%); RoW £48m (-6%)**. As a result of the regulatory updates in both the US and EU, GSK now expects global sales of Avandia products to be in a range of approximately £100m - £150m in the second half of 2010 and with minimal annual sales thereafter. These estimates are net of customer returns of product

previously sold. Associated one-off costs in 2010 comprising stock write-offs, asset write-offs and other related one-off costs are currently expected to be approximately £100m on a pre-tax basis.

To access the full EMA announcement visit www.ema.europa.eu.
To access the full FDA announcement visit www.fda.gov.

S M Bicknell
Company Secretary
23 September 2010

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

* The 27 voting members of the EMA are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom. In addition, Norway, Iceland and Liechtenstein who are non-voting members of the EMA are also affected.

** All growth rates are shown at constant exchange rates and relate to the prior comparative period

GlaxoSmithKline Enquiries:

UK Media enquiries:	David Mawdsley	(020) 8047 5502
	Claire Brough	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Alexandra Harrison	(020) 8047 5502
	Jo Revill	(020) 8047 5502
US Media enquiries:	Nancy Pekarek	(919) 483 2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483

	Sarah Alspach	2839 (919) 483 2839
European Analyst/Investor enquiries:	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503
US Analyst/ Investor enquiries:	Tom Curry	(215) 751 5419
	Jen Hill Baxter	(215) 751 7002

Cautionary statement regarding forward-looking statements
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2009.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: September 23 2010

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc