GLAXOSMITHKLINE PLC
Form 6-K
March 06, 2013

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 March 2013

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

Yes No x

--

GlaxoSmithKline plc
Publication of Annual Report 2012

Today, 6 March 2013, GlaxoSmithKline plc published on the Company's website, www.gsk.com/corporatereporting, its Annual Report for the year ended 31 December 2012.

A hard copy version of the Annual Report 2012, together with the Notice of Annual General Meeting, will be sent to those shareholders who have elected to continue to receive paper communications on or about 20 March 2013. Shareholders who have not elected to continue to receive paper communications, will be sent an Annual Summary 2012 notifying them of the availability of these documents on the Company's website. The Annual Report 2012, Annual Summary 2012 and Notice of Annual General Meeting will be submitted to the UK Listing Authority.

In accordance with the requirements of Rules 4.1 & 6.3.5 of the Disclosure and Transparency Rules of the UK Financial Services Authority, the Appendix to this announcement contains a description of the principal risks and uncertainties affecting the Group and a responsibility statement.

The unaudited Preliminary Results for the year ended 31 December 2012 were announced on 6 February 2013.

V A Whyte
Company Secretary
6 March 2013

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 the Group's operations are described under 'Risk Factors' in Appendix A of this announcement.

Brand names
Brand names appearing in italics throughout this announcement are trademarks either owned by and/or licensed to GlaxoSmithKline or associated companies.

APPENDIX

(i) Principal risk factors and uncertainties
There are risks and uncertainties relevant to the Group's business, financial condition and results of operations that may affect the Group's performance and ability to achieve its objectives. The factors below are among those that the Group believes could cause its actual results to differ materially from expected and historical results. There are other risks and uncertainties that may affect the Group's performance and ability to achieve its objectives that are not

currently known to the Group, or which are deemed immaterial.

The Group reviews and assesses significant risks on a regular basis and has implemented an oversight programme to help ensure that there is a system of internal controls in place. This system includes policies and procedures, communication and training programmes, supervision and monitoring and processes for escalating issues to the appropriate level of senior management. Such a system helps facilitate the Group's ability to respond appropriately to risks and to achieve Group objectives and helps ensure compliance with applicable laws, regulations and internal policies. In addition, the Group's Audit & Assurance function is responsible for independently assessing the adequacy and effectiveness of the management of significant risks and reporting outcomes to business management, the Risk Oversight & Compliance Council, and the Audit & Risk Committee as necessary. The Group's management of risks is further discussed on pages 100 to 102 'Corporate Governance' in the Annual Report 2012.

The principal risks and uncertainties that might affect the Group's business are identified below. United Kingdom regulations require a discussion of mitigating activities a company takes to address these risks and uncertainties. However, it is not possible for the Group to implement controls to respond to all the risks that it may face, and complete assurance cannot be provided that the steps the Group has taken to address certain risks, including those listed below under "Mitigating activities include," will manage these risks effectively or at all. The principal risk factors and uncertainties are not listed in order of significance.

Delivering commercially successful new products
Risk description: Risk that R&D will not deliver commercially successful new products
The Group operates in highly competitive markets. In the Pharmaceuticals and Vaccines businesses, it faces competition from proprietary products of large, international manufacturers and from producers of generic pharmaceuticals. The Pharmaceuticals and Vaccines businesses also face increasing competition from manufacturers in emerging markets, with a lower cost manufacturing base than that of the Group. Significant product innovations, technical advances or the intensification of price competition by competitors may materially and adversely affect the Group's financial results. The Group cannot always predict the timing or impact of competitive products or their potential impact on sales of the Group's products. In light of the competitive environment in which the Group operates, continued development of commercially viable new products as well as the development of additional uses for existing products is critical to the Group's ability to replace sales of older products that decline upon expiration of exclusive rights, and to increase overall sales.

Developing new pharmaceutical and vaccine products is a costly, lengthy and uncertain process. A new product candidate can fail at any stage of the development process, and one or more late stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but, after significant investment of Group economic and human resources, may fail to reach the market or may have only limited commercial success. This could be, for example, as a result of efficacy or safety concerns, an inability to obtain necessary regulatory approvals, difficulty manufacturing or excessive manufacturing costs, erosion of patent coverage as a result of a lengthy development period, infringement of patents or other intellectual property rights of others or an inability to differentiate the product adequately from those with which it competes.

Furthermore, health authorities have increased their focus on safety and product differentiation when assessing the benefit/risk balance of drugs, which has made it more difficult for pharmaceutical and vaccine products to gain regulatory approval. There is also increasing pressure on healthcare budgets as a result of the financial crisis, the increase in the average age of the population in developed markets, and the Increase in the absolute population in developing markets. Payers, therefore, increasingly have demanded greater incremental benefit from pharmaceutical and vaccine products before agreeing to reimburse drug manufacturers at prices manufacturers consider appropriate. A failure to develop commercially successful products or to develop additional uses for existing products for any of these reasons could materially and adversely affect the Group's financial results.

Mitigating activities include: The Group has changed the Pharmaceuticals and Vaccines R&D organisation in recent years in an attempt to deliver a large and diverse late-stage pipeline and a discovery organisation structure that can sustain a flow of innovative new medicines and vaccines. To do this, the Group has evolved from our traditional hierarchical Pharmaceuticals and Vaccines R&D business model to an R&D business model based on smaller units in an attempt to encourage greater entrepreneurialism and accountability for our scientists, which the Group believes will create an environment that will be more conducive to the development of commercially viable new products and the development of additional uses for existing products.

In addition, the Group plans to continue collaborating with partners in academia, biotechnology companies and other pharmaceutical companies, which the Group believes can both improve our ability to develop competitive products and decrease the amount of time it takes to do so. The Group is also increasing consultation with patients and payers to ensure the medicines it develops provide improvements that healthcare systems will value and reward.

The Group reviews both product development and external collaborations through a series of formal governance committees. These committees progressively evaluate both the scientific and financial considerations for a product as well as the potential benefits/risks associated with the continued development of the assets. These committees include R&D executives as well as medical, scientific and commercial specialists for relevant therapy and business areas.

Protecting intellectual property rights
Risk description: Risks of failing to secure and protect intellectual property rights
Failure to obtain effective intellectual property protection for our products.
As an innovator Pharmaceutical, Vaccine and Consumer Healthcare company, the Group seeks to obtain appropriate intellectual property protection for our products. Our ability to obtain and enforce patents and other proprietary rights with regard to our products is critical to the Group's business strategy and success.

In a number of markets in which the Group operates, the intellectual property laws and patent offices are still developing, and some markets may be unwilling to extend intellectual property protection to innovative products in a fashion similar to markets in more developed regions such as the EU, Japan and the USA or to enforce previously granted intellectual property rights.

The Group's inability to obtain and enforce effective intellectual property protection for our products in certain markets could have a material adverse result on the Group's financial results.

In some of the countries in which the Group operates, patent protection and data exclusivity may be significantly weaker than in the USA or the EU. Some developing countries have reduced, or threatened to reduce, effective patent protection for pharmaceutical products generally, or in particular therapeutic areas, to facilitate early competition within their markets from generic manufacturers. Any loss of patent protection, including reducing the scope of patent rights or compulsory licensing (in which a government forces a manufacturer to license its patents to a competitor), could materially and adversely affect the Group's financial results in those markets. Absence of adequate patent or data exclusivity protection could limit the opportunity to rely on such markets for future sales growth for the Group's products.

Expiry of intellectual property rights protection on the Group's products and on competitive products; Competition from generic manufacturers.
Pharmaceutical and vaccine products are usually only protected from being copied by generic manufacturers during the period of exclusivity provided by an issued patent or related intellectual property rights such as Regulatory Data Protection or Orphan Drug status. Following expiry of intellectual property rights protection, a generic manufacturer may produce a generic version of the product.

The Group faces intense competition from manufacturers of generic pharmaceutical products in all of its major markets. Introduction of generic products, particularly in the USA where the Group has its highest turnover and

margins, typically leads to a dramatic loss of sales and reduces the Group's revenues and margins for its proprietary products. The Group had 10 pharmaceutical and vaccine products with over £500 million in annual global sales in 2012. For certain of these products, there is generic competition in the USA and some markets in Europe.

The timing and impact of entry in the USA and major markets in Europe for a 'follow-on' product toSeretide/Advairthat contains the same active ingredients is uncertain. The US patent for compositions containing the combination of active substances inSeretide/Advair expired during 2010. The Group has not been notified of any acceptance by the US Food & Drug Administration (FDA) of an application for a 'follow-on' product that refers to Seretide/Advair and contains the same active ingredients and is not able to predict when this may occur or when any such 'follow-on' product may enter the US market.

Generic drug manufacturers have also exhibited a readiness to market generic versions of many of the Group's most important products prior to the expiration of the Group's patents. Their efforts may involve challenges to the validity or enforceability of a Group patent or assertions that their generic product does not infringe the Group's patents. If the Group is not successful in defending an attack on its patents and maintaining exclusive rights to market one or more of its major products, particularly in the USA and Europe, the Group's financial results would be adversely affected. The expiration dates for patents for the Group's major products and a description of litigation settlements which may affect the dates on which generic versions of the Group's products may be introduced are set out on pages 229 to 230 in the Annual Report 2012. Legal proceedings involving patent challenges are set out in Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2012.

The Group may also experience an impact on sales of one of its products due to the expiry or loss of patent protection for a product marketed by a competitor in a similar product class or for treatment of a similar disease condition. The availability of generic products in the same or similar product class in which one of the Group's products competes could have a material adverse impact on sales of the Group's products.

Regulations outlining the requirements for establishing biosimilars and interchangeable products, as well as the operation of complicated patent litigation provisions, have not yet been proposed by the FDA, although the FDA currently is implementing the biosimilar pathway without such regulations, based on the statute and guidance documents. In Europe, the European Medicines Agency (EMA) has finalised guidelines for similar biological medicinal products containing monoclonal antibodies (mAbs). Such new regulations for establishing biosimilars and interchangeable products could allow for earlier competition for certain of the Group's products.

The loss of patent or data exclusivity protection for some or all of the Group's products could have a material adverse impact on sales of the Group's products.

Mitigating activities include: The Group is supported by a Global Patents organisation within the Legal group whose focus is to seek to ensure and protect the intellectual property rights of the Group. Beginning in 2011 and continuing through 2012, the Global Patents group sought to implement improvements to certain time-driven processes and controls in order to better manage its ability to obtain and maintain patent protection for the Group's key assets and to minimize risk of invalidity or unenforceability of its patents. These processes relate to (1) implementing a new review process designed to help with obtaining and maintaining appropriate patent protection for key assets; (2) identifying opportunities for and obtaining patent term extensions; (3) ensuring timely payment of required renewal fees; and (4) ensuring appropriate listing of patents in the Orange Book.

The enhanced processes seek to ensure that all key patent applications are reviewed by senior management prior to worldwide filing and prior to grant and that senior management approval is obtained prior to listing of patents in the Orange Book or the initiation of Abbreviated New Drug Application (ANDA) litigation. In addition, the Group has initiated a post approval patent review process to ensure ongoing review of the quality of patents after grant.

The Global Patents group maintains internal litigation processes designed to ensure successful enforcement and defence of patents with the goal of maintaining exclusive rights to market major products.

The Global Patents group monitors new developments in patent law in the major markets in which the Group operates to seek to ensure appropriate protection of the Group's assets. The Group (sometimes acting through trade associations) works with local governments to seek to secure effective and balanced intellectual property protection designed to meet the needs of patients and payers while supporting long-term investment in innovation.

Ensuring product quality
Risk description: Risk to the patient or consumer as a result of the failure by GSK, its contractors or suppliers to comply with good manufacturing practice regulations in commercial manufacturing or through inadequate governance of quality through product development
Patients, consumers and healthcare professionals trust the quality of our products at the point of use. A failure to ensure product quality is an enterprise risk which is applicable across all of the Group.

A failure to ensure product quality could have far reaching implications in terms of the health of our patients and customers, reputation, regulatory, legal, and financial consequences for the Group.

Product quality may be influenced by many factors including product and process understanding, consistency of manufacturing components, compliance with current Good Manufacturing Practice (cGMP), accuracy of labelling, reliability and security of the supply chain, and the embodiment of an overarching quality culture. The internal and external environment continues to evolve as new products, new markets and new legislation are introduced. Particular attention is currently being focused on global supply. In the EU, the new Falsified Medicines Directive is focused on security of supply. In the USA, the passage of the Food Drug and Administration Safety and Innovation Act (FDASIA) will focus attention on reducing current levels of drug shortages in the marketplace, and new cGMP legislation is being introduced in many emerging markets including China and Brazil. On the inspection front, pharmaceutical inspectors are increasingly looking for global application of corrective actions beyond the original site of inspection.

Mitigating activities include: The Group has adopted a single Quality Management System (QMS) that defines Corporate quality standards and systems for the business units associated with Pharmaceuticals and Consumer Healthcare products, vaccines and R&D investigational materials. The QMS has a broad scope, covering the end to end supply chain from starting materials to distributed product, and is applicable throughout the complete life cycle of products from R&D to mature commercial supply.

The QMS is periodically updated based on experience, new regulation and improved scientific understanding to seek to ensure operations comply with cGMP requirements globally, and supports the delivery of consistent and reliable products.

A large network of Quality and Compliance professionals are aligned with each business unit to provide oversight and assist the delivery of quality performance and operational compliance. Management oversight of those activities is accomplished through a hierarchy of Quality Council Meetings. Staff are trained to seek to assure that standards, as well as expected behaviours based on the Group's values, are followed.

The Group's Chief Product Quality Officer oversees the activities of the GSK Quality Council which serves as a forum to escalate emerging risks, share experiences of handling quality issues from all business units and ensure that the learnings are assessed and deployed across the Group.

The Group has implemented a risk-based approach to assessing and managing its third-party suppliers that provide materials used in finished products. Contract manufacturers making Group products are audited to help assure expected standards are met.

Maintaining product supply
Risk description: Risk of interruption of product supply
The manufacture of pharmaceutical and vaccine products and their constituent materials requires compliance with good manufacturing practice regulations. The Group's manufacturing sites are subject to review and approval by the FDA and other regulatory agencies. Compliance failure by the Group's manufacturing facilities or by suppliers of key services and materials could lead to product recalls and seizures, interruption of production, delays in the approval of new products, and revoking of license to operate pending resolution of manufacturing issues. For example, non-compliance with cGMP requirements for US supply could ultimately result, in the most severe circumstances, in fines and disgorgement of profits. Any interruption of supply or the incurring of fines or disgorgement impacting significant products or markets could materially and adversely affect the Group's financial results.

Materials and services provided by third-party suppliers are necessary for the commercial production of our products, including specialty chemicals, commodities and components necessary for the manufacture and packaging of many of the Group's pharmaceutical, vaccine and consumer healthcare products. Some of the third-party services procured, for example, services provided by clinical research organisations to support development of key products, are very important to the operation of the Group's businesses. Although the Group undertakes business continuity planning, single sourcing for certain components, bulk active materials, finished products, and services creates a risk of failure of supply in the event of regulatory non-compliance or physical disruption at the manufacturing sites. The failure of a small number of single-source, third-party suppliers or service providers to fulfil their contractual obligations in a timely manner or as a result of regulatory non-compliance or physical disruption at the manufacturing sites may result in delays or service interruptions, which may materially and adversely affect the Group's financial results.

Mitigating activities include: Our supply chain model is designed to help ensure the supply, quality and security of the Group's products globally, and the Group closely monitors the delivery of our products with the intent of ensuring that our customers have the medicines and products they need.

Safety stocks and backup supply arrangements for high revenue and critical products are in place to help mitigate this risk. In addition, the standing of manufacturing external suppliers is also routinely monitored in order to identify and manage supply base risks.

Where practical, dependencies on single sources of critical items are removed.

Securing adequate pricing and reimbursement
Risk description: Risk that the Group may fail to secure adequate pricing/reimbursement for its products or existing regimes of pricing laws and regulations become more unfavourable

Pharmaceutical and vaccine products are subject to price controls or pressures and other restrictions in many markets, around the world. Some governments intervene directly in setting prices. In addition, in some markets, major purchasers of pharmaceutical or vaccine products (whether governmental agencies or private health care providers) have the economic power to exert substantial pressure on prices or the terms of access to formularies. Difficult economic conditions, particularly in the major markets in Europe, could increase the pricing pressures on the Group's pharmaceutical and vaccine products. The Group cannot accurately predict whether existing controls, pressures or restrictions will increase or whether new controls, pressures or restrictions will be introduced. Such measures may materially and adversely affect the Group's ability to introduce new products profitably and its financial results.

In the USA, where the Group has its highest margins and the most sales of any country, there are no direct government price controls over private sector purchases, but federal law requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to be eligible for reimbursement under several state and federal healthcare programmes, primarily Medicare and Medicaid. Pricing pressures are likely to increase as the US Government's share of national health spending continues to increase.

Additionally, due to passage of comprehensive health care reform in 2010, the US Government's role in providing or subsidising health insurance is expected to significantly expand in 2014, which indicates the growing role and leverage the government will bring to bear on the Group's rebate liability with respect to US federal programs.

As part of ongoing deficit reduction discussions in the USA, the Obama administration recently has suggested that pharmaceutical manufacturers be required to offer federally mandated rebates to the government on drugs for people who are elderly and disabled and who qualify for both Medicare and Medicaid (known as 'dual eligibles'). These individuals currently receive drug benefits through Medicare Part D. A manufacturer's Medicare Part D rebates are negotiated with health plans and typically are lower than the federally mandated Medicaid rebates. If legislation passes requiring manufacturers to pay mandated Medicaid level rebates for the dual eligibles, there would be a significant additional rebate liability for pharmaceutical companies such as the Group.

In recent years, a number of states have also proposed or implemented various schemes to control the pharmacy budget for drugs used by their low-income and senior citizens' programmes, including increasing the rebate liability of pharmaceutical companies, importation from other countries and bulk purchases of drugs.

Given the possible expansion of Medicaid under the US health care reform law and the economic pressures on state government budgets, pricing pressures on the Group's pharmaceutical and vaccine products are likely to increase. Any of these trends may materially and adversely affect the Group's financial results.

Mitigating activities include: The Group's effort to improve reimbursement evidence for development assets is designed to help defend our future innovation. More clearly demonstrating the value our medicines and vaccines provide to patients, providers and payers using relevant comparators, meaningful endpoints and targeted patient populations will help to support appropriate price levels and formulary access.

The Group communicates with governments to reinforce their awareness of the value of medicines, and also works with national industry associations to reinforce these messages. In addition, the Group monitors the global economic environment to identify areas with potential pricing pressure. The Group will continue to explore different pricing models for innovative products and support more modest pricing of older products. This provides an opportunity for new products to be reimbursed and rewards companies that invest in R&D to meet unmet patient needs.

Given the sustained shift witnessed in the European reimbursement and pricing environment, the Group plans to initiate further restructuring of our European Pharmaceuticals business to reduce costs, improve efficiencies and reallocate resources to support identified growth opportunities in these markets. As the Group reduces its European cost base, the Group is also evaluating further strategic options to ensure the development of new capabilities and the ability to maximise the value of the Group's current and future portfolio in this region. This initiative is expected to progress in 2013. This additional restructuring supports our strategy to change the shape of our business and deliver sustainable long-term growth. In the short term, it will also help to offset some of the pressure the Group is seeing on our margin structure resulting from changes in our business mix.

In selected developed markets, the Group has engaged in new reimbursement approaches for our medicines, where the Group agrees to outcomes-based risk-sharing arrangements with payers.

From a policy and advocacy perspective, the Group works with our trade associations to help support government adoption of policies that are fair, balanced, transparent, and that do not unfairly impact innovative pharmaceutical companies.

Compliance with relevant laws and regulations
Risk description: Risks arising from non-compliance with laws and regulations affecting the Group

The Group operates on a global basis and must comply with a broad range of laws and regulatory controls on the development, manufacturing, testing, approval, distribution and marketing of many of its pharmaceutical, vaccine and consumer healthcare products that affect not only the cost of product development but also the time required to reach the market and the uncertainty of successfully doing so. The Group operates globally in complex legal and regulatory environments that often vary among jurisdictions.

As those rules and regulations change or as governmental interpretation of those rules and regulations evolve, the potential exists for conduct of the Group to be called into question.
Historically, there have been more stringent regulatory requirements in developed markets. However, in recent years, emerging markets have been increasing their regulatory expectations based on their own national interpretations of US and EU standards. Stricter regulatory controls heighten the risk of changes in product profile or withdrawal by regulators on the basis of post-approval concerns over product safety, which could reduce revenues and result in product recalls and product liability lawsuits. There is also greater regulatory scrutiny, especially in the USA, on advertising and promotion and in particular on direct-to-consumer advertising.

Furthermore, interaction and exchange of information between the Group and external communities in order to advance scientific and medical understanding may be, or may be perceived to be, promotional in intent by regulators, potentially resulting in a loss of credibility with authorities, prescribers, and patients. Such an interpretation could result in a regulatory action or a government investigation which could have far-reaching effects including impacting product liability actions, the regulatory pathway for assets, significant fines, exclusion from government programs, and even individual criminal liability.

Additionally, the development of the post-approval adverse event profile for a product or the product class may materially and adversely affect the Group's financial results.

The Group is also subject to laws of the USA, the EU and other jurisdictions regulating the export of its products to certain countries. For instance, Iran is subject to wide-ranging sanctions under the laws of the USA, the EU, and other jurisdictions. The Group has exported certain pharmaceutical and vaccine products from its Pharmaceuticals and Vaccines businesses, and certain healthcare products including over-the counter-medicines and medical devices from its Consumer Healthcare business, to Iran via sales by non-US entities to three privately held Iranian distributors. US law requires specific disclosure of certain dealings with Iran, including transactions or dealings with government-owned entities and entities sanctioned for activities related to terrorism or proliferation of weapons of mass destruction. We do not believe that our Iranian distributors fall within any of the relevant categories. The Group also does business, via non-US entities, in other jurisdictions targeted by sanctions laws, including Cuba, Syria, and Sudan. Failure to comply with these laws could expose the Group to civil and criminal penalties, including fines, prosecution, the imposition of export or economic sanctions against the Group and reputational damage, all of which could materially and adversely affect the Group's financial results.

Mitigating activities include: The Group's internal control framework is designed to help ensure we adhere to legal and regulatory requirements. While significant work has been accomplished to strengthen the Group's compliance programme, the Group continuously evaluates and enhances it based on changes to the healthcare marketplace, changes to the Group's commercial model, guidance by governmental agencies, and requirements set out by the Corporate Integrity Agreement (CIA) entered into in 2012 to which the Group is subject.

The Group has implemented numerous mechanisms to support our compliance with legal and regulatory requirements. The following represent some examples of these mechanisms.

The Group's Chief Regulatory Officer oversees the activities of the Regulatory Governance Board which includes promoting compliance with regulatory requirements and companywide standards, making regulatory services more efficient and agile, and further aligning regulatory capabilities with business needs at global and local levels.

The Medical Governance Executive Committee, accountable to the Chief Medical Officer, oversees the system of principles, policies and accountabilities to help ensure the Group applies the generally recognized principles of good medical science, integrity and ethics to the discovery, development and marketing of products. This includes reinforcing the Group's commitment to respecting a clear distinction between scientific engagement on the one hand, and product promotion on the other.

The Group has implemented an above-country medical governance risk management framework which covers relevant Group activities and supports the development and implementation of appropriate management controls for applicable policies, with a focus on ensuring patient safety. For additional mitigating activities related to the medical governance framework, please see the 'Potential Litigation and Government Investigations' risk factor.

With regards to sales and marketing activities, the Group has defined and communicated its expectations for pharmaceutical marketing and promotional activities in its global code of practice. The code sets the minimum Group standard for these activities, but requires all activities to comply with applicable laws, regulations, and industry codes in effect.

In both the Pharmaceutical and Consumer Healthcare business units, the copy review process is used to review materials to help assure those materials are accurate and fairly portray our products, including ensuring that no off-label claims are made with respect to the Group's over the counter products. The Legal group, as a member of certain US Pharmaceutical and Consumer Healthcare committees, advises on appropriate policies to help mitigate this risk in the USA. Working with the business and compliance groups, legal also undertakes a periodic assessment of current sales and promotional activities.

With regards to the economic sanctions risk, the Group has implemented a global policy and procedure that reflects the Group's commitment to strict adherence to applicable sanctions and export control laws relevant to its business. The global policy requires each business unit and global support function to perform appropriate risk assessments. Following a review of its business with Iran, the Group has ceased sales of products from its Consumer Healthcare business and intends to supply only products of high medical/public health need (as determined using criteria set by the World Health Organization) from its Pharmaceuticals and Vaccines businesses.

Changing global political and economic conditions
Risk description: Risk of exposure to various external political and economic conditions, as well as natural disaster that may impact the Group's performance and ability to achieve its objectives
Many of the world's largest economies, including the major markets in which the Group operates, and financial institutions have recently faced extreme financial difficulty, including a decline in asset prices, liquidity problems and limited availability of credit. In addition, the Group operates across a wide range of markets and these markets have the potential to encounter natural disasters that could impact business operations.

The economic uncertainty of 2011 continued into 2012, particularly in Europe. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. The austerity measures in certain countries in Europe have increased pressures on the payers in those countries to force healthcare companies such as the Group to decrease the price of its products. The debt crisis has given rise to concerns that some countries may not be able to pay for our products. Current economic conditions may also adversely affect the ability of our distributors, customers, suppliers and service providers to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with the Group, which could disrupt our operations, and negatively impact our business and cash flow. Some of our distributors, customers, suppliers and service providers may be unable to pay their bills in a timely manner, or may even become insolvent, which could also negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to risk from business interactions directly with fiscally-challenged government payers.

Such continued economic weakness and uncertainty could materially and adversely affect the Group's revenues, results of operations and financial condition. The Group's businesses, including Pharmaceuticals, Vaccines and Consumer Healthcare, may be particularly sensitive to declines in consumer or government spending. In addition, further or renewed declines in asset prices may result in a lower return on the Group's financial investments and may cause the value of the Group's investments in its pension plans to decrease, requiring the Group to increase its funding of those pension plans. See Note 28 to the financial statements, 'Pensions and other post-employment benefits' in the Annual Report 2012 for a discussion of the investment strategy and general pension overview.

The Group has no control over changes in inflation and interest rates, foreign currency exchange rates and controls or other economic factors affecting its businesses or the possibility of political unrest, legal and regulatory changes or nationalisation in jurisdictions in which the Group operates.

Mitigating activities include: The extent of the Group's portfolio and geographic footprint assist in mitigating our exposure to any specific localised risk to a certain degree. External uncertainties are carefully considered when developing strategy and reviewing performance.

The Group has continued the conscious commercial decision to maintain supply to countries with funding problems within agreed limits on total receivables. The Group has designated a cross- business team to specifically evaluate the European economic risk. That team has developed response plans to different European economic events to attempt to ensure preparedness and with the aim of reducing the potential impact to the Group of such events.

Several mitigating steps have also been taken to attempt to reduce the Group's financial exposure in certain key countries including exercising additional caution in counterparty exposures, taking prudent balance sheet measures in relation to high risk countries, and proactively managing our short-term liquidity positions. For additional mitigating activities related to European prices pressures, please see the 'Government Payers and Pricing' risk factor.

The Group has a formal Crisis and Continuity Management strategy and global policy and procedure that are managed centrally. The strategy requires documentation of crisis and continuity plans and periodic review of those plans. The Crisis and Continuity Management team assists in critical crisis preparedness and response efforts globally and incorporates lessons learned into the global strategy.

Managing alliances and acquisitions
Risk description: Risks from alliances and acquisitions
As part of the Group's strategy to diversify into new product areas and markets, the Group has grown, and expects to continue to grow, in part through acquisitions and business alliances. There is intense competition for alliance and acquisition candidates in the pharmaceutical industry, and, as such, the Group may be unable to make these deals on acceptable terms or at all. In acquiring or forming alliances with companies, the Group may assume significant debt, become subject to unknown or contingent liabilities or fail to realise the benefits expected from these transactions. For example, most pharmaceutical or biotech companies, including those that the Group may consider acquiring, are involved in patent disputes, product liability litigation, government investigations and other legal proceedings whose outcome is subject to considerable uncertainty.

The assumption of debt or unknown or contingent liabilities or the failure to realise the expected benefits may materially and adversely affect the Group's financial results.

The process of integrating companies the Group may acquire may result in disruption to the ongoing business as the effort of integrating organisations in different locations and with, among other things, differing systems and corporate cultures may divert attention and resources, result in the loss of key employees or have other adverse consequences, any of which may materially and adversely affect the Group's financial results.

Mitigating activities include: The Group engages in significant due diligence prior to any alliance or acquisition to assess the operational, financial and reputational risk that may result from any alliance or acquisition. Such diligence includes documentary review and discussions with employees and representatives of collaborator companies. Group employees with key roles in diligence are required to complete training prior to working on any transactions.

Major transactions entered into by the Group are reviewed by various management boards throughout the Group including, for instance, the Technology Investment Board, the Product Management Board, the Corporate Executive Team and the Board.

The contractual arrangements that the Group enters into include provisions to reduce or eliminate the Group's financial exposure from a particular transaction.

Integration of acquired companies is managed by the Group's Corporate Strategy group pursuant to specific standards, working with the responsible management for each business affected by the acquisition. An integration team is appointed for each company acquisition to seek to ensure a smooth integration and minimise disruption to the business. The integration team attempts to ensure that the Group attains the maximum value that may be generated from a deal, whilst ensuring that key risks are managed in a timely manner.

Compliance with financial reporting and disclosure requirements
Risk description: Risk associated with financial reporting and disclosure and changes to accounting standards
New or revised accounting standards, rules and interpretations issued from time to time by the International Accounting Standards Board could result in changes to the recognition of income and expense that may materially and adversely affect the Group's financial results.

Under International Financial Reporting Standards, changes in the market valuation of certain financial instruments are required to be reflected in the Group's reported results before those gains or losses are actually realised. This could have a significant impact on the income statement in any given period. Accounting for deferred taxation on inter-company inventory may give rise to volatility depending upon the Group entity that owns the inventory.

Regulators regularly review the financial statements of listed companies for compliance with accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning its financial statements and disclosures. However, other companies have experienced investigations into potential non-compliance with accounting and disclosure requirements that have resulted in restatements of previously reported results and sometimes significant penalties. Any such investigation and required restatement could materially and adversely affect the Group's financial results.

Mitigating activities include: The Group maintains a control environment designed to identify material errors. Management periodically tests the design and operating effectiveness of key financial reporting controls. This provides management with the assurance that controls have operated effectively over key financial reporting and disclosure processes.

The Group keeps up to date with the latest developments for financial reporting requirements by working with the external auditor and other advisors to ensure adherence to relevant reporting requirements.

There is a shared accountability for financial results across the Group. Financial results are reviewed and signed off by regions and then reviewed with the Corporate Controller and the Chief Financial Officer (CFO). This allows both the Corporate Controller and the CFO to assess the evolution of the business over time, and to evaluate performance to plan. Significant judgments are reviewed and confirmed by senior management.

Compliance with tax law and managing treasury investments

Risk description: Risk that as the Group's business models and tax law and practice change over time, the Group's existing tax policies and operating models are no longer appropriate, or that significant losses arise from treasury investments

The Group's effective tax rate is driven by rates of tax in jurisdictions that are both higher and lower than that applied in the UK. In addition, many jurisdictions such as the UK, Belgium and the USA currently offer regimes that encourage innovation and new scientific endeavours by providing tax incentives, for example R&D tax credits, and lower tax rates on income derived from patents.

Furthermore, given the scale and international nature of the Group's business, intra-group transfer pricing is an inherent tax risk as it is for other international businesses. Changes in tax laws or in their application with respect to matters such as transfer pricing, foreign dividends, controlled companies, R&D tax credits, taxation of intellectual property or a restriction in tax relief allowed on the interest on intra-group debt, could impact the Group's effective tax rate and materially and adversely affect its financial results.

The tax charge included in the financial statements is the Group's best estimate of its tax liability, but until such time as audits by tax authorities are concluded, there is a degree of uncertainty regarding the final tax liability for the period. The Group's policy is to submit tax returns within the statutory time limits and engage with tax authorities to ensure that the Group's tax affairs are as current as possible, and that any differences in the interpretation of tax legislation and regulation are resolved as quickly as possible. In exceptional cases where matters cannot be settled by agreement with tax authorities, the Group may have to resolve disputes through formal appeals or other proceedings. For example, in October 2012, the Supreme Court of Canada delivered its decision on an appeal in respect of the Group's transfer pricing, as discussed in Note 14 to the financial statements, 'Taxation' in the Annual Report 2012. The Group, like other international businesses, is also subject to a range of other duties and taxes for which it incurs similar types of risk.

The Group deals in high value transactions on a frequent basis which may result in an increased risk of financial loss due to the mismanagement of cash or entering into high risk positions on hedge transactions, any of which could materially and adversely affect the Group's financial results.

Mitigating activities include: The Group monitors Government debate on tax policy in its key jurisdictions to deal proactively with any potential future changes in tax law.

Tax risk is managed by a set of policies and procedures to ensure consistency and compliance with tax legislation. The Group engages advisors and legal counsel to review tax legislation and applicability to the Group. The Group has attempted to mitigate the risk of more aggressive audits by being as up to date as possible with our tax affairs and working in real time with tax authorities where possible.

The Group has undertaken a number of projects to move to a more centralised and simplified intellectual property ownership and trading model. The new model centralises our pharmaceutical intellectual property into the UK, reducing the complexity of our intercompany arrangements and enabling us to drive more bilateral Advance Pricing Agreements ('APAs') in the future between the UK and other jurisdictions in which the Group operates. APAs give greater certainty to the application of transfer pricing and our direct tax affairs and hence reduce the risks the Group faces.

The Treasury department does not act as a profit centre for the Group, which reduces the incentive to take risks in order to increase returns. The department strives to minimise risk and centralise financial transactions.

Treasury risk is managed by a detailed set of Treasury policies that is reviewed and approved by the Board on an annual basis. The Group proactively monitors Treasury activities with the intent of identifying exceptions to policy.

Compliance with anti-bribery and corruption legislation

Risk description: Risk of failing to create a corporate environment opposed to corruption or failing to instil business practices that prevent corruption and comply with anti-corruption legislation
The Group's extensive and increasingly international operations may give rise to possible claims of bribery and corruption. The Group operates in a number of markets where the corruption risk has been identified as high by groups such as Transparency International. Failure to comply with applicable legislation such as the US Foreign Corrupt Practices Act and the UK Bribery Act, or similar legislation in other countries, could expose the Group and senior officers to civil and criminal sanction.

This could potentially include fines, prosecution, debarment from public procurement and reputational damage, all of which could materially and adversely affect the Group's financial results.

Mitigating activities include: The Group has implemented a global Anti-Bribery/Anti-Corruption (ABAC) programme. The programme includes a global ABAC policy, ongoing training, and detailed requirements in respect to third-party due diligence, contracting and oversight. In addition, the programme has strengthened controls over interactions with Government Officials and when entering into business development transactions. Operational performance is reviewed by the Group's ABAC Oversight Committee.

A dedicated ABAC team is responsible for driving implementation of the programme and the design and execution of the ABAC audit strategy and methodology. They are supported by an extended team of functional experts within the legal group, Compliance and Audit & Assurance. The ABAC team provides continued support to the business through ongoing training and communication of guidance. A community of experts meet to provide timely guidance to the business on issues that they have escalated. The ABAC programme continues to evolve in response to the external environment, ongoing benchmarking and internal stakeholder feedback.

Potential litigation
Risk description: Risk of substantial adverse outcome of litigation and government investigations
Note 44 to the financial statements, 'Legal proceedings' in the Annual Report 2012, contains a discussion of material proceedings and governmental investigations currently involving the Group which, if proven, could give rise to civil and/or criminal liabilities. Unfavourable resolution of these and similar future proceedings or investigations may have a material adverse effect on the Group's financial condition and results of operations. As an example, in 2012, the Group entered into a settlement agreement with the US federal government resulting in a payment of US$3 billion by the Group. The Group has made provisions related to such legal proceedings and investigations, which have reduced its earnings.

In the future, the Group may also make additional significant provisions related to legal proceedings and investigations which would reduce its earnings. In many cases, the Group believes that it is the practice of the plaintiff bar to claim damages in amounts that bear no reasonable relationship to the underlying harm allegedly caused by the Group's products or its actions. Accordingly, it may be potentially misleading for the Group to quantify, based on the amount of damages claimed, its potential exposure to claims, proceedings and investigations of the type described in Note 44 to the financial statements. 'Legal proceedings' in the Annual Report 2012.

Recent insurance loss experience, including pharmaceutical product liability exposures, has increased the cost, and reduced the capacity, of insurers to provide coverage for pharmaceutical companies generally, including the Group.

Product liability litigation
Pre-clinical and clinical trials are conducted during the development of potential pharmaceutical, vaccine and consumer healthcare products to determine the safety and efficacy of the products for use by humans following approval by regulatory authorities. Notwithstanding the efforts the Group makes to determine the safety of its products through regulated clinical trials, unanticipated side effects may become evident only when drugs and vaccines are widely introduced into the marketplace.

In other instances, third-parties may perform analyses of published clinical trial results which, although not necessarily accurate or meaningful, may raise questions regarding the safety of pharmaceutical, vaccine or consumer healthcare products which may be publicised by the media and may result in product liability claims. The Group is currently a defendant in a substantial number of product liability lawsuits, including class actions, that involve significant claims for damages related to the Group's pharmaceutical and consumer healthcare products. Litigation, particularly in the US, is inherently unpredictable. Class actions that sweep together all persons who were prescribed the Group's products can inflate the potential liability by the force of numbers. Claims for pain and suffering and punitive damages are frequently asserted in product liability actions and, if allowed, can represent potentially open ended exposure and thus could materially and adversely affect the Group's financial results.

In some cases, the Group may voluntarily cease marketing a product or face declining sales based on concerns about efficacy or safety, even in the absence of regulatory action.

Anti-trust litigation

In the USA, it has become increasingly common for patent infringement actions to prompt claims that anti-trust laws have been violated during the prosecution of the patent or during litigation involving the defence of that patent. Such claims by direct and indirect purchasers and other payers are typically filed as class actions. The relief sought may include treble damages and restitution claims. Similarly, anti-trust claims may be brought by government entities or private parties following settlement of patent litigation, alleging that such settlements are anti-competitive