

GLAXOSMITHKLINE PLC
Form 6-K
March 14, 2017

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 14 March 2017

GlaxoSmithKline plc

(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS

(Address of principal executive offices)

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

Form 20-F x Form 40-F

--

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

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

GlaxoSmithKline plc

Publication of 2016 Annual Report

GlaxoSmithKline plc (the 'Company') will today publish on the Company's website, <http://annualreport.gsk.com/> , its Annual Report for the year ended 31 December 2016 (the '2016 Annual Report').

A hard copy version of the 2016 Annual Report, together with the 2016 Annual Summary (the '2016 Summary') and 2017 Notice of Annual General Meeting (the '2017 AGM Notice'), will be sent to those shareholders who have elected to receive paper communications on or about 30 March 2017. Shareholders who have not elected to receive paper communications will be sent the 2016 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 2016 Annual Report, 2016 Summary and 2017 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 .

The information included in the unaudited preliminary results announcement released on 8 February 2017, together with the information in the Appendix to this announcement which is extracted from the 2016 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 2016 Annual Report in full. Page and note references in the Appendix below refer to page and note references in the 2016 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 2016	22 February 2017	23 February 2017	24 February 2017	13 April 2017

Q1 2017	10 May 2017	11 May 2017	12 May 2017	13 July 2017
Q2 2017	9 August 2017	10 August 2017	11 August 2017	12 October 2017
Q3 2017	8 November 2017	9 November 2017	10 November 2017	11 January 2018

V A Whyte
Company Secretary

14 March 2017

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

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 risks 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 regulations 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 46, 'Legal proceedings,' on pages 226 to 231.

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 risks 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 about the safety of our products 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 take 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 within the Pharmaceutical, Vaccines and Consumer Healthcare businesses and the Group's substantial 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 products 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 risk/benefit profile of one of the Group's products 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, maintain and enforce intellectual property rights.

Risk impact

Any failure to obtain or subsequent loss of patent protection in a market, 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 that market. Absence of adequate patent or data exclusivity protection in a market could limit the opportunity to rely on that market for future sales growth for our products, which could also materially and adversely affect our financial results in that market.

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 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. Since there is no abbreviated pathway that leads to substitutable generic vaccines, competition in that market arises from branded products or generic branded products and erosion of sales, revenues and margins is less dramatic. In addition, the proprietary technology used in manufacture and the capital investment in facilities create barriers to entry into the vaccine markets.

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 patent for compositions containing the combination of active substances in Seretide/Advair has expired. Generic products containing the same combination of active substances as Seretide/Advair (in both dry powder inhalers and metered dose inhalers) have been launched by several manufacturers in a number of European markets. New drugs applications (ANDAs) have been filed in the US by generic competitors for Seretide/Advair Diskus and were approved in January 2017. The date of such approvals is uncertain at this time but could come as early as March 2017. The timing of an ANDA for Advair HFA in the US is uncertain. We have patents on the

formulation and device used in the metered dose inhaler, although the protection afforded by these patents is uncertain at present. Similar patents exist for Ventolin HFA and Flovent HFA.

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 250 to 251. The listed annual expiration dates are not meant to indicate the certainty of exclusivity for the listed products, as patents may be designed around or invalidated prior to their expiration, resulting in earlier entry of a generic product. Legal proceedings involving patent challenges are set out in Note 46 to the financial statements, 'Legal proceedings'.

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 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.

Mitigating activities

Our Global Patents group focuses on securing, maintaining and enforcing 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 lawfully 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 laws 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 GSK's reputation. Associated regulatory, legal, and financial consequences could materially and adversely affect company reputation and financial results.

Context

Patients, consumers and healthcare professionals trust the quality of our products. 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 data integrity, supply continuity and drug shortages. Review of inspections conducted across the industry by national regulatory authorities during 2016 highlighted an ongoing focus on data integrity, third party oversight 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 product lifecycle from R&D to mature commercial supply.

There is no single external quality standard or system that governs the detailed global regulatory expectations for the quality of medicinal products. Requirements are often complex and fragmented across national and regional boundaries. Consequently, we have adopted the internationally recognised principles from the 'ICH Q10: Pharmaceutical Quality Systems' framework as the basis for the GSK PQS. This is an industry standard which incorporates quality concepts throughout the product lifecycle. The GSK PQS is augmented by a consolidation of the numerous regulatory requirements defined by markets across the world, which assures that the GSK PQS meets external expectations for product quality in the markets supplied. The PQS is regularly updated to ensure that it keeps pace with the evolving external regulatory environment. New scientific understanding and operational improvements are incorporated into the PQS 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. In 2016 we introduced a revised approach to monitoring Regulated Quality (GxP) performance to provide the Corporate Executive Team with an integrated assessment of key performance indicators (KPIs). The defined KPIs cover manufacturing practice, clinical practice, pharmacovigilance practice, regulatory practice, drug safety assessment, and animal welfare.

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

All staff members are regularly trained to ensure that cGMP standards and behaviours based on our values are followed. Additionally, advocacy and communication programmes are routinely deployed to ensure consistent messages are conveyed across the organisation, whether they originate from changes in regulation, 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 controls 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 disruption 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. These transactions involve market volatility and counterparty risk. 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 takes into account regimes that encourage innovation and investment in science by providing tax incentives which, if changed, could affect the Group's tax rate. In addition, the worldwide nature of our operations and cross-border supply routes can result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. The tax charge included in our financial statements is our best estimate of the Group's tax liability pending audits by tax authorities.

There continues to be a significant international focus on tax reform, including the OECD's Base Erosion and Profit Shifting (BEPS) project and European Commission initiatives such as the increased use of fiscal state aid investigations. Together with domestic initiatives around the world, these may result in significant changes to established tax principles 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 unethical business practices. 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 judgements are reviewed and confirmed by senior management. Business reorganisations and newly acquired activities are integrated into risk assessments and appropriate controls and reviews are applied. Counterparty exposure is subject to defined limits approved by the Board for both credit rating and individual counterparties.

In 2016, we created a Finance Risk and Controls Centre of Excellence to maintain the Finance control framework. We added resources to ensure processes and controls were maintained during business transformation, the upgrade of our financial systems and processes and the ongoing integration of the former Novartis' businesses into our control and reporting framework. Additional risk mitigation was introduced by amending the programme timelines of system upgrades.

The Group maintains a Disclosure Committee reporting to the Board, which reviews the Group's quarterly results and Annual Report and Form 20-F 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 meets on a regular basis to seek to ensure that liquidity, interest rate, counterparty, 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, who operates independently of Treasury. Further details on mitigation of Treasury Risks can be found on pages 212 to 213 in Note 42, '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. Significant decisions are considered and agreed by the Tax Governance Board, which meets quarterly and is made up of senior personnel from across the Finance group.

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 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 our 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 the Third Party Oversight programme managed through the Global Ethics and Compliance organisation. The global programme, which completed deployment across LATAM and South East Asia countries in 2016, takes an enterprise wide 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.

Anti-Bribery and Corruption

Risk definition

Failure of GSK employees, consultants and third parties to comply with our Anti-bribery and corruption (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.

In addition to legal penalties, a failure to prevent bribery through complying with ABAC legislation and regulations could have substantial implications for the reputation of the company, the credibility of senior leaders, and an erosion of investor confidence in our governance and risk management.

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 Group has been subject to a number of ABAC inquiries. We have reached a resolution with US authorities in 2016 regarding their ABAC inquiry, whilst the inquiry of the UK authorities is ongoing. These investigations are discussed further in Note 46 '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 evolve 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 headquarters and local markets.

The Group has an enterprise-wide ABAC programme designed to ensure compliance with the Group's ABAC policies and prevent the risk of bribery and corruption. It builds on our values and business standards to form a comprehensive and practical approach to compliance, and is flexible to the evolving nature of our business.

Our ABAC programme is built on best in class principles and a range of features which collectively enable us to manage the risk from top down and bottom up. For example, the programme comprises top-level commitment from the Group Board of Directors and leadership; a global risk assessment to enable targeted intervention and compliance monitoring activities. The programme is underpinned by a global ABAC policy and written standards that address commercial and other practices that give rise to ABAC risk and ongoing training and communications. In addition, the programme mandates enhanced controls over interactions with government officials and during business development transactions. All employees are required to complete comprehensive ABAC training dependent on role requirements.

Programme governance is provided by the Group's ABAC Governance Board which includes representation from key functional areas and business units. 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 independent oversight and assurance undertaken by the Audit and Assurance and Independent Business Monitoring teams.

We continually benchmark our ABAC programme against other large multinational companies and use external expertise to drive improvements in the programme.

Commercialisation

Risk definition

Failure to execute business strategies, or effectively manage competitive opportunities and threats in accordance with the letter and spirit of legal, industry, or the Group's 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 for patients and consumers. 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 risk/benefit 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 external 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. As do other pharmaceutical, vaccine and consumer companies, the Group faces downward price pressure in major markets, declining emerging market growth, and negative foreign exchange impact.

Developing new Pharmaceutical, Vaccine and Consumer Healthcare products is a costly, lengthy and an uncertain process. 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 healthcare professionals (HCPs) globally have access to information they need, that patients and consumers have access to the information and 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.

While business units within the Group are confronted by common types of commercialisation risks, differences do exist in the types of risks that present themselves, the degree of risk presented in that business unit and, consequently, how those risks are managed. This reflects the different nature and profile of the business units across the Group.

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 strive for new product launches that are competitive and resourced effectively, as well as a healthy proportion of its sales ratio attributable to new product or innovation sales. This innovation helps the Group defray the effect, for example, of downward price pressure in major markets, declining emerging market growth and negative foreign exchange impact.

Establishing new products that are priced to balance expectations of patients and consumers, HCPs, payers, shareholders, and the community enables the Group to maintain a strong global business and remain relevant to the needs of patients and consumers. 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.

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. Each business unit within the Group has adopted GSK's Internal Control Framework to support the assessment and management of its risks. Commercial practices activities have appropriate monitoring programmes and oversight from both business unit Risk Management and Compliance Boards and Country Executive Boards 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.

The Group continues to evolve its commercial operating model, embedding industry leading changes in the compensation model for sales professionals and their managers who interact with HCPs. These changes eliminated rewards based on sales or market share of prescription products in individuals' territories in favour of rewards based on the quality of the individuals' interactions with HCPs. Furthermore, from the beginning of 2016, GSK stopped paying HCPs to deliver promotional presentations for GSK to other HCPs or sponsor their travel to medical educational conferences.

Research practices

Risk definition

Failure to adequately 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 human subjects, 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 address this proactively, 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. Nonetheless, we are continually seeking ways in which we can minimise our use of animals in research, whilst complying with regulatory requirements.

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), 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, is an essential part of scientific discourse. 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. 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, 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 make information available on our studies, including summaries of the results - whether positive or negative. GSK was the first company to publish clinical study reports that form the basis of submissions to regulatory agencies and we have publically posted more than 1,830 clinical study reports in addition to more than 6,000 study result summaries. Detailed patient-level data from approximately 2,000 clinical studies can be requested and accessed through clinicalstudydatarequest.com.

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. 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 SE activity is not promotional.

Specific accountability and authorisation for SE resides within the Medical Governance framework that is overseen by the Global Medical Topic Board (GMTB), accountable to the Chief Medical Officer. GMTB is responsible for oversight of applicable policies and seeking to ensure the highest level of integrity and continuous development of SE at GSK. This framework seeks to ensure the right level of accountability and clear programme guidance at above country across R&D business units and in Local Operating Companies.

The Research Practices risk is now aligned with a new Enterprise framework that seeks to ensure strengthened governance across the R&D businesses in Pharmaceutical, Vaccines and Consumer Healthcare. Under the leadership of the Chief Research Practices Officer, management of the risk will take a practical approach to information sharing, streamlining risk identification and escalation while ensuring ownership stays at the business unit level and allows for a proportional risk treatment plan.

Environment, health and safety and sustainability

Risk definition

Failure to manage environment, health and safety and sustainability (EHS&S) risks in line with our objectives and policies and with relevant laws and regulations.

Risk impact

Failure to manage EHS&S 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 in the US. 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 46 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 (CET) is responsible for EHS&S 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 EHS&S and for assigning responsibility to senior managers for providing and maintaining those controls. Individual managers seek to ensure that the EHS&S 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 by them and

expected to take responsibility for EHS&S matters.

Our risk-based, proactive approach is articulated in our refreshed Global EHS&S standard which supports our EHS&S policy and our 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 EHS&S performance results are shared externally each year in our Responsible Business Supplement.

Information protection

Risk definition

The risk to GSK business activities if information becomes disclosed to those not authorised to see it, or if information or systems fail to be available or are corrupted.

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 (PII), intellectual property, manufacturing systems and trade secrets. There is the potential that our computer systems or information may be exposed to misuse or unauthorised disclosure. We are also subject to various laws that govern the processing of PII.

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. A Privacy Centre of Excellence has been established to ensure compliance prior to the deadline with the new General Data Protection Requirements (GDPRs). All employees are required to complete training on the appropriate handling and maintaining of 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 recognised by 29 European states and Switzerland allowing us to transfer PII internationally between the Group's entities without individual privacy agreements in each European Union country. The approval in the remaining two countries, Greece and Romania is expected in 2017.

Supply continuity and crisis management

Risk definition

Failure to deliver a continuous supply of compliant finished product; inability to respond effectively to a crisis incident in a timely manner to recover and sustain critical operations, including key supply chains. This risk was previously called Crisis and continuity management.

Risk impact

We recognise that failure to supply 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 and financial penalties that could adversely affect the Group's financial results.

The Group's international operations, and those of its partners, expose our workforce, facilities, operations and information technology to potential disruption from natural events (e.g. storm or earthquake), man-made events (e.g. civil unrest, terrorism), and global emergencies (e.g. Ebola outbreak, Flu pandemic). It is important that GSK has 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.

We rely on materials and services provided by third party suppliers to make our products, including active pharmaceutical ingredients (API), antigens, intermediates, commodities, and components for the manufacture and packaging of Pharmaceutical, Vaccine and Consumer Healthcare products. Some of the third party services procured, such as services provided by contract manufacturing 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 supply risk in the event of regulatory non-compliance or physical disruption at the manufacturing sites or logistics system. If any of the small number of single-source, third party suppliers and service providers we use fail to fulfil their contractual obligations in a timely manner or experience regulatory non-compliance or physical disruption of their logistics and manufacturing sites, this could also result in delays or service interruptions.

We use effective crisis management and business continuity planning to provide for the health and safety of our people and to minimise impact to the Group, by maintaining functional operations following a natural or man-made disaster, or a public health emergency.

Mitigating activities

Our supply chain model is designed to ensure the supply, quality and security of our products globally, as far as possible. We closely monitor, through the Supply Chain Governance Committees, the inventory status and delivery of our products with the aim to ensure that customers have the Pharmaceutical, Vaccines and Consumer Healthcare products they need.

Improved links between commercial forecasting and manufacturing made possible by our core commercial cycle should, over time, reduce the risk associated with demand fluctuations and any impact on our ability to supply or the cost of write-offs where products exceed their expiry date. Each node of the supply chain is periodically reviewed to ensure adequate safety stock, while balancing working capital in our 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, we routinely monitor the compliance of manufacturing external suppliers in order to identify and manage risks in our supply base. Where practical, we minimise our dependence on single sources of supply for critical items.

Where alternative sourcing arrangements are not possible, our inventory strategy aims to protect the supply chain from unanticipated disruption.

We continue to implement anti-counterfeit systems such as product serialisation in accordance with emerging supply chain requirements around the world. A corporate policy requires each business unit and functional area head to ensure 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 any business disruption occurs.

Corporate Security supports the business by: coordinating crisis management and business continuity training; facilitating simulation exercises; assessing Group preparedness and recovery capability; and providing assurance oversight of the Group's central repository of plans supporting our critical business processes. Each business unit has a governance board which performs risk oversight and monitoring including identifying new and emerging threats. The Group has a coordinated approach to evaluate and manage the implications for our business regarding the UK's exit from the European Union.

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.

(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 state of affairs of the Group and its profit; 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	Independent Non-Executive Chairman
Sir Andrew Witty	Chief Executive Officer
Emma Walmsley	CEO Designate
Simon Dingemans	Chief Financial Officer
Dr Moncef Slaoui	Chairman, Global Vaccines
Dr Patrick Vallance	President, R&D
Professor Sir Roy Anderson	Independent Non-Executive Director
Vindi Banga	Senior Independent Non-Executive Director
Vivienne Cox	Independent Non-Executive Director
Lynn Elsenhans	Independent Non-Executive Director
Dr Jesse Goodman	Independent Non-Executive Director
Judy Lewent	Independent Non-Executive Director
Urs Rohner	Independent 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 14, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc