3.D Risk Factors

Principal risks and uncertainties

We outline below the principal risks and uncertainties relevant to GSK's business, financial condition and operations that may affect our performance and ability to achieve our objectives. These are the risks that we believe could cause our actual results to differ materially from expected and historical results.

Operating in the pharmaceutical sector carries various inherent risks and uncertainties that may affect our business.

We must comply with a broad range of laws and regulations which apply to the research and development, manufacturing, testing, approval, distribution, sales, and marketing of pharmaceutical, vaccine and consumer healthcare products. These affect the cost of product development, the time required to reach the market and the likelihood of doing so successfully on an uninterrupted basis.

As rules and regulations change, government interpretation evolves, and our business activities develop, the nature of a particular risk may also alter. Changes to regulatory regimes may be substantial. Any alteration in, and failure to comply with, applicable laws and regulations could materially and adversely affect our financial results.

Similarly, our global business exposes us to litigation and government investigations, including product liability litigation, patent and antitrust litigation and sales and marketing litigation. Litigation and government investigations, and the related provisions we may make for unfavourable outcomes and increases in related costs such as insurance premiums, could also materially and adversely affect our financial results.

More detail on the status and various uncertainties in our significant unresolved disputes and potential litigation is set out in Note 46, 'Legal proceedings' on pages 248 to 250 of the GSK Annual Report 2021, which is incorporated by reference herein.

Patient safety

Risk definition

Potential failure to appropriately collect, review, follow up, or report human safety information (HSI), including adverse events from all potential sources, and to act on any relevant findings in a timely manner.

Risk impact

GSK has zero tolerance for an unfavourable benefit-to-risk ratio for patients who use our products. We collect, review, follow up and report human safety information from all potential sources, and use this to conduct robust and timely safety signal detection and take all appropriate measures to safeguard patients and consumers. If we do not effectively manage risks to our patient safety activities, the most serious repercussion could be harm to patients. If we are not compliant with all pharmacovigilance (or 'drug safety') regulations globally, consequences could include inspection findings, regulatory scrutiny, civil or criminal sanctions and either temporary or permanent loss of product marketing authorisation. Ineffective management of patient safety risks could also lead to reputational damage, loss of trust by patients and healthcare providers, product-related litigation, and loss of shareholder confidence.

Context

We are fully accountable for safeguarding patients, and our licence to operate depends on our compliance with increasingly complex and variable global regulatory requirements. These include not only pharmacovigilance regulations, but also stringent privacy protections and information security considerations. Our compliance depends on employees and third parties acting on our behalf managing human safety information in accordance with our internal processes.

We balance routine pharmacovigilance activities against a variety of business change initiatives. While supporting our current product portfolio, we are optimising how we perform pharmacovigilance so we are prepared to deliver our future strategy, including an increased focus on oncology, vaccines and specialty medicines and the successful separation of the Consumer Healthcare business in 2022.

We collect information on the safety and efficacy of our products in humans during clinical development and gain more comprehensive information on real-world use once our products are on the market. In addition to our own safety surveillance activities, external parties analyse publicly-available clinical trial results or other data, while new external initiatives use real-world evidence from sources which are not accessible to GSK, but may be used by regulatory agencies to supplement and validate the evidence we use to support the safety and efficacy of our products.

Extensive news and social media coverage of the safety and efficacy of COVID vaccines and therapies has increased the public's recognition of the importance of pharmacovigilance in the drug development process and in the product marketing phase, but a rise in misinformation has also led to distrust and vaccine hesitancy. This environment could undermine regulatory, governmental, and public trust in medicines for treating COVID-19, which could negatively influence healthcare decisions for other diseases, leading to reputational damage or product liability lawsuits.

Product quality

Risk definition

Failure by GSK, its contractors or suppliers to ensure:

- Appropriate controls and governance of quality in product development;
- Compliance with good manufacturing practice or good distribution practice regulations in commercial or clinical trials manufacture and distribution activities;

- Compliance with the terms of GSK product licences and supporting regulatory activities.

Risk impact

A failure to ensure product quality could have far-reaching implications for patient and consumer safety, cause product launch delays, drug shortages or product recalls, and have regulatory, legal, and financial consequences. These could materially and adversely affect GSK's reputation and financial results.

Context

The external environment for product quality remains challenging, affected by misinformation fuelling vaccine hesitancy, and increased cyber-attacks and data breaches across the industry. Cyber-attacks remain a key risk to the integrity of product quality data and its audit trail.

We are prepared to meet the 2021 European Medicines Agency (EMA) requirements for licensing of Medical Devices and continue to prepare for the in Vitro Diagnostic Medical Device Regulation which becomes effective May 2022. We continue to plan for the implementation of the New Annex 1 guidance for the manufacture of Sterile Medicinal products in the first half of 2022.

We are increasingly using new technology to enhance the manufacture and testing of our products. For example, we use new electronic documentation systems and advanced laboratory information management tools.

Significant changes are taking place in GSK as we implement our new strategy and structure. Our quality organisations assess these changes to make sure our quality procedures and governance can facilitate the strategy, while also ensuring that no unintended consequences increase our product quality risk. The industry is experiencing an increased regulatory on-site inspection presence - resumed since the onset of the pandemic and we are taking steps to ensure our inspection readiness.

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 GSK to litigation and regulatory action and could materially and adversely affect our financial results. In the current global pandemic, there can be significant changes at short notice. Failure to comply with changes in the substance or application of the laws governing transfer pricing, dividends, tax credits and intellectual property could also materially and adversely affect our financial results.

Inconsistent application of treasury policies, transactional or settlement errors, or counterparty defaults could lead to significant losses.

Context

We are required by the laws of various jurisdictions to publicly disclose our financial results and events that could materially affect the Group's financial results. Regulators routinely review the financial statements of listed companies for compliance with new, revised, or existing accounting and regulatory requirements. We believe that we comply with the appropriate regulatory requirements concerning our financial statements and the 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 could lead to restatements of previously reported results and significant penalties.

Our Treasury group deals daily in high value transactions, mostly foreign exchange, and cash management transactions. These transactions involve market volatility and counterparty risk.

The Group's effective tax rate reflects the locations of our activities and the value they generate, which determine the jurisdictions in which profits arise and the applicable tax rates. These may be higher or lower than the UK statutory rate and may reflect regimes that encourage innovation and investment in R&D by providing tax incentives which, if changed, could affect GSK's tax rate. In addition, the worldwide nature of our operations means that our cross-border supply routes, necessary to ensure supplies of medicines, can result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. This can lead to double taxation, with profits taxed in more than one country. The complexity of tax regulations also means that we may occasionally disagree with tax authorities on the technical interpretation of a particular area of tax law. The tax charge included in our financial statements is our best estimate of tax liability pending any audits by tax authorities.

We expect there to be a continued focus on tax reform, driven by initiatives by the OECD and the EC to address the tax challenges arising from digitalisation of the economy. Together with domestic initiatives around the world, these may result in significant changes to established tax principles and an increase in tax authority disputes. Regardless of their merit or outcomes, these may be costly, divert management attention and adversely impact our reputation and relationship with key stakeholders.

Anti-bribery and corruption (ABAC)

Risk definition

The bribery and corruption risk is the 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, failure to prevent bribery or corruption could have substantial implications for GSK's reputation and the credibility of senior leaders and might erode investor confidence in our governance and risk management. It could also lead to legal and financial penalties.

Context

The overall environment for ABAC continues to be challenging. Countries are holding individuals, as well as corporations, accountable by increasing the employer duty of care. Divergence of legislation, increasing political protectionism, social inequality and pricing pressures are making compliance harder. Society is holding corporations to ever higher standards, with technology providing a rapid and anonymous avenue for dissemination of previously confidential information and even for damaging false reports.

Enforcement actions and penalties continued across the globe with the focus on use of third-party intermediaries. Proposed EU legislation would require businesses to conduct due diligence on potential human rights and related environmental impacts of their operations and supply chains, imposing a legal standard of care. In addition, the ongoing impact of COVID-19 could increase the risk of bribery and corruption.

Supportive aspects of the external environment include an increase in transparency and collaboration among enforcement authorities with the aim of reducing bribery and corruption globally. Advances in technology and the use of data analytics are also providing better platforms to streamline processes and detect potential issues.

Commercial practices

Risk definition

Failure to engage in commercial activities that are consistent with the letter and spirit of the law, industry regulations, or the Group's requirements relating to sales and promotion of our medicines and vaccines; appropriate interactions with healthcare professionals/ organisations and patients; legitimate and transparent transfers of value; and competition (or antitrust) regulations in commercial practices, including trade channel activities and tendering business.

Risk impact

Failure to engage in activities that are consistent with the letter and spirit of the law, industry regulations, or the Group's requirements relating to sales and promotion of medicines and vaccines; with appropriate interactions with healthcare professionals (HCPs), organisations and patients; with legitimate and transparent transfers of value; and with pricing and competition (or antitrust) regulations in commercial practices, including trade channel activities and business tendering, could, materially and adversely affect our ability to deliver our strategy and long-term priorities. Additionally, it may result in incomplete awareness of the risk/benefit profile of our products and possibly suboptimal treatment of patients and consumers; 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. Any practices that are found to be misaligned with our values and expectations could also result in reputational harm and dilute trust established with external stakeholders.

Context

We operate in a highly regulated and extremely competitive biopharma and consumer industry, amongst peers who make significant product innovations and technical advances and intensify price competition. Additional external factors impacting our business operations include the ongoing COVID-19 global pandemic, access limitations to our customers, macroeconomic inflationary dynamics, and pricing pressure across markets.

To achieve our strategic objectives, we must continue to develop commercially viable new products and deliver additional uses for existing products that address the needs of patients, consumers, HCPs and payers. Financially, new products/indications carry with them an uncertainty with regards to future success. Product development is costly, timely, and uncertain, and carries with it the potential for failure at any stage. Even upon successful product development, we still face challenges in how we launch and how our competitors' products or pricing strategies could render our assets less competitive. Supporting our efforts on product innovation is a continued focus on creating an omnichannel way of engagement, with a continued focus on our patient.

Once we have an approved medicine or vaccine, it is our obligation to provide important information to the healthcare community in various ways, always in a responsible, legal, and ethical manner. Appropriate product promotion ensures HCPs have access to the information they need, that patients and consumers have the facts about the medicines and vaccines they require, and prescribed, recommended, or used in a manner that provides healthcare benefit.

We are committed to the ethical and responsible commercialisation of our products in support of our purpose to improve the quality of human life by enabling people to do more, feel better, and live longer.

Non-promotional engagement

Risk definition

Failure to engage in non-promotional activities that are consistent with local laws, regulations and guidance, Industry Codes, internal GSK policies, standards and other controls, and GSK values, including i) communications to HCP/OHS or non-HCPs relating to our medicines and/or associated disease areas; ii) appropriate conduct of non-promotional interactions; and iii) legitimacy and transparency of non-promotional interactions.

Risk impact

Without controls in place, the risk could result in real, perceived, or disguised promotion including off-label and prior-authorisation promotion, and real or perceived provision of medical advice. This in turn could lead to criminal investigations and penalties, civil litigation, or competitor complaints. At the same time, if we do not engage fully and appropriately, this could result in patient harm, failure to advance science and innovation, reputational damage, and financial loss. Such consequences may reduce the trust of the public, patients, healthcare professionals, payers, regulators, and governments.

Context

Non-promotional engagements are diverse activities directed at healthcare professionals, as well as patients, payers, and external stakeholders. Such engagements are conducted to improve patient care through the exchange or provision of knowledge on the use of our products and related diseases. Non-promotional engagement with external stakeholder groups is vital to GSK, as a research-based healthcare company, and necessary for scientific and medical advances. We expect our non-promotional activities to be scientifically sound and accurate, conducted ethically and transparently, and compliant with applicable codes, laws, and regulations. However, non- promotional engagements are largely unregulated. Therefore, measured risk-taking, rooted in sound values, and principles- based decision-making, training, communication, and monitoring of such activities are key to managing the risk and enabling full and appropriate engagement.

Privacy

Risk definition

The failure to collect, secure, use, share and destroy Personal Information (PI) in accordance with data privacy laws can lead to harm to individuals (e.g. financial, stress, prejudice) and GSK (e.g. fines, operational, financial and reputational).

Risk impact

Non-compliance with data privacy laws globally could lead to harm to individuals and GSK. It could also damage trust between GSK and individuals, communities, business partners and government authorities. Many countries have increased the enforcement powers of their data protection authorities by allowing them to impose significant fines, impact cross-border data flows, or temporarily ban data processing. Many new country laws also give individuals the right to bring collective legal actions against companies like GSK for failure to follow data privacy laws.

Context

Data privacy legislation is diverse with limited harmonisation or simplification. It is challenging for multinationals to standardise their approach to compliance with data privacy laws. Governments are enforcing compliance with data privacy laws more rigorously. The focus on the ethical use of personal information is growing, over and above compliance with data privacy laws, due to an increase in the volume of data processed and advances in technology.

Workforce protection and effective privacy controls for research during the COVID-19 pandemic create unique challenges.
Additionally, new data privacy laws, such as the Personal Information Protection Law (PIPL) in China, and court decisions - like the Court of Justice of the European Union ruling for Schrems II – are invalidating established international data transfer mechanisms that international companies had relied on. The increasing trend for data sovereignty affects our ability to drive medical innovation and to effectively operate internationally.

Research practices

Risk definition

Research Practices risk is the failure to adequately conduct ethical and sound pre-clinical and clinical research. In addition, it is the failure to engage in scientific activities that are consistent with the letter and spirit of the law and industry, or the Group’s requirements. It comprises the following sub-risks: Data Governance, Laboratory Research, and Human Subject Research.

Risk impact

The potential 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 GSK by governmental and private plaintiffs (product liability suits and claims for damages), loss of revenue due to inadequate patent protection or inability to supply our products, and regulatory action such as fines, penalties, or loss of product authorisation. Poor data integrity and governance could compromise GSK’s R&D efforts and negatively impact our reputation. Any of these could materially and adversely affect our financial results and damage the trust of patients and customers.

Context

Research involving animals can raise ethical concerns. In many cases, however, research in

animals is the only way to investigate the effects of a potential new medicine in a living body other than in humans. Animal research provides critical information about the causes and mechanisms of diseases and therefore remains a vital part of our research. We continually seek ways in which we can minimise our use of animals in research, development, and testing, while complying with regulatory requirements and reducing the impact on the animals used.

Human subject research is critical to assessing and demonstrating the safety and efficacy of our investigational products or further evaluate our products once they have been approved. This research includes clinical trials in healthy volunteers and patients and follows regulations and high ethical, medical, and scientific standards. We disclose the results of this research externally regardless of whether they reflect positively or negatively on our products, so that the scientific community can learn from the outcomes of our research.

We also work with human biological samples which are fundamental to the discovery, development, and safety monitoring of our products. We are committed to managing human biological samples in accordance with relevant laws, regulations, and ethical principles, and in a manner that respects the interests of sample donors.

Data is pivotal to our R&D strategy and we are maximising the use of data to serve patients. Governing our data in accordance with relevant laws, regulations, contractual obligations, expectations, and our culture across privacy, information security, and data integrity is essential.

We use a wide variety of biological materials in the discovery, research, and development of our assets. 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 research and development.

We support the principles of access to, and benefit-sharing of, genetic resources as outlined in the CBD and the Nagoya Protocol. We also recognise the importance of appropriate, effective, and proportionate implementation measures at national and regional levels.

Environment, health and safety

Risk definition

Failure in management of:

- execution of hazardous activities;
- GSK’s physical assets and infrastructure;
- handling and processing of hazardous chemicals and biological agents;
- control of releases of substances harmful to the environment in both the short and long-term;

leading to incidents which could disrupt our R&D and Supply activities, harm employees, harm the communities and harm the local environments in which we operate.

Risk impact

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

Context

GSK is subject to the health, safety, and environmental laws of various jurisdictions. These laws impose duties to protect people, the environment, and the communities in which we operate.

Environmental sustainability

Risk definition

Failure in the management of:

- Physical climate and environmental risks;
- Current and future regulatory requirements for environmental policies and taxes;
- Delivery and performance of management environmental objectives;

leading to: reduced supply chain resilience; product life cycle management issues, loss of trust/reputation with employees, investors, customers, regulators and other stakeholders; increased costs; loss of sales or market access; negative impacts on the environment.

Risk impact

We recognise that the way we respond to climate change and manage environmental risks affects our ability to supply products to patients and consumers and could lead to harm to the environment and our reputation. Failure to meet fast-evolving regulatory requirements and stakeholder expectations could result in litigation or regulatory actions, which may have a material adverse impact on our financial results and longer term loss of trust, undermining the credibility of the company.

Context

It is increasingly understood that the interconnected effects of climate change, nature loss, and society’s impact on both are influencing human health. Internal and external expectations for companies to address their impact on the environment are increasing, as are the effects of climate change on operational resilience, in regard to access to energy, water and the natural resources used in products, along with potential cost increases from any regulatory changes or environmental taxes.

Information security

Risk definition

Risk in Information Security at GSK is characterised as the unauthorised disclosure, theft, unavailability or corruption of GSK's Information or key information systems that may lead to harm to our patients, workforce and customers, disruption to our business and/or loss of commercial or strategic advantage, regulatory sanction, or damage to our reputation.

Risk impact

Failure to adequately protect our information, or key information systems, may cause harm to our patients, workforce and customers, disruption to our business and/or loss of commercial or strategic advantage, regulatory sanction, or damage to our reputation.

Context

The overall information security environment is challenging, because of the difficulty of keeping pace with increasingly sophisticated cyber threats. This is due to many factors including, the complexity of large regulated organisations; the well-resourced nature of hacking activities; and the increasing demands for accountability of data handled by companies. Additionally, the GSK separation is a period of significant change which increases our risk and requires additional vigilance. We continue to reassess our reliance on interconnectivity with third party contractors, partners, and suppliers.

The COVID-19 pandemic continues as another significant external factor affecting how we manage information security at GSK. COVID-19-related threats include an increase in ransomware attacks against the healthcare sector, as hackers continue to use the opportunity to disrupt critical healthcare operations and, in some cases, seize healthcare research related to COVID-19 vaccines and treatments.

We operate a highly connected information network which holds confidential research and development, manufacturing, commercial, workforce and financial data. This means that our systems and information have been and will continue to be the target of cyberattacks. We continue to consolidate information systems to reduce attack points and enable more focused controls. GSK's strategic approach to digital analytics will further increase our dependency on digital assets and distributed data. Our continued analysis and assessment of our critical data assets and the threats to those assets will require a continuous re-evaluation of emerging risks to GSK. Mitigating actions identified in these areas include the secure deployment and operation of our resources in high-risk markets, the risk posed by GSK having data in the Cloud, and the potential for complexity resulting from agile business-led IT development across the enterprise.

Supply continuity

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.

Risk impact

We recognise how important the continuity of supply of our products is to the patients and consumers who rely on them.

Supply disruption can lead to:

- Product shortages and product recalls
- Regulatory intervention
- Reputational harm
- Lost sales revenue

Consequently, we need sophisticated end-to-end supply chain management with robust crisis management and business continuity plans in place to respond.

Context

We run our supply chains in a continually evolving, highly regulated environment. There is no single set of global regulations which governs the manufacture and distribution of medicines and we must adhere to the requirements in all those markets in which we licence, sell, or manufacture our products. We rely upon our internal Quality Management System and our internal Control Framework to ensure we continue to preserve our licence to operate.

Our complex end-to-end supply chains often involve third party suppliers, from Active Pharmaceutical Ingredient (API) manufacturers and raw material suppliers through to Third Party Logistics Providers and contract engineering firms. We embed integrated risk management into our sourcing and day to day business processes, alongside our Third-Party Oversight programme.

COVID-19 is an exemplar of events in the external environment which result in unforeseen, significant supply challenges, including staffing shortages for essential manufacturing operations, critical raw materials supply pressures (e.g. glass vials, plastic tubing) and interruptions in distribution.

Cybersecurity remains a significant threat to our supply chain operations. The global cyber threat has increased during the global pandemic and we remain hyper-vigilant to data security breaches and Operational Technology risks.

Transformation and separation

Risk definition

Failure to deliver the plan for successful transformation and separation of GSK into two new, leading companies: one BioPharma and one Consumer Healthcare.

Risk impact

The failure to manage the macro level risk due to COVID-19 and a highly competitive labour market, in relation to the delivery of the separation plan, could materially and adversely affect our ability to deliver GSK's strategy and long-term priorities.

Context

In February 2020, GSK announced a new 'Future Ready' programme to prepare for its separation into two companies: new GSK, a pharma company with an R&D approach focused on science related to the immune system, the use of genetics and new technologies; and a new leader in consumer healthcare. As GSK increases investment in R&D and new product launches, the two-year separation programme aims to drive a common approach to innovation with improved capital allocation; to align and improve the capabilities and efficiencies of global support functions to support new GSK; to further optimise the supply chain and portfolio, including divesting non-core assets; and to prepare Consumer Healthcare to operate as a standalone company. Once complete, the outlook of both companies will have been fundamentally strengthened, making them more efficient, modern, and automated, with skills and capabilities that will serve them into the future.

Risks associated with COVID-19

The potential impact of the COVID-19 pandemic on GSK's trading performance and all our principal risks has been assessed. In 2021, as anticipated, the pandemic impacted Group performance primarily in demand for vaccines and reflected the prioritisation of COVID-19 vaccination programmes by governments, including social distancing rules resulting from COVID-19 that affected customers' ability and willingness to access vaccination services across all regions.

This continues to be a dynamic situation, with the future severity, duration and impact unknown at this point including potential impacts on trading results, clinical trials, supply continuity and our employees. The situation could change at any time and there can be no assurance that the COVID-19 pandemic will not have a material adverse impact on the future results of the Group.

Risks relating to the demerger and separation

Completion of the demerger and separation of the Consumer Healthcare business is subject to conditions which may not be satisfied or waived

The demerger and separation of the Consumer Healthcare business to form Haleon are subject to a number of conditions, including the approval of a demerger resolution by GSK shareholders at a general meeting and the approval of a demerger dividend by the GSK Board. There can be no assurance that any or all of these conditions will be satisfied or, where relevant, waived. If any condition is not satisfied or waived, the demerger and separation will not complete.

Failure to complete the demerger and separation would result in the potential benefits of the demerger and separation not being realised and may have an adverse effect on the reputation of the Group and on the external perception of its ability to implement large-scale projects successfully. This may be the case even where the failure to implement the demerger and separation is due to factors outside the control of the Group.

In addition, if completion of the demerger and separation does not occur, the Consumer Healthcare business will remain part of the Group, which may: (i) result in a delay in the execution of the strategic objectives of the Group and the Consumer Healthcare business; (ii) have a disruptive effect on management and employees of the Group and/or the Consumer Healthcare business; or (iii) prevent the anticipated benefits and opportunities that GSK's management believes will result from the demerger and separation from being realised. There are also costs associated with the implementation of the demerger and separation which will still be payable if the demerger and separation does not proceed.

The aggregate consequences of a failure to complete the demerger and separation could have a material impact on the business, financial condition, results of operations and/or prospects of the Group.

The Group post-demerger may fail to realise any or all of the anticipated benefits of the demerger and separation, and could fail to meet the challenges involved in operating as a standalone business

The realisation of the anticipated benefits of the demerger and separation is subject to a number of factors, including many which are outside the control of the post-demerger Group. There can be no guarantee that the anticipated benefits of the demerger and separation will be realised in full or in part, or as to the timing of when any such benefits may be realised. In addition, even if the anticipated benefits of the demerger and separation are realised, the market price of the GSK shares may not reflect such benefits.

The post-demerger Group will face a number of challenges relating to the implementation of the demerger and separation and operating as a standalone business. There may be adverse financial, operational, regulatory, consumer, patient and reputational implications if the Group fails (either wholly or in part) to meet these challenges. Such adverse implications could impact on the ordinary course business of the Group following the demerger and, consequently, its financial condition, results of operations and/or prospects.