

GLAXOSMITHKLINE PLC

Form 6-K

March 17, 2016

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 2016

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 2015 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 2015 (the '2015 Annual Report').

A hard copy version of the 2015 Annual Report, together with the 2015 Annual Summary (the '2015 Summary') and 2016 Notice of Annual General Meeting (the '2016 AGM Notice'), will be sent to those shareholders who have elected to receive paper communications on or about 30 March 2016. Shareholders who have not elected to receive paper communications will be sent the 2015 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 2015 Annual Report, 2015 Summary and 2016 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).

The information included in the unaudited preliminary results announcement released on 3 February 2016, together with the information in the Appendix to this announcement which is extracted from the 2015 Annual Report, constitute the materials required by the FCA's Disclosure and Transparency Rule 6.3.5 to be communicated to the media in full unedited text through a Regulatory Information Service. This announcement is not a substitute for reading the 2015 Annual Report in full. Page and note references in the Appendix below refer to page and note references in the 2015 Annual Report.

The Company further announces the following dividend dates for 2016 and 2017.

	ADS ex-dividend date	Ex-dividend date	Record date	Payment date
Q4 2015 and special dividend	17 February 2016	18 February 2016	19 February 2016	14 April 2016
Q1 2016	11 May 2016	12 May 2016	13 May 2016	14 July 2016
Q2 2016	10 August 2016	11 August 2016	12 August 2016	13 October 2015
Q3 2016	2 November 2016	3 November 2016	4 November 2016	12 January 2017

V A Whyte  
Company Secretary

17 March 2016

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 must 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 likelihood of doing so successfully.

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 our significant unresolved disputes and potential litigation is set out in Note 45, 'Legal proceedings,' on pages 206 to 210.

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 our products. 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 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.

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 significant 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 228 to 229. 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 seek to 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 seek to 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 Practices (cGMP) or inadequate controls and governance of quality in the supply chain covering supplier standards, manufacturing and distribution of products.

##### Risk impact

A failure to ensure product quality could have far reaching implications in terms of patient and consumer safety resulting in product launch delays, supply interruptions and product recalls which would have the potential to do damage to our reputation. Associated regulatory, legal, and financial consequences 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, 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, with increasing scrutiny of supply continuity, a focus on improved distribution practice and the introduction of novel cell and gene based therapies. Review of inspections conducted across the industry by national regulatory authorities during 2015 highlighted an ongoing focus on data integrity, contamination prevention and the rigour of quality investigations including the robustness of decision making and the timely escalation of pertinent issues to regulatory authorities.

##### Mitigating activities

We have developed and implemented a single Pharmaceutical Quality System (PQS) that defines the quality standards and systems for our businesses associated with Pharmaceuticals, Vaccines and Consumer Healthcare products and clinical trial materials. This system has a broad scope and is applicable throughout the lifecycle of products from R&D to mature commercial supply.

There is no single external global quality standard or system which governs the lifecycle of medicinal products and requirements are often complex and fragmented across national and regional boundaries. The ICH guideline Q10: Pharmaceutical Quality Systems provides a model for a comprehensive quality framework which takes into account international quality concepts and is designed to be implemented through the product lifecycle. This framework has been adopted by GSK and is augmented with a consolidation of multiple regulatory requirements from across the world in order to seek to ensure that the GSK PQS meets external expectations for Product Quality in the markets supplied. The PQS is regularly updated to seek to ensure it keeps pace with external regulatory changes, and reflects both operational improvements and new scientific understanding to support the delivery of consistent and reliable products.

An extensive global network of quality and compliance professionals is aligned with each business unit to provide oversight and assist with the delivery of quality performance and operational compliance, from site level to senior management level. Management oversight of those activities is accomplished through a hierarchy of Quality Councils and through an independent Chief Product Quality Officer and Global Product Quality Office.

GSK has 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 GSK and are audited to help provide assurance that expected standards are met.

All staff members are regularly trained to seek to ensure that cGMP standards and behaviours based on our GSK values are followed. Additionally, advocacy and communication programmes are routinely deployed to seek to ensure consistent messages are conveyed across GSK, whether they originate from changes in regulation or learnings from inspections or regulatory submissions. There is a continued emphasis on the value of quality performance metrics to facilitate improvement and foster a culture of 'right first time'.

#### Financial control and reporting

##### Risk definition

Failure to comply with current tax law or incurring significant losses due to treasury activities; failure to report accurate financial information in compliance with accounting standards and applicable legislation; failure to maintain adequate governance and oversight over third-party relationships.

##### 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. 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 inconsistent application of treasury policies, transactional or settlement errors, or counterparty defaults. Any changes in the substance or application of the governing tax laws, failure to comply with such tax laws or significant losses due to treasury activities could materially and adversely affect our financial results.

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

The Group is 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 new, revised or existing accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning our financial statements and disclosure of material information including any transactions relating to business restructuring such as acquisitions and divestitures. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements, this may lead to restatements of previously reported results and significant penalties.

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 reflects rates of tax in the jurisdictions in which the Group operates that are both higher and lower than the UK rate and take into account regimes that encourage innovation and investment in science by providing tax incentives which, if changed, could affect the Group's tax rate.

The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities. The worldwide nature of our operations and cross-border supply routes can be complex and can lead to questions on tax audit.

There continues to be a significant international focus on tax reform, including the OECD's 'BEPS' project and European Commission initiatives such as the proposed 'anti-BEPS' Directive and the increased use of fiscal state aid investigations. Together with domestic initiatives around the world, these may result in significant changes to established tax principals and an increase in tax authority disputes. These, regardless of their merit or outcomes, can be costly, divert management attention and may adversely impact our reputation.

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.

Third party 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

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 are regularly tested by management and via independent business monitoring. 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.

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. Business reorganisations and newly acquired activities such as Novartis acquired businesses and Oncology divestitures are integrated into risk assessments and appropriate controls and reviews have been applied.

We introduced additional resources and monitoring to ensure that robust financial controls were maintained during 2015, effectively managing risks while the initial phase of integrating the former Novartis' businesses into our control and reporting framework were implemented, and the ongoing transformation and upgrade to our financial systems and processes continued. Additional risk mitigation was introduced by amending the programme timelines of the ongoing system upgrades.

The Group maintains a Disclosure Committee reporting 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.

The Treasury Management Group (TMG) meets on a regular basis to seek to ensure that liquidity, interest rate, foreign currency transaction and foreign currency translation risks are all managed in line with the conservative approach as detailed in the associated risk strategies and policies which have been adopted by the Board.



Oversight of Treasury's role in managing counterparty risk in line with agreed policy is performed by a Corporate Compliance Officer (CCO), who operates independently of Treasury.

Further details on mitigation of Treasury Risks can be found on page 192, Note 41, 'Financial instruments and related disclosures'.

Tax risk is managed by a set of policies and procedures to seek to ensure consistency and compliance with tax legislation.

We seek to maintain open, positive relationships with governments and tax authorities worldwide. We monitor government debate on tax policy in our key jurisdictions to deal proactively with any potential future changes in tax law. We engage advisors and legal counsel to review tax legislation and the implications for our business. Where relevant we are active in providing relevant business input to tax policy makers.

A centralised team of dedicated specialists are responsible for managing transactional tax reporting and compliance.

We submit tax returns according to statutory time limits and engage with tax authorities to seek to ensure our tax affairs are current, entering into arrangements such as Continuous Audit Programmes and Advance Pricing Agreements to provide long-term certainty over tax treatment where appropriate. 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.

Each business unit leadership team retains ultimate accountability for managing third party interactions and risks. 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. 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.

To seek to 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 seek to 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.

Continuous monitoring and performance of third parties is enhanced through a Third Party Oversight team in the Global Ethics and Compliance organisation. This team commenced implementation of a global programme that takes an enterprise view of third party related risks, the programme is strengthening risk assessment and due diligence efforts on third parties and improving the overall management of our third party risks through the lifecycle of the third party engagement. Oversight for the programme is provided by the newly created global risk office within GSK's Global Ethics and Compliance group.

#### Anti-Bribery and Corruption

##### Risk definition

Failure to prevent GSK employees and third parties not complying with our ABAC principles and standards, as well as with all applicable legislation.

##### 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.

The US and UK authorities are leading extra-territorial ABAC enquiries into certain of the Group's operations. These investigations are discussed further in 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, and is flexible to the evolving nature of our business. For example, we scaled our acquisition ABAC due diligence specific to the 2015 Novartis transaction.

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 ABAC policy; and written standards 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 Governance Board 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, ABAC Audit and Independent Business Monitoring 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. During 2015, we also completed an ABAC review and reduced our presence in a number of high-risk markets.

#### Commercialisation

##### Risk definition

Failure to execute business strategies, or manage competitive opportunities or threats effectively and in accordance with the letter and spirit of legal, industry or company requirements.

##### Risk impact

Failure to manage risks related to commercialisation could materially and adversely affect our ability to grow a diversified global business and deliver more products of value.

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 products and possibly suboptimal treatment of patients and consumers. Any of these consequences could materially and adversely affect the Group. Any practices that are found to be misaligned with our values could also result in reputational damage and dilute trust established with key stakeholders.

#### Context

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 achieve our strategic objectives.

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 ability to achieve our strategic objectives.

We are committed to the ethical and responsible commercialisation of our products 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 provide important information about our medicines.

Promotion of approved products seeks to ensure that HCPs globally have access to information they need, that patients and consumers have access to the products they need and that products are prescribed, recommended or used in a manner that provides the maximum healthcare benefit to patients and consumers. 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 or recommending 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.

In 2012, we paid \$3 billion (£1.9 billion) to resolve government investigations in the US focused in large part on promotional practices and in 2014 we paid RMB 3 billion (£301 million), to resolve a government investigation in China focused on offering money or property to non-government personnel in order to obtain improper commercial gains.

#### Mitigating activities

Our strategic objectives are designed to ensure the Group achieves its mission of helping people do more, feel better and live longer. The Group continues to transform by strengthening our presence in key emerging markets, restructuring R&D, simplifying core business operations and reducing our manufacturing footprint. Our recent transaction with Novartis has helped further accelerate this pace of change, while strengthening our three core businesses: Pharmaceuticals, Vaccines and Consumer Healthcare.

These changes are allowing us to be more global and more relevant to the needs of the world. Our aim is to reach as many patients and consumers as we can, improving their health and wellbeing through the use of our products. How we deliver this goal is just as important as what we achieve. Our values provide a guide for how we lead and make decisions. We constantly strive to do the right thing and deliver quality products, seeking to ensure our behaviours reflect our values and the mission of our company.

The Corporate Executive Team has set out their shared objectives which describe the most important priorities we need to deliver across the Group and a set of enterprise-wide projects which are critical to achieving these objectives. The strategic objectives are cascaded throughout the Group to ensure enterprise-wide alignment. Processes are in place to regularly review achievement towards these objectives.

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

The Group has harmonised policies and procedures to guide above country Commercial Practices processes as well as clarified applicable standards when engaging in the markets. 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 seek to 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.

In 2015, GSK also implemented globally changes already made in the US to the compensation model for sales professionals and their managers who interact with HCPs. The changes eliminate rewards based on sales or market shares in individuals' territories in favour of rewards based on the quality of the individuals' interactions with healthcare professionals. Starting in 2016, GSK will implement its prior commitment to stop paying HCPs to deliver promotional presentations for GSK or directly to sponsor their travel to medical educational conferences.

#### Research practices

##### Risk definition

Failure adequately to conduct ethical and sound preclinical and clinical research. In addition, failure to engage in scientific activities that are consistent with the letter and spirit of the law, industry, or the Group's requirements.

##### 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 brought against the Group by governmental and private plaintiffs (product liability suits and claims for damages), and regulatory action such as fines, penalties or loss of product authorisation. Any of these consequences 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.

Scientific Engagement (SE) is an essential part of scientific discourse defined as the interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding, including the appropriate development and use of our products. Such non-promotional engagement with external stakeholder groups is vital to GSK's mission and necessary for scientific and medical advance.

The scope of SE activities includes: advisory boards; scientific consultancies; pre-planned informal discussions with Healthcare Professionals (HCP); sharing medical information; publications (including abstracts to congresses); scientific interactions with payers, patients, governments and the media; and support for Independent Medical Education. Non-independent educational activities are covered by Commercial Practices (CP).

SE activities are essential but present legal, regulatory, and reputational risk if the sharing of data, invited media coverage or payments for service providers has, or is perceived to have, inappropriate promotional intent. The risks are particularly high where HCP engagement and associated Financial and/or Transfer of Value disclosures are required by GSK.

#### Mitigating activities

We established an Office of Animal Welfare, Ethics and Strategy (OAWES), led by the Chief of Animal Welfare, Ethics and Strategy, to seek to 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 2015, we disclosed over 450 Clinical Study Reports of marketed and terminated medicines (once the research results were published in the scientific literature) on our register, bringing the total reports available to over 550. By the end of 2015, we listed over 1,700 clinical trials on the GSK online system, [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com), and have completed our commitment to list completed global studies conducted since the formation of GSK in 2000. The online system allows researchers to request access to anonymised patient-level data from the Group's clinical trials after the medicine has been approved or terminated and the trial has been published.

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 2015 we began work on a new written standard to seek to ensure the integrity of our data across Research and Development (R&D). A Data Integrity Committee was in place throughout the year to provide oversight and a Data Integrity Quality Assurance team began conducting assessments intended 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.

The Group strictly prohibits promotional practices prior to marketing authorisation, and care is taken to seek to ensure that Scientific Engagement activity is not perceived to be promotional.

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 seeking to ensure the highest level of integrity and continuous development of Scientific Engagement at GSK. This framework seeks to ensure the right level of accountability and clear programme guidance above country across R&D business units and in Local Operating Companies (LOC).

The Group takes an integrated approach to managing both Scientific Engagement and Commercial Practices related risks, including a combined guidance document for Promotional Code and Scientific Engagement standards. In this way, those considerations and risks that are common to both Scientific Engagement and Commercial Practices such as ABAC and Healthcare Professionals (HCP) engagements are managed in the right context and in one place to seek to ensure clarity and clear lines of accountability.

Environment, health and safety and sustainability

Risk definition

Failure to manage EHSS risks in line with our objectives and policies and with 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', 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 seeks to ensure there is a control framework 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 controls. Individual managers seek to ensure that the EHSS control framework 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 refreshed 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.

Through our continuing efforts to improve environmental sustainability we have reduced our value chain carbon intensity per pack, water consumption and waste generation. We actively manage our environmental remediation obligations and seek to 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

Failure to protect and maintain access to critical or sensitive computer systems or information.

##### Risk impact

Failure to adequately protect critical and sensitive systems and information may result in loss of commercial or strategic advantage, damage to our reputation, litigation, or other business disruption including regulatory sanction, 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.

Several GSK employees were indicted for theft of GSK research information. While the charges against the individuals are concerning, based on what we know, we do not believe this breach has had any material impact on the company's R&D activity or ongoing business. GSK is conducting a full internal review into what occurred, and planning to continue to enhance the multiple layers of data protection that we already have in place.

##### 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). 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 have been signed by 23 European states allowing us transfer PII internationally between the Group's entities without individual privacy agreements in each European Union country.

#### Crisis and continuity management

##### Risk definition

Failure to deliver a continuous supply of compliant finished product; inability to recover and sustain critical operations, including key supply chains, following a disruption, or to respond to a crisis incident, in a timely manner.

##### Risk impact

We recognise that failure to supply of our products can adversely impact consumers and patients who rely on them. A material interruption of supply or exclusion from healthcare programmes could expose us to litigation or regulatory action, incurring of fines or disgorgement and materially and adversely affect the Group's financial results. The Group's international operations, and those of its partners, maintain a vast global footprint also expose 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). It is important for GSK to have robust crisis management and recovery plans in place to manage such events.

##### 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.

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 organisations 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 fulfil 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.

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

Our supply chain model is designed to seek to 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 seek to ensure that our customers have the medicines, vaccines and products they need.

The improved linkage between commercial forecasting and manufacturing made possible by our Core Commercial Cycle methodology should over time, decrease the risk associated with demand fluctuations impacting our ability to supply or write-offs associated with product exceeding expiry dating. During 2015, each node of the supply chain was



optimised to seek to ensure adequate safety stock while balancing working capital associated with the end-to-end supply chain.

Safety stocks and backup supply arrangements for medically-critical and high-revenue products are in place 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 has been further reduced for certain 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.

We continued to implement anti-counterfeit systems such as product serialisation in accordance with emerging supply chain requirements around the world.

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 continue to evaluate the implications for our business of a possible exit of the United Kingdom from the European Union. While the UK leaving the EU would create uncertainty and potentially add complexity to a wide range of our business activities, we do not currently believe that there would be a material adverse impact on the Group's results in the longer term.

We continually improve our CCM risk management programme and tools based on learning from plan activations. For example, the Group has implemented a global system that provides GSK leaders with access to the vital information they need to effectively respond to disruptions and for monitoring the status of their preparedness and response capability. We regularly solicit and take recommendations for improvements from many different sources/suppliers charged with the responsibility for assisting in managing GSK's risks and introduce new tools to improve our CCM practices.

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 Philip Hampton	Non-Executive Chairman
Sir Andrew Witty	Chief Executive Officer
Simon Dingemans	Chief Financial Officer
Dr Moncef Slaoui	Chairman, Global Vaccines
Professor Sir Roy Anderson	Non-Executive Director
Vindi Banga	Non-Executive Director
Dr Stephanie Burns	Non-Executive Director
Stacey Cartwright	Non-Executive Director
Lynn Elsenhans	Non-Executive Director
Dr Jesse Goodman	Non-Executive Director
Judy Lewent	Non-Executive Director
Sir Deryck Maughan	Senior Independent Non-Executive Director
Dr Daniel Podolsky	Non-Executive Director
Urs Rohner	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: March 17, 2016

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