

- 3.B Capitalization and indebtedness
Not applicable.
- 3.C Reasons for the offer and use of proceeds
Not applicable.
- 3.D Risk factors

Principal risk factors 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 factors below are those that we believe could cause our actual results to differ materially from expected and historical results.

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

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

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

Moreover, as rules and regulations change, and governmental interpretation of those rules and regulations evolves, the nature of a particular risk may alter. Changes to certain regulatory requires, such as the US healthcare system, 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, antitrust litigation and sales and marketing litigation. Litigation and government investigations, including related provisions we may make for unfavourable outcomes and increases in related costs such as insurance premiums, could materially and adversely affect our financial results. More detail on the status and various uncertainties involved in the significant unresolved disputes and potential litigation is set out in Note 44, 'Legal proceedings,' on pages 204 to 210 of the GSK Annual Report 2013.

The principal risk factors and uncertainties are not listed in order of significance.

Failure to appropriately collect, review, follow up, or report adverse events from all potential sources. This could 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.

Risk impact

The impacts of the risk include 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 who 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.

Failure to appropriately secure and protect intellectual property rights.

Risk impact

Any loss of patent protection, including reducing the scope of patent rights or compulsory licensing (in which a government forces a manufacturer to license its patents 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 but may face technological or regulatory barriers to marketing.

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 USA. Some developing countries have reduced, or threatened to reduce, effective patent protection for Pharmaceutical products generally, or in particular therapeutic areas, to facilitate early competition within their markets from generic manufacturers.

We face competition from manufacturers of proprietary and generic pharmaceutical products in all of our major markets. Introduction of generic products, particularly in the USA where we have our highest turnover and margins, typically leads to a dramatic loss of sales and reduces our revenues and margins for our proprietary products. In 2013, we had 10 Pharmaceutical and Vaccine products with over £500 million in annual global sales. For certain of these products, there is generic competition in the USA and some markets in Europe. We may also experience an impact on sales of one of our products due to the expiry or loss of patent protection for a product marketed by a competitor in a similar product class or for treatment of a similar disease condition.

We depend on certain key products for a significant portion of our sales. The timing and impact of entry in the USA and major markets in Europe for a 'follow-on' product to *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. We are not able to predict when a generic competitor to *Seretide / Advair* may enter the US market.

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

The expiration dates for patents for our major products which may affect the dates on which generic versions of our products may be introduced are set out on pages 229 to 231. Legal proceedings involving patent challenges are set out in Note 44 to the financial statements, 'Legal proceedings', on pages 204 to 206 of the GSK Annual Report 2013.

Failure to ensure product quality throughout manufacturing and distribution processes resulting in non-compliance with good manufacturing practice (GMP) and regulations.

Risk impact

A failure to ensure product quality could have far reaching implications in terms of the health of patients and customers, product recalls, potential damage to our reputation, as well as regulatory, legal, and financial consequences, which could materially and adversely affect our financial results.

Context

Patients, consumers and healthcare professionals trust the quality of our products at the point of use. A failure to ensure product quality is an enterprise risk which is applicable across all of 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 and security of the supply chain, and the embodiment of an overarching quality culture. The internal and external environment continues to evolve as new products, new markets and new legislation are introduced, particularly around security of supply, good distribution practice and product standards.

Failure to deliver a continuous supply of compliant finished product.

Risk impact

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

Context

Our supply chain operations are subject to review and approval by various regulatory agencies that effectively provide our licence to operate. Failure by our manufacturing and distribution facilities or by suppliers of key services and materials could lead to litigation or regulatory action such as product recalls and seizures, interruption of supply, delays in the approval of new products, and revocation of our licence to operate 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 clinical research organisations to support development of key products, are important to the 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 and to logistics.

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.

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.

Context

New or revised accounting standards, rules and interpretations issued from time to time by the International Accounting Standards Board could result in changes to the recognition of income and expense that may materially and adversely affect our financial results.

The Group is also required by the laws of various jurisdictions to publicly disclose its financial results, and regulators routinely review the financial statements of listed companies for compliance with accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning our financial statements and disclosures. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements there is potential for restatements of previously reported results and we could be subject to significant penalties.

Failure to comply with tax law or significant losses due to treasury activities.

Risk impact

Changes in tax laws or in their application with respect to matters such as transfer pricing, foreign dividends, controlled companies, R&D tax credits, taxation of intellectual property or a restriction in tax relief allowed on the interest on intra-group debt, could impact our effective tax rate. Significant losses may arise from Treasury activities through inconsistent application of Treasury policies, dealing or settlement errors, or counterparty defaults. Any such changes in tax laws or their application, failure to comply with tax law or significant losses due to treasury activities could materially and adversely affect our financial results.

Context

The Group's Treasury group deals in high value transactions, mostly foreign exchange and cash management transactions, on a daily basis.

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

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

There is an increased focus on the tax position of multinational businesses, as a consequence of the challenging economic environment and the priority placed by the G20 on addressing allegations of tax avoidance. We have seen some increase in audits as governments seek to raise revenues, both from corporate taxes and above the line taxes such as customs duties.

Failure to foster a culture within the Group in which bribery and corruption are unacceptable; adopt measures and embed procedures to prevent bribery and corruption by employees, complementary workers and through third party interactions; investigate allegations of bribery and corruption and remediate issues identified; and comply with applicable anti-bribery and corruption (ABAC) legislation.

Risk impact

Failure to comply with applicable local and international ABAC legislation 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, all of which could materially and adversely affect our financial results.

Context

Like other large organisations, the Group faces the risk of fraud by members of staff. The nature, scale and geography of our international business activities increase the possibility of this bribery and corruption risk. Additionally, the healthcare industry is highly regulated, and some of our overseas markets, such as our operations in emerging markets, are more susceptible to bribery and corruption risks.

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

Risk impact

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

Context

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

There are legal, regulatory, financial and reputational risks for the Group if these activities are, or are perceived to be, exceeding their proper boundaries or inappropriately influencing HCPs. In 2012, we paid \$3 billion to resolve government investigations in the USA focused in large part on promotional practices.

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

Risk impact

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

Context

Research relating to animals and humans 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, which is generally mandated by regulators and ethically imperative. Animal research can also 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. Currently, rapid changes in submission requirements in developing countries are increasing the complexity of meeting regulatory requirements.

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

Risk impact

Failure to manage EHSS risks could lead to significant harm to people, the environment and communities in which we operate, fines, failure to meet stakeholder expectations and regulatory requirements, litigation or regulatory action and 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 actual and 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 44 to the financial statements, 'Legal proceedings', on pages 204 to 210 of the GSK Annual Report 2013, for a discussion of the environmental related proceedings in which we are involved. We routinely accrue amounts related to our liabilities for such matters.

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

Risk impact

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

Context

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

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

Risk impact

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

Context

Patients, consumers and healthcare professionals rely on our products being readily available when needed even in the event of a crisis. Our international operations, and those of our partners, maintain a vast global footprint exposing our people, facilities, operations and information technology to potential disruption resulting from a natural event (eg storm or earthquake), a man-made event (eg civil unrest, terrorism), or a global emergency (eg global public health emergency).