

3.D Risk Factors

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 global 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 227 to 232 of the GSK Annual Report 2017.

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 risk impact has the potential 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.

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. This would have the potential to do damage to our reputation, as well as result in other regulatory, legal and financial consequences.

Context

Patients, consumers and HCPs 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 and new legislation are introduced. Critically, we are addressing the impact of Brexit on our supply chain management and quality oversight between the UK and the EU and are developing and deploying appropriate contingency plans to avoid interruption of supply to patients.

Financial controls and reporting

Risk definition

Failure to comply with current tax laws or incurring significant losses due to treasury activities; failure to report accurate financial information in compliance with accounting standards and applicable legislation.

Risk impact

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

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 means that our intellectual property, R&D and manufacturing operations are centred in a number of key locations. A consequence of this is that our cross-border supply routes, necessary to ensure supplies of medicines into numerous end markets, can be complex and result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. Tax legislation itself is also complex and differs across the countries in which we operate. As such, tax risk can also arise due to differences in the interpretation of such legislation. The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities.

We expect there to be continued focus on tax reform in 2018 and future years driven by the Organisation for Economic Cooperation & Development's Base Erosion and Profit Shifting project and European Commission initiatives including the 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 and relationship with key stakeholders.

Anti-bribery and corruption

Risk definition

Failure of GSK employees, consultants and third parties to comply with our Anti-bribery & 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 and may compromise the Group's ability to supply its products under certain government contracts. 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 by its very nature maintains relationships with government bodies, 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 reached a resolution with the US authorities in 2016 regarding their ABAC inquiry, following which we are subject to a self-monitoring arrangement until September 2018. Government investigations regarding our China and other business operations are ongoing. These investigations are discussed further in Note 45, 'Legal proceedings'.

Commercial practices

Risk definition

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

Risk impact

Failure to manage risks related to commercial practices 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 which could result in government sanctions, and criminal and/or financial penalties. 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 practices that are found to be misaligned with our values could also result in reputational harm 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 that reflect insights which help ensure those products address the needs of patients/consumers, HCPs, and payers are critical to achieve our strategic objectives.

As do other pharmaceutical, vaccine and consumer companies, we face 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 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 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.

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, and failure to secure adequate patent protection for GSK's products.

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), loss of revenue due to inadequate patent protection or inability to supply GSK products, and regulatory action such as fines, penalties, or loss of product authorisation. Any of these consequences could materially and adversely affect our financial results and cause loss of trust from our customers and patients.

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 form the content of regulatory submissions. Poor data integrity can compromise our research efforts and negatively impact company reputation.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Continually changing and increasingly stringent submission requirements 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 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. SE activities are essential but present legal, regulatory, and reputational risk if the sharing of data, invited media coverage or payments to HCPs have, or are perceived to have, promotional intent.

A wide variety of biological materials are used by GSK in discovery, research and development phases. Through the Convention on Biological Diversity (CBD) and the Nagoya Protocol, the international community has established a global framework regulating access to, and use of, genetic resources of non-human origin in R&D. We support the principles of access and benefit sharing to genetic resources as outlined in the CBD and the Nagoya Protocol, recognising the importance of appropriate, effective and proportionate implementation measures at national and regional levels.

In addition, any loss of patent protection in a market for GSK's products developed through our R&D, 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, which could lead to, for example, competition from manufacturers of generic pharmaceutical products, could limit the opportunity to rely on such markets for future sales growth for our products, which could also materially and adversely impact our financial results. Following expiration of certain intellectual property rights, a generic manufacturer may lawfully produce a generic version of a product, and 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. Introduction of generic products typically leads to a rapid and dramatic loss of sales and reduces our revenues and margins for our proprietary products. 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.

Third party oversight risk

Risk definition

Failure to maintain adequate governance and oversight over third party relationships and failure of third parties to meet their contractual, regulatory, confidentiality or other obligations.

Risk impact

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

Context

Third parties are critical to our business delivery and are an integral part of the solution to meeting our business objectives. We rely on third parties, including suppliers, advisors, distributors, individual contractors, licensees, and other pharmaceutical and biotechnology collaboration partners for discovery, manufacture, and marketing of our products and for supporting other important business processes.

These business relationships present a material risk. For example, we share critical and sensitive information such as marketing plans, clinical data, and employee data with specific third parties who are conducting the relevant outsourced business activities. 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 across a diverse geographical spread.

Environment, health and safety and sustainability

Risk definition

Failure to manage environment, health & 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, which could materially and adversely affect our financial results.

Context

We are 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 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.

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, typically because of cybersecurity threats, although accident or malicious insider action may be contributory causes.

This also includes the risk of failure to collect, secure, and use personal information in accordance with data privacy laws.

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in loss of commercial or strategic advantage and could materially affect our ongoing business operations, such as scientific research, clinical trials and manufacturing and supply chain activities. Failure to comply with data privacy laws could lead to adverse impact on individuals (for example financial loss, distress or prejudice). In both cases, damage to our reputation, litigation, or other business disruption including regulatory sanction could occur, which could materially and adversely affect our financial results.

Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, 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 believe that the cyber security incidents that we have experienced to date have not resulted in significant disruptions to our operations, and have not had a significant adverse effect on our results of operations, or on third parties. However, as the threats evolve we cannot provide assurance that our significant efforts in protecting and monitoring our systems and information will always be successful in preventing compromise or disruption in future.

All parts of our business process personal information. The use of this information is critical to our operations and innovation, including the development and sale of our products, as well as management of our employees.

New and evolving laws and regulations, such as the European Union General Data Protection Regulation (GDPR), are likely to bring increased scrutiny of our data management.

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.