

GLAXOSMITHKLINE PLC

Form 6-K

February 26, 2015

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 February 2015

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  Form 40-F

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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

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GlaxoSmithKline plc  
Publication of 2014 Annual Report

GlaxoSmithKline plc (the 'Company') will today publish on the Company's website, [www.gsk.com/corporatereporting](http://www.gsk.com/corporatereporting) its Annual Report for the year ended 31 December 2014 (the '2014 Annual Report'), together with its 2014 Annual Summary (the '2014 Summary').

A hard copy version of the 2014 Annual Report, together with the 2015 Notice of Annual General Meeting (the '2015 AGM Notice'), will be sent to those shareholders who have elected to receive paper communications, on or about 25 March 2015. Shareholders who have not elected to receive paper communications will be sent the 2014 Summary notifying them of the availability of these documents on the company's website.

In compliance with Listing Rule 9.6.1 of the UK Financial Conduct Authority ('FCA'), the 2014 Annual Report, 2014 Summary and 2015 AGM Notice will be submitted to the UK Listing Authority and will in due course be available for inspection at [www.morningstar.co.uk/uk/NSM](http://www.morningstar.co.uk/uk/NSM)

In accordance with FCA's Disclosure and Transparency Rules 4.1.12 and 6.3.5, 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 2014 were announced on 4 February 2015.

The Company further announces the following dividend dates for 2015 and 2016.

	ADS ex-dividend date	Ex-dividend date	Record date	Payment date
Q4 2014	18 February 2015	19 February 2015	20 February 2015	9 April 2015
Q1 2015	13 May 2015	14 May 2015	15 May 2015	9 July 2015
Q2 2015	12 August 2015	13 August 2015	14 August 2015	1 October 2015
Q3 2015	10 November 2015*	12 November 2015	13 November 2015	14 January 2016

V A Whyte  
Company Secretary

26 February 2015

\*11 November 2015 is a non-settlement day as US banks are closed on Veterans Day.

Cautionary statement regarding forward-looking statements

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. Such factors include, but are not limited to, those set out 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 A

(i) Principal risks and uncertainties

Risk factors

The principal risks discussed below are the risks and uncertainties relevant to our business, financial condition and results of operations that may affect our performance and ability to achieve our objectives. The factors below are those that we believe could cause our actual results to differ materially from expected and historical results.

We operate on a global basis in an industry that is both highly competitive and highly regulated. Our competitors may make significant product innovations and technical advances and may intensify price competition. In light of this competitive environment, continued development of commercially viable new products and the development of additional uses for existing products are critical to our ability to maintain or increase overall sales.

Developing new pharmaceutical, vaccine and consumer healthcare products is a costly, lengthy and uncertain process, however, and a product candidate may fail at any stage, including after significant Group economic and human resources have been invested. Our competitors' products or pricing strategies or any failure on our part to develop commercially successful products, or to develop additional uses for existing products, could materially and adversely affect our financial results.

We must also adapt to and comply with a broad range of laws and regulations. These requirements apply to research and development, manufacturing, testing, approval, distribution, sales and marketing of Pharmaceutical, Vaccine and Consumer Healthcare Products, and affect not only the cost of product development but also the time required to reach the market and the uncertainty of successfully doing so.

Moreover, as rules and regulations change, and governmental interpretation of those rules and regulations evolves, the nature of a particular risk may change. Changes to certain regulatory regimes may be substantial. Any change in, and any failure to comply with, applicable law and regulation could materially and adversely affect our financial results.

Similarly, our business exposes us to litigation and government investigations, including but not limited to product liability litigation, patent and antitrust litigation and sales and marketing litigation. Litigation and government investigations, including related provisions we may make for unfavourable outcomes and increases in related costs such as insurance premiums, could materially and adversely affect our financial results. More detail on the status and various uncertainties involved in the significant unresolved disputes and potential litigation is set out in Note 45, 'Legal proceedings,' on page 206 of the 2014 Annual Report.

UK regulations require a discussion of the mitigating activities a company takes to address principal risks and uncertainties. A summary of the activities that the Group takes to manage each of our principal risks accompanies the description of each principal risk below. The principal risk factors and uncertainties are not listed in order of significance.

Patient safety

Risk definition

Failure to appropriately collect, review, follow up, or report adverse events from all potential sources, and to act on any relevant findings in a timely manner.

Risk impact

The impact of this risk is potentially to compromise our ability to conduct robust safety signal detection and interpretation and to ensure that appropriate decisions are taken with respect to the risk/benefit profile of our products, including the completeness and accuracy of product labels and the pursuit of additional studies/analyses, as

appropriate. This could lead to potential harm to patients, reputational damage, product liability claims or other litigation, governmental investigation, regulatory action such as fines, penalties or loss of product authorisation.

#### Context

Pre-clinical and clinical trials are conducted during the development of investigational Pharmaceutical, Vaccine and Consumer Healthcare Products to determine the safety and efficacy of the products for use by humans. Notwithstanding the efforts we make to determine the safety of our products through appropriate pre-clinical and clinical trials, unanticipated side effects may become evident only when products are widely introduced into the marketplace. Questions may be raised not only by our ongoing safety surveillance and post-marketing studies but also by governmental agencies and third-parties that may analyse publicly available clinical trial results.

The Group is currently a defendant in a number of product liability lawsuits, including class actions, that involve significant claims for damages related to our products. Litigation, particularly in the US, is inherently unpredictable. Class actions that seek to sweep together all persons who were prescribed our products increase the potential liability. 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.

#### Mitigating activities

The Chief Medical Officer (CMO) is responsible for medical governance for the Group under a global policy. Under that policy, safeguarding human subjects in our clinical trials and patients who take our products is of paramount importance, and the CMO has the authoritative role for evaluating and addressing matters of human safety. Individual Medical Officers and the Group's substantial Global Safety and Pharmacovigilance organisation keep track of any adverse issues reported for our products during the course of clinical studies.

Once a Group product is approved for marketing, the Group has an extensive post-marketing surveillance and signal detection system. Information on possible side effects of medicines is received from several sources including unsolicited reports from health professionals and patients, regulatory authorities, medical and scientific literature and the media. It is our policy that employees are required to report immediately any issues relating to the safety or quality of its medicines. Each of our country managers is responsible for monitoring, exception tracking and training that helps assure the collection of safety information and reporting the information to the relevant central safety department, in accordance with Group policy and legal requirements.

Information that changes the benefit/risk profile of one of the Group's medicines will result in certain actions to characterise, communicate and minimise the risk. Proposed actions are discussed with regulatory authorities and can include modifying the prescribing information, communications to physicians and other healthcare providers, restrictions on product prescribing/availability to help assure safe use, and sometimes carrying out further clinical trials. In certain cases, it may be appropriate to stop clinical trials or to withdraw the medicine from the market. The Group's Global Safety Board (GSB), comprising senior physicians and representatives of supporting functions, is an integral component of the system. The GSB (including subsidiary boards dedicated to Consumer Healthcare Products and Vaccines) reviews the safety of investigational and marketed products across the Group and has the authority to stop a clinical trial if continued conduct of such trial is not ethically or scientifically justified in light of information that has emerged since the start of the trial.

In addition to the medical governance framework within the Group as described above, the Group uses several mechanisms to foster the early evaluation, mitigation, and resolution of disputes as they arise and of potential claims even before they arise. The goal of the programmes is to create a culture of early identification and evaluation of risks and claims (actual or potential), in order to minimise liability and litigation.

#### Intellectual property

#### Risk definition

Failure to appropriately secure and protect intellectual property rights.

#### Risk impact

Any failure to obtain or subsequent loss of patent protection, including reducing the availability or scope of patent rights or compulsory licensing (in which a government forces a manufacturer to license its patents for specific products to a competitor), could materially and adversely affect our 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 our products, which could also materially and adversely affect our financial results.

#### Context

As an innovative Pharmaceutical, Vaccine and Consumer Healthcare Products company, we seek 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 our business strategy and success. 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 expiration of certain intellectual property rights, a generic manufacturer may lawfully produce a generic version of the product.

We operate in markets where intellectual property laws and patent offices are still developing and where governments may be unwilling to grant or enforce intellectual property rights in a fashion similar to more developed regions such as the EU, Japan and the US. Some developing countries have limited, or threatened to limit, effective patent protection for pharmaceutical products generally, or in particular therapeutic areas, in order to facilitate early competition within their markets from generic manufacturers.

We face competition from manufacturers of proprietary and generic pharmaceutical products in all of our major markets. Introduction of generic products, particularly in the US where we have our highest turnover and margins, typically leads to a rapid and dramatic loss of sales and reduces our revenues and margins for our proprietary products. In 2014, we had nine Pharmaceutical and Vaccine products with over £500 million in annual global sales. For certain of these products, there is generic competition in the US and some markets in Europe. We may also experience an impact on sales of one of our 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.

We depend on certain key products for a significant portion of our sales. One such product is our respiratory pharmaceutical product Seretide/Advair which accounts for 18% of Group sales worldwide. The timing and impact of entry in the US for a generic product containing the same combination of active substances as Seretide/Advair is uncertain. The US patent for compositions containing the combination of active substances in Seretide/Advair expired during 2010 although the US patent on a component of the Advair Diskus device continues until August 2016. Generic products containing the same combination of active substances as Seretide/Advair (in both metered dose inhalers and dry powder inhalers) have been launched by several manufacturers in a number of European markets. The timing and impact of entry in the US and major markets in Europe for a 'follow-on' product to Seretide/Advair is uncertain.

Generic drug manufacturers have also exhibited a readiness to market generic versions of many of our most important products prior to the expiration of our patents. Their efforts may involve challenges to the validity or enforceability of a patent or assertions that their generic product does not infringe our patents. As a result, we are and may continue to be involved in legal proceedings involving patent challenges, which may materially and adversely affect our financial results. Moreover, in the US, 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 and in violation of anti-trust laws. A successful anti-trust claim by a private party or government entity could materially and adversely affect our financial results.

The expiration dates for patents for our major products which may affect the dates on which generic versions of our products may be introduced are set out on pages 229 to 231 of the 2014 Annual Report. Legal proceedings involving patent challenges are set out in Note 45 to the financial statements, 'Legal proceedings'.

#### Mitigating activities

Our Global Patents group focuses on securing and protecting our patent rights. This global group maintains internal processes designed to help ensure successful procurement, enforcement and defence of our patents with the goal of maintaining exclusive rights in markets for our products.

The Global Patents group monitors new developments in international patent law to help ensure appropriate protection of our assets. Sometimes acting through trade associations, we work 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.

#### Product quality

##### Risk definition

Failure to comply with current Good Manufacturing Practice (cGMP) requirements in commercial manufacture, through the distribution chain, by GSK, its contractors or suppliers; or through inadequate controls and governance of quality through product development, and in supporting regulated activities.

##### Risk impact

A failure to ensure product quality could have far reaching implications in terms of patient and consumer safety, delays in launching new products, drug shortages, product recalls, potential damage to our reputation and that of the relevant product, as well as regulatory, legal, and financial consequences, which could materially and adversely affect our reputation and financial results.

##### Context

Patients, consumers and healthcare professionals trust the quality of our products. A failure to ensure product quality is an enterprise risk which is applicable across all of our business activities. Product quality may be influenced by many factors including product and process understanding, supply chain security, consistency of manufacturing components, compliance with GMP, accuracy of labelling, reliability of the external 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, particularly around security of supply, good distribution practice and product standards. Inspectional trending from national authorities during 2014 has highlighted a focus on issues relating to data integrity, contamination and the robustness of quality investigations.

##### Mitigating activities

In medicines development, scientists adopt the principles of quality by design for new products and devise control strategies to be deployed throughout the product lifecycle to help ensure consistency and reliability in their performance and supply.

We have adopted a single Quality Management System (QMS) that defines our quality standards and systems for our businesses associated with Pharmaceuticals, Vaccines and Consumer Healthcare Products 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 lifecycle of products from R&D to mature commercial supply.

The QMS is periodically updated based on experience, evolving regulatory agency expectations and requirements and improved scientific understanding to help ensure that operations comply with cGMP requirements globally, and support the delivery of consistent and reliable products. A large network of quality and compliance professionals is 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 help ensure that standards, as well as expected behaviours based on our values, are followed. Refresher training on cGMP issues includes a focus on the issues raised in inspectional trends.

We have implemented a risk-based approach to assessing and managing our third-party suppliers that provide materials used in finished products. Contract manufacturers making our products are expected to comply with standards identified by the Group and are audited to help provide assurance that expected standards are met.

The 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 of our businesses and help ensure that lessons learned are assessed and deployed globally. The preparation for and implementation of new legislation is regularly reviewed by the GSK Quality Council and advocacy and communication programmes are used to maintain awareness of the external environment and convey consistent messages across the Group. There is emphasis on quality performance metrics and a culture of 'right first time'.

#### Supply chain continuity

##### Risk definition

Failure to deliver a continuous supply of compliant finished product.

##### Risk impact

A material interruption of supply or exclusion from healthcare programmes could impact patient access to our products, expose us to litigation or regulatory action and materially and adversely affect our financial results. In particular, the incurring of fines or disgorgement as a result of noncompliance with manufacturing practice regulations could also materially and adversely affect the Group's financial results and result in reputational damage.

##### Context

Our supply chain operations are subject to review and approval by various regulatory agencies that effectively provide our licence to operate. Failure by our manufacturing and distribution facilities or by suppliers of key services and materials could lead to litigation or regulatory action such as product recalls and seizures, interruption of supply, delays in the approval of new products, and suspension of manufacturing operations pending resolution of manufacturing or logistics issues. In 2014, our Consumer Healthcare business, particularly our Smokers' Health products, alli and Bactroban, were impacted by various supply issues and our Vaccines business, particularly our hepatitis vaccines and Boostrix, were impacted by supply constraints.

Materials and services provided by third-party suppliers are necessary for the commercial production of our products, including active pharmaceutical ingredients (API), antigens, intermediates, commodities and components necessary for the manufacture and packaging of many of our Pharmaceutical, Vaccine and Consumer Healthcare Products. Some of the third-party services procured, such as services provided by contract manufacturing organizations and clinical research organisations to support development of key products, are important to ensure continuous operation of our businesses. Although we undertake business continuity planning, single sourcing of certain components, bulk API, 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 or logistics system.

The failure of a small number of single-source, third-party suppliers or service providers to fulfill their contractual obligations in a timely manner or as a result of regulatory non-compliance or physical disruption of logistics and manufacturing sites may result in delays or service interruptions.

#### Mitigating activities

Our supply chain model is designed to help ensure the supply, quality and security of our products globally. We closely monitor, through the Supply Chain Governance Committees, the inventory status and delivery of our products to help ensure that our customers have the medicines, vaccines and products they need. Safety stocks and backup supply arrangements for high revenue and medically-critical products are in place, where practical, to help mitigate this risk. In addition, the compliance of manufacturing external suppliers is routinely monitored in order to identify and manage supply base risks.

Where practical, dependencies on single sources of critical items are removed. Our reliance on single source components was reduced in 2014 for some key products through qualification of alternative materials that will help improve supply chain robustness. In cases, where dual sourcing is not possible, an inventory strategy has been developed to protect the supply chain from unanticipated disruption.

In 2014, we continued to implement anti-counterfeit systems such as product serialization in accordance with emerging requirements to mitigate this risk.

Throughout 2014, our supply chain operating model was improved to strengthen the link between commercial forecasting and manufacturing by implementation of the Core Commercial Cycle methodology. This action will over time, decrease the risk associated with demand fluctuations impacting ability to supply or write-offs associated with product exceeding expiry dating. Under the new model, each node of the supply chain is being optimised to help ensure adequate safety stock while balancing working capital associated with the end-to-end supply chain.

#### Financial reporting and disclosure

##### Risk definition

Failure to report accurate financial information and material events in compliance with accounting standards and applicable legislation.

##### Risk impact

Non-compliance with existing or new financial reporting and disclosure requirements, or changes to the recognition of income and expenses, could expose us to litigation and regulatory action and could materially and adversely affect our financial results.

##### Context

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 our financial results.

The Group is also required by the laws of various jurisdictions to disclose publicly its financial results and events that could materially affect the financial results of the Group. Regulators routinely 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 our financial statements and disclosure of material information. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements, there is potential for restatements of previously reported results and we could be subject to significant penalties.

#### Mitigating activities

The Group maintains a control environment designed to identify material errors in financial reporting and disclosure. The design and operating effectiveness of key financial reporting controls is periodically tested. This provides us with the assurance that controls over key financial reporting and disclosure processes have operated effectively.



We keep up-to-date with the latest developments in financial reporting requirements by working with our external auditors and legal advisors to help ensure adherence to relevant reporting and disclosure requirements.

There is shared accountability for financial results across our businesses. Financial results are reviewed and approved by regional management and then reviewed with the Financial Controller and the Chief Financial Officer (CFO). This allows our Financial Controller and our 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.

The Group maintains a Disclosure Committee which reports to the Board which reviews the Group's quarterly results and Annual Report and determines throughout the year, in consultation with its legal advisors, whether it is necessary to disclose publicly information about the Group through Stock Exchange announcements.

#### Tax and treasury

##### Risk definition

Failure to comply with current tax law, or react to the rapidly evolving tax environment. Incurring significant losses due to treasury activities.

##### Risk impact

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 our effective tax rate. Significant losses may arise from Treasury activities through inconsistent application of Treasury policies, dealing or settlement errors, or counterparty defaults. Any such changes in tax laws or their application, failure to comply with tax law or significant losses due to treasury activities could materially and adversely affect our financial results.

##### Context

Our Treasury group deals in high value transactions, mostly foreign exchange and cash management transactions, on a daily basis. The Group's effective tax rate is driven by rates of tax in jurisdictions that are both higher and lower than the UK. In addition, many jurisdictions currently offer regimes that encourage innovation and investment in science by providing tax incentives, such as R&D tax credits and lower tax rates on income derived from patents. Furthermore, as an international business, we face risks associated with intra-group transfer pricing.

The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities. We submit tax returns according to statutory time limits and engage tax authorities to help ensure our tax affairs are current. In exceptional cases where matters cannot be settled by agreement with tax authorities, we may have to resolve disputes through formal appeals or other proceedings. As an international business, we are also subject to a range of other duties and taxes carrying similar types of risk.

There is an increased focus on the tax position of multinational businesses, as a consequence of the challenging economic environment and the priority placed by the G20 on addressing allegations of unlawful tax avoidance. We have seen some increase in audits as governments seek to raise revenues, both from corporate taxes and above the line taxes such as customs duties. Such audits regardless of their merit or outcomes can be costly, divert management attention and may adversely impact our reputation. In addition, there are an increasing number of changes to the international tax framework which could lead to an increase or decrease in our tax costs.

##### Mitigating activities

The Group's Treasury function does not operate as a profit centre and does not enter into financial derivative transactions for speculative purposes. All transactions in financial instruments are undertaken to manage the risks arising from underlying business activities. Treasury activities are governed by policies approved by the Board of

Directors and compliance is regularly reviewed by the Treasury Management Group (TMG), which is chaired by the CFO.

Liquidity risk is managed by diversifying our liquidity sources using a range of facilities and by maintaining broad access to funding markets in order to meet anticipated future funding requirements. We also hold significant amounts of cash and investments which are invested in line with strict investment guidelines.

Interest rate risk is managed by limiting the amount of floating rate interest payments to a prescribed percentage of operating profit, and the mix of debt at fixed and floating interest rates is monitored regularly by the TMG.

Foreign currency transaction risk arising on internal and external trade flows is not generally hedged. Our internal trading transactions are matched centrally, and we manage inter-company payment terms to reduce foreign currency risk. Foreign currency cash flows can be hedged selectively under the management of Treasury and the TMG. Where possible, we manage the cash surpluses or borrowing requirements of subsidiary companies centrally. In order to reduce foreign currency translation exposure, we seek to denominate borrowings in the currencies of our principal assets and cash flows. The TMG reviews the ratio of borrowings to assets for the major currencies monthly.

Counterparty risk is managed by setting global counterparty limits for each of our banking and investment counterparties based on long-term credit ratings from Moody's and Standard and Poor's. Treasury's usage of these limits is monitored daily by a Corporate Compliance Officer (CCO) who operates independently of Corporate Treasury. The CCO also monitors the credit rating of these counterparties and, when changes in ratings occur, notifies Treasury so that changes can be made to investment levels or to authority limits as appropriate.

Further details on mitigation of Treasury Risks can be found on in the 2014 Annual Report page 190, Note 41, 'Financial instruments'.

We monitor government debate on tax policy in our 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 help ensure consistency and compliance with tax legislation. We engage advisors and legal counsel to review tax legislation and applicability to our business.

We attempt to mitigate the risk of more aggressive tax authority audits by being as up to date as possible with our tax affairs and working proactively with tax authorities where possible. We have also moved to a more centralised and simplified intellectual property ownership and trading model. The model centralises our Pharmaceutical intellectual property in the UK, reducing the complexity of our inter-company arrangements and enabling us to drive more bilateral Advance Pricing Agreements (APAs) between the UK and other jurisdictions where we operate. APAs give greater certainty to the application of transfer pricing and our direct tax affairs and hence reduce risks. A centralised team of dedicated specialists are responsible for managing transactional tax reporting and compliance.

#### Anti-bribery and corruption

##### Risk definition

There is a risk that GSK personnel, or third parties acting on our behalf, seek to induce improper performance of someone's role in order to gain or retain GSK a business advantage through the offer, promise or giving of a bribe. This goes against our ethical standards and is contrary to the laws by which we are bound.

##### Risk impact

Failure to mitigate this risk could expose the Group and associated persons to governmental investigation, regulatory action and civil and criminal liability, as well as damage the Group's reputation, shareholder value, and our licence to operate in particular jurisdictions, all of which could materially and adversely affect our financial results.

##### Context

We are exposed to bribery and corruption risk through our global business operations. In some markets, the government structure and the rule of law are less developed, and this has a bearing on our bribery and corruption risk exposure. In addition to the global nature of our business, the healthcare sector is highly competitive and subject to regulation. This increases the instances where we are exposed to activities and interactions with bribery and corruption risk.

As has previously been disclosed, the Group in 2014 has been subject to regulatory action and media focus with regard to bribery investigations in China and other markets. On 19 September 2014, the Group announced that the Changsha Intermediate People's Court in Hunan Province, China ruled that, according to Chinese law, GSK China Investment Co. Ltd ("GSKCI") had offered money or property to non-government personnel in order to obtain improper commercial gains, and been found guilty of bribing non-government personnel. The verdict followed investigations initiated by China's Ministry of Public Security in June 2013. As a result of the Court's verdict, GSKCI has paid a fine of RMB 3 billion (£301 million) to the Chinese government.

The US and UK authorities are leading extra-territorial ABAC inquiries into certain of the Group's operations. These investigations are further discussed in the 2014 Annual Report Note 45 'Legal Proceedings'.

#### Mitigating activities

Our Code of Conduct, values and behaviours and commitment to zero tolerance are integral to how we mitigate this risk. In light of the complexity and geographic breadth of this risk, we constantly enhance our oversight of activities and data, reinforce to our employees and contractors clear expectations regarding acceptable behaviours, and maintain on-going communications between the Group centre headquarters and local markets.

The Group has an enterprise-wide ABAC programme designed to respond to the threat and risk of bribery and corruption. It builds on the Group's values and existing standards to form a comprehensive and practical approach to compliance. Our ABAC programme is supported by: top-level commitment from the Group Board of Directors and leadership throughout the business; ongoing risk assessment; a global policy; control documents that address commercial and other practices that give rise to ABAC risk; due diligence of high risk third parties; ongoing training and communications; a confidential reporting line; monitoring of compliance and an investigations team. In addition, the programme mandates enhanced controls over interactions with government officials and when undertaking business development transactions. Programme governance is provided by the Group's ABAC Oversight Committee which includes representation from key functional areas and business units.

Additionally, we have a dedicated ABAC team responsible for the implementation and evolution of the programme in response to developments in the internal and external environment. This is complemented with ABAC investigations and ABAC Audit teams which have separate reporting lines.

We continually benchmark our ABAC programme against other large multi-national companies and use external expertise to review and help improve elements of our ABAC programme. As a result of the China and other country investigations, the Group has increased resources in both its centrally located ABAC team as well as regional ABAC teams.

#### Commercial practices and scientific engagement

##### Risk definition

Failure to engage in commercial and/or scientific activities that are consistent with the letter and spirit of legal, industry, or the Group's requirements relating to marketing and communications about our medicines and associated therapeutic areas; appropriate interactions with healthcare professionals (HCPs) and patients; and legitimate and transparent transfer of value.

##### Risk impact

Failure to comply with applicable laws, rules and regulations may result in governmental investigation, regulatory action and legal proceedings brought against the Group by governmental and private plaintiffs. Failure to provide accurate and complete information related to our products may result in incomplete awareness of the benefit: risk profile of our medicines and possibly suboptimal treatment of patients. Any of these consequences could materially and adversely affect our financial results. Any practices that are found to be misaligned with our values could also result in reputational damage and dilute trust established with key stakeholders. In 2012, we paid \$3 billion to resolve government investigations in the US focused in large part on promotional practices.

#### Context

We are committed to legitimate Scientific Engagement and the ethical and responsible commercialisation of medicines to support our mission to improve the quality of human life by enabling people to do more, feel better, and live longer. To accomplish this mission, we engage the healthcare community in various ways to advance our scientific knowledge as well as to provide important information about our medicines.

The Group disseminates information about its products through both non-promotional Scientific Engagement and promotional activities. The former is the interaction and exchange of information between the Group and partners and external communities in order to advance scientific and medical understanding including the appropriate development and use of our products; the management of disease; and patient care. It is distinct from promotional activities which may take place only after authorisation of a new product or indication, and must be conducted strictly in accordance with promotional laws, codes and the Group's Policy.

Promotion of approved medicines helps ensure that HCPs globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients. We are committed to communicating information related to our approved products in a responsible, legal, and ethical manner.

At times, researchers, HCPs, healthcare organisations (HCOs) and other external experts that we engage may be compensated for services and expertise provided. However, payments must not be excessive and must never be or be perceived to be an inducement or reward for prescribing our products. Consistent with our ABAC policies, they also must comply with a market's ABAC laws if the recipient of any payment is a government official.

#### Mitigating activities

We have taken action at all levels of the Group to enhance and improve standards and procedures for Scientific Engagement and promotional interactions, based on our values of transparency, respect, integrity and patient focus. We have policies and standards governing promotional activities and Scientific Engagement undertaken by the Group or on its behalf. All of these activities we conduct worldwide must conform to high ethical, medical, and scientific standards. Where local standards differ from global standards, the more stringent of the two applies.

The Group has harmonized policies and procedures to guide above country Commercial Practices and Scientific Engagement processes as well as clarified applicable standards when engaging in the markets. Specific accountability and authorisation for Scientific Engagement resides within the Medical Governance framework that is overseen by the Medical Governance Executive Committee (MGEC), accountable to the Chief Medical Officer. MGEC is responsible for oversight of applicable Policies and ensuring the highest level of integrity and continuous development of Scientific Engagement at GSK. Commercial Practices activities have oversight from both business unit Risk Management and Compliance Boards (RMCBs) and Country Executive Boards (CEBs) that manage risks across in-country business activities.

All promotional materials and activities must be reviewed and approved according to the Group's policies and standards, and conducted in accordance with local laws and regulations, to help ensure that these materials and activities fairly represent the products or services of the Group. When necessary, we have disciplined (up to and including termination) employees who have engaged in misconduct and have broadened our ability to claw back remuneration from senior management in the event of misconduct.

During 2014, we took further proactive risk mitigation steps to assure our operations reflect our values. GSK publicly committed to stop in 2016 various payments to HCPs and Healthcare Organisations (HCOs). GSK also committed extended steps already taken in the US to changing its sales compensation model globally from one based on sales targets to an approach that individually rewards our sales force on the quality of their interactions with healthcare professionals, not on the end result.

#### Research practices

##### Risk definition

Failure adequately to protect and inform patients involved in human clinical trial research; conduct objective, ethical preclinical and clinical trials using sound scientific principles; guarantee the integrity of discovery, preclinical, and clinical development data; manage human biological samples according to established ethical standards and regulatory expectations; treat animals ethically and practice good animal welfare; appropriately disclose human subject research for medicinal products; and ensure the integrity of our regulatory filings and of the data that we publish.

##### Risk impact

The impacts of the risk include harm to patients, reputational damage, failure to obtain the necessary regulatory approvals for our products, governmental investigation, legal proceedings (product liability suits and claims for damages), and regulatory action such as fines, penalties or loss of product authorisation, which could materially and adversely affect our financial results.

##### Context

Research relating to animals can raise ethical concerns. While we attempt to proactively address this, animal studies remain a vital part of our research. In many cases, they are the only method that can be used to investigate the effects of a potential new medicine in a living body before it is tested in humans, and they are generally mandated by regulators and ethically imperative. Animal research can provide critical information about the causes of diseases and how they develop. Some countries require additional animal testing even when medicines have been approved for use elsewhere.

Clinical trials in healthy volunteers and patients are used to assess and demonstrate an investigational product's efficacy and safety or further evaluate the product once it has been approved for marketing. We also work with human biological samples. These samples are fundamental to the discovery, development and safety monitoring of our products.

The integrity of our data is essential to success in all stages of the research data lifecycle: design, generation, recording and management, analysis, reporting and storage and retrieval. Our research data is governed by legislation and regulatory requirements.

Research data and supporting documents are core components at various stages of pipeline progression decision-making and also form the content of regulatory submissions. Poor data integrity can compromise our research efforts.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Rapid changes in submission requirements in developing countries continue to increase the complexity of worldwide product registration.

##### Mitigating activities

We established an Office of Animal Welfare, Ethics and Strategy (OAWES), led by the Chief of Animal Welfare, Ethics and Strategy, to help ensure the humane and responsible care of animals and increase the knowledge and application of non-animal alternatives for the Group. OAWES embeds a framework of animal welfare governance,

promotes application of 3Rs (replacement, refinement and reduction of animals in research), explores opportunities for cross-industry data sharing, and conducts quality assessments.

We report the results of our human subject research for our medicines and vaccines on our publicly accessible clinical study register website, on government-required repositories, and we submit human research results as manuscripts for publication in peer reviewed scientific journals. During 2014, we disclosed over 130 Clinical Study Reports of marketed and terminated medicines (once the research results were published in the scientific literature) on our register. In early 2014, the GSK online system to allow researchers to request access to anonymised patient-level data from the Group's clinical trials, was re-configured into a multi-sponsor request site, [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com), to include studies conducted by other sponsors and by the end of 2014 we had listed over 1000 GSK trials available for request.

We have a Global Human Biological Samples Management (HBSM) governance framework in place to oversee the ethical and lawful acquisition and management of human biological samples. Our global HBSM network champions HBSM activities and provides an experienced group to support internal Sample Custodians on best practice.

It remains an important priority to enhance our data integrity controls. During 2014 we established plans to develop new written standards to ensure the integrity of our data across Research and Development (R&D). A Data Integrity Committee was established to provide oversight and a Data Integrity Quality Assurance team was created to provide independent business monitoring of our internal controls for R&D activities.

The Chief Regulatory Officer oversees the activities of the Regulatory Governance Board which includes promoting compliance with regulatory requirements and Group-wide standards, making regulatory services more efficient and agile, and further aligning regulatory capabilities with our international business needs at the enterprise and local levels.

Environment, health and safety and sustainability

Risk definition

Failure to manage environment, health and safety and sustainability (EHSS) risks consistent with the Group's ethics, objectives, policies and relevant laws and regulations.

Risk impact

Failure to manage EHSS risks could lead to significant harm to people, the environment and communities in which we operate, fines, failure to meet stakeholder expectations and regulatory requirements, litigation or regulatory action, and damage to the Group's reputation and could materially and adversely affect our financial results.

Context

The Group is subject to health, safety and environmental laws of various jurisdictions. These laws impose duties to protect people, the environment and the communities in which we operate as well as potential obligations to remediate contaminated sites. We have also been identified as a potentially responsible party under the US Comprehensive Environmental Response Compensation and Liability Act at a number of sites for remediation costs relating to our use or ownership of such sites. Failure to manage these environmental risks properly could result in litigation, regulatory action and additional remedial costs that may materially and adversely affect our financial results. See Note 45 to the financial statements, 'Legal proceedings' in the 2014 Annual Report, for a discussion of the environmental related proceedings in which we are involved. We routinely accrue amounts related to our liabilities for such matters.

Mitigating activities

The Corporate Executive Team is responsible for EHSS governance for the Group under a global policy. Under that policy, the CET ensures there are systems in place to manage the risks, impacts and legal compliance issues that relate to EHSS and for assigning responsibility to senior managers for providing and maintaining those systems. Individual

managers are responsible for making sure the EHSS management system is effective and well implemented in their respective business area and that it is fully compliant with all applicable laws and regulations, adequately resourced, maintained, communicated, and monitored. Additionally, each employee is personally responsible for ensuring that all applicable local standard operating procedures are followed and expected to take responsibility for EHSS matters.

Our risk-based, proactive approach is articulated in our Global EHS Standards which support our EHSS policy and objective to discover, develop, manufacture, supply and sell our products without harming people or the environment. In addition to the design and provision of safe facilities, plant and equipment, we operate rigorous procedures that help us eliminate hazards where practicable and protect employees' health and well-being. Our employment practices are designed to create a work place culture in which all employees feel valued, respected, empowered and inspired to achieve our goals.

Through our continuing efforts to improve environmental sustainability we have reduced water consumption, hazardous waste, and energy consumption. We actively manage our environmental remediation obligations to help ensure practices are environmentally sustainable and compliant.

Our EHSS performance results are shared with the public each year in our Responsible Business Supplement.

#### Information protection

##### Risk definition

Risk to the Group's business activity if critical or sensitive computer systems or information are not available when needed, are accessed by those not authorised, or are deliberately changed or corrupted.

##### Risk impact

Failure to adequately protect critical and sensitive systems and information may result in our inability to maintain patent rights, loss of commercial or strategic advantage, damage to our reputation or business disruption including litigation or regulatory sanction and fines, which could materially and adversely affect our financial results.

##### Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, sensitive personally identifiable information, intellectual property, manufacturing systems and trade secrets. There is the potential that malicious or careless actions expose our computer systems or information to misuse or unauthorised disclosure.

##### Mitigating activities

The Group has a global information protection policy that is supported through a dedicated programme of activity. To increase our focus on information security, the Group established the Information Protection & Privacy function to provide strategy, direction, and oversight while enhancing our global information security capabilities.

We assess changes in our information protection risk environment through briefings by government agencies, subscription to commercial threat intelligence services and knowledge sharing with other Pharmaceutical and cross-industry companies.

We aim to use industry best practices as part of our information security policies, processes and technologies and invest in strategies that are commensurate with the changing nature of the security threat landscape.

We are also subject to various laws that govern the processing of Personally Identifiable Information (PII). To help ensure compliance with cross-border PII transfer requirements, the Group's Binding Corporate Rules (BCRs) have been approved by the UK Information Commissioner's Office for human resource and research activities data. BCRs make it possible to transfer PII internationally between the Group's entities without individual privacy agreements in each European Union country.

## Crisis and continuity management

### Risk definition

Inability to recover and sustain critical operations following a disruption or to respond to a crisis incident in a timely manner.

### Risk impact

Failure to manage crisis and continuity management (CCM) effectively can lead to prolonged business disruption, greater damage to the Group's assets, and risk of supply disruption to patients of a medicine, any of which could materially and adversely affect our financial results. Delays to operational activities and delivery of our products to consumers and patients who rely on them could also expose us to litigation or regulatory action, materially and adversely affect our financial results and lead to reputational damage.

### Context

The Group's international operations, and those of its partners, maintain a vast global footprint exposing our workforce, facilities, operations and information technology to potential disruption resulting from a natural event (e.g. storm or earthquake), a man-made event (e.g. civil unrest, terrorism), or a global emergency (e.g. Ebola outbreak, Flu pandemic). Through effective crisis management and business continuity planning we are committed to providing for the health and safety of our people, minimising damage and impact to the Group, and maintaining functional operations following a natural or man-made disaster, or a public health emergency.

### Mitigating activities

CCM governance for the Group is set forth in a global policy. Under that policy, each business unit and functional area head ("BU") ensures effective crisis management and business continuity plans are in place that include authorised response and recovery strategies, key areas of responsibility and clear communication routes before a business disruption occurs. Additionally, each BU is represented on a CCM governance board which performs risk oversight and provides vital information to the CCM programme team regarding new threats, acquisitions or significant business or organisational changes.

A dedicated team of CCM experts supports the business. Their responsibilities include: chairing the governance board; coordinating crisis management and business continuity training; facilitating exercises and monitoring to provide for global consistency and alignment; and centrally storing and monitoring updates for plans supporting our critical business processes. These activities help ensure an appropriate level of readiness and response capability is maintained. We also develop and maintain partnerships with external bodies like the Business Continuity Institute and the UN International Strategy for Disaster Risk Reduction which helps improve our business continuity initiatives in disaster prone areas and supports the development of community resilience to disasters.

We continually improve our CCM risk management programme and tools based on learning from plan activations. For example, the Group has implemented a Global Disaster Monitoring tool to monitor disruptions and support local crisis teams with guidance and central support as needed. We regularly evaluate and introduce new tools to improve our CCM practices.

## Third-Party Oversight

### Risk definition

Failure to maintain adequate governance and oversight over third-party relationships; failure of third-parties to meet their contractual, regulatory, confidentiality or other obligations; failure of third-parties to comply with the law or appropriately manage their respective operations to mitigate the Principal Risks to the Group outlined above.

### Risk impact



Failure to adequately manage third-party relationships could result in business interruption and exposure to risk ranging from sub-optimal contractual terms and conditions, to severe business sanctions and/or significant reputational damage. Any of these consequences could materially and adversely affect our business operations and financial results.

#### Context

Third parties are critical to our business delivery and are an integral part of the solution to improve our productivity, quality, service and innovation. We rely on third-parties, including suppliers, distributors, individual contractors, licensees, and other pharmaceutical and biotechnology collaboration partners for discovery, manufacture, and marketing of our products and important business processes.

However, these business relationships present a material risk. For example, we share critical and sensitive information such as marketing plans, clinical data, and employee data with specific third parties who are conducting the relevant outsourced business operations. Inadequate protection or misuse of this information by third parties could have significant business impact. Similarly, we use distributors and agents in a range of activities such as promotion and tendering which have inherent risks such as inappropriate promotion or corruption. Insufficient internal compliance and controls by the distributors could affect our reputation. These risks are further increased by the complexities of working with large numbers of third parties.

#### Mitigating activities

It is our responsibility that all activities are performed safely and in compliance with applicable laws and GSK's values, standards and code of conduct. Each business unit leadership team retains ultimate accountability for managing third party interactions and risks, and for appropriately governing these interactions. When working with third parties, all GSK employees are expected to manage external interactions and commitments responsibly. This expectation is embedded in our values and code of conduct.

To help guide and enforce our global principles for interactions with third-parties we have in place a policy framework applicable to buying goods and services, managing our external spend, paying and working with our third-parties. This policy framework applies to all employees and complementary workers worldwide. The framework is complemented by technical and local standards designed to help ensure alignment with the nature of third party interactions, such as good manufacturing practice and adherence to local laws and regulations. Independent business monitoring of key financial and operational controls is in place and is supplemented by periodic checks from the company's independent Audit & Assurance function.

To help enhance continuous monitoring and performance of third party interactions we established in 2014 the Third Party Oversight programme. This global programme takes an enterprise view of third party related risks, and will help strengthen due diligence efforts on third parties and improve overall management of our third party risks through the lifecycle of the third-party engagement. Oversight for the programme is provided from GSK's Global Ethics and Compliance group.

#### ii) Directors' responsibility statement

Each of the current Directors, whose names and functions are listed below, confirms that, to the best of his or her knowledge:

- 1) the Group financial statements, which have been prepared in accordance with IFRS as adopted by the EU and IFRS as issued by the IASB, give a true and fair view of the assets, liabilities, financial position and profit of the Group; and
- 2) the Strategic Report and risk sections of the Annual Report include a fair review of the development and performance of the business and the position of the Group, together with a description of the principal risks and uncertainties that it faces.

Name	Function
Sir Christopher Gent	Chairman
Sir Philip Hampton	Chairman Designate
Sir Andrew Witty	Chief Executive Officer
Simon Dingemans	Chief Financial Officer
Dr Moncef Slaoui	Chairman, Global Vaccines
Professor Sir Roy Anderson	Non-Executive Director
Dr Stephanie Burns	Non-Executive Director
Stacey Cartwright	Non-Executive Director
Lynn Elsenhans	Non-Executive Director
Judy Lewent	Non-Executive Director
Sir Deryck Maughan	Senior Independent Director
Dr Daniel Podolsky	Non-Executive Director
Urs Rohner	Non-Executive Director
Tom de Swaan	Non-Executive Director
Jing Ulrich	Non-Executive Director
Hans Wijers	Non-Executive Director

## 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: February 26, 2015

By: VICTORIA WHYTE  
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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc