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 biopharmaceutical 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 and vaccine 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 47, 'Legal proceedings' on pages 265 to 267 of the GSK Annual Report 2022, which is incorporated by reference herein.

Patient safety

Risk definition

The risk that GSK, including our third parties, potentially fails to appropriately collect, review, follow up, or report human safety information, including adverse events, from all potential sources or that GSK potentially fails to act on any relevant findings in a timely manner.

Risk impact

GSK will not tolerate an unfavourable benefit-to-risk profile for patients who use our products. As the most important consequence of ineffective pharmacovigilance is the potential for harm to patients, we maintain robust processes for managing human safety information, conducting timely safety signal detection, and ensuring appropriate measures are in place to manage risks to patients. GSK also intends to fully comply with pharmacovigilance and other relevant regulations worldwide. Non-compliance could result in inspection findings, regulatory scrutiny, civil or criminal sanctions and either temporary or permanent loss of product marketing authorisation. We regularly review and respond to all patient safety risks to limit the potential for 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; our failure to do so effectively could result most importantly in harm to patients, as well as reputational damage and/or product liability litigation. We conduct internal safety surveillance and rely on access to safety information from external sources. Information on the safety and efficacy of our products in humans is collected during clinical development, with more comprehensive information incorporated from real-world use once our products are marketed. There are examples of regulatory agencies using real-world evidence from sources which may not be accessible to the industry to supplement and validate the evidence we use to support the safety and efficacy of our products. There is a potential emerging risk that technology companies or other data custodians may similarly draw and communicate conclusions about the safety of our products based on digital health data collected through their platforms that is inaccessible by either the industry or regulatory agencies.

Our licence to operate depends on our compliance with regulatory requirements worldwide, not only those directly related to patient safety but extending to privacy and information security regulations as well. Regulatory compliance depends on appropriate identification and management of human safety information by all employees and third parties acting on our behalf. We are pursuing innovative solutions to enhance our ability to perform pharmacovigilance, including Artificial Intelligence and Machine Learning technology to augment our capacity to manage increasing volumes of adverse event reports from varied sources, and advancing technical solutions for delivering safety information and risk minimisation measures to patients and health care providers.

The COVID-19 pandemic has had an impact on pharmacovigilance activities by increasing public focus on safety and efficacy of medicines and vaccines, highlighting the importance of robust business continuity planning for uninterrupted safety oversight and regulatory compliance (including the ability to accommodate remote regulatory inspections), and accelerating automation to manage increasing volumes of adverse events.

Product quality

Risk definition

The risk that GSK or our third parties potentially fail to ensure appropriate controls and governance of quality for development and commercial products; compliance with industry practices and regulations in manufacturing and distribution activities; and terms of GSK product licenses and supporting regulatory activities.

Risk impact

A failure to ensure product quality could have far-reaching implications for patient 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, with 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 met our commitments for the 2021 European Medicines Agency (EMA) requirements for licensing of Medical Devices. We continue to plan for the deployment of the New Annex 1 guidance for the manufacture of Sterile Medicinal products which was published in September 2022 and sets an expectation for compliance by August 2023. We are actively managing this implementation in the context of global equipment and component supply chain constraints affecting the industry. We are increasingly applying advanced digital technologies and insights to drive scientific excellence to enhance the development, manufacture and testing of our products. For example, we use new electronic documentation systems and advanced laboratory information management tools. Our quality organisations are aligned to make sure quality procedures and governance can facilitate the new company strategy. Pre-pandemic levels of on-site inspections have resumed, and we continue to take steps to ensure our inspection readiness.

Financial controls and reporting

Risk definition

The risk that GSK fails to comply with current tax laws, fails to report accurate financial information in compliance with accounting standards and applicable legislation, or incurs significant losses due to treasury activities.

Risk impact

Non-compliance with existing or new financial or new ESG 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. 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. Failure to comply with applicable sanctions laws and regulations could result in GSK being investigated by relevant government agencies and authorities and/or in legal proceedings against us. Government investigations and litigation, can be unpredictable and regardless of their outcome, may be costly, require significant management attention, and damage our reputation. 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 and vaccines, 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. Laws, regulations, orders and other measures restrict dealings with certain countries, governments, government officials, entities, individuals, use of financial institutions and movement of funds. Circumvention of sanctions and export controls can be a criminal offence and GSK has a zero tolerance policy for breaches of its sanctions obligations. While we believe the Group complies with all applicable sanctions in all material respects, such laws are complex and continue to evolve rapidly.

Anti-bribery and corruption (ABAC)

Risk definition

The risk that GSK or our third parties potentially fail to comply with applicable laws, regulations, or internal requirements and to ensure appropriate controls and governance over bribery and corruption in business activities.

Risk impact

Failure to mitigate this risk could expose GSK and associated persons to governmental investigation, regulatory action, and civil and criminal liability. It may compromise GSK’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. It might erode investor confidence in our governance, risk

management and future performance, and have a consequential negative impact on share performance. It could also lead to the imposition of significant financial penalties and the imposition of additional reporting obligations.

Context

There continues to be a strong enforcement appetite for foreign bribery investigations and prosecutions, with a particular focus on the conduct of multinational companies wherever they operate. Financial penalties handed down in proven corruption cases are often very significant.

Disruption to global supply chains and the commercial pressures caused by higher than usual inflation rates are likely to increase the risks of bribery and corruption in certain contexts.

However, greater transparency and collaboration among enforcement authorities, advances in technology and the use of data analytics are providing better platforms to streamline processes and detect potential issues.

Commercial practices

Risk definition

The risk that GSK or our third parties potentially engage in commercial activities that fail to comply with laws, regulations, industry codes, and internal controls and requirements.

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 the trust established with external stakeholders.

Context

We operate in a highly regulated and extremely competitive biopharma 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 effects of the 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, lengthy, and uncertain, and carries with it the potential for failure at any stage. Even after successful product development, we face challenges in how we launch, and our competitors' products or pricing strategies could render our assets less competitive. We support product innovation through our continued focus on both in-person and virtual engagement, with a constant 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 that products are 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 and get ahead of disease together.

Scientific and patient engagement

Risk definition

The risk that GSK or our third parties potentially fail to engage externally to gain insights, educate and communicate on the science of our medicines and associated disease areas, and provide grants and donations in a legitimate and transparent manner compliant with laws, regulations, industry codes and internal controls and requirements.

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

Scientific and patient engagements are diverse non-promotional activities directed at healthcare professionals, patients, payers, and external stakeholders. Such engagements aim to improve patient care through the exchange or provision of knowledge on the use of our products and related diseases. Scientific and patient engagement with external stakeholder groups is vital to GSK, as a research-based biopharma company that is ambitious for patients and is necessary to advance science and medicine.

We expect our activities to be scientifically sound and accurate, conducted ethically and transparently, and compliant with applicable codes, laws, and regulations. There are many industry and local codes and laws and other regulations that apply (such as Privacy, Data integrity). That means measured risk-taking, rooted in sound ethical considerations, and principles-based decision-making, training, communication, and monitoring of such activities

are key to managing the risk and enabling full and appropriate engagement.

Data ethics and privacy

Risk definition

The risk that GSK or our third parties potentially fail to ethically collect; use; re-use through artificial intelligence, data analytics or automation; secure; share and destroy personal information in accordance with laws, regulations, and internal controls and requirements.

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 national laws also enable individuals to bring collective legal actions against companies such as GSK for failure to follow data privacy laws.

Context

Data protection and privacy legislation is diverse, with limited global harmonisation or simplification. It is challenging for multinationals to standardise their approach to compliance with data privacy laws. Governments are enforcing compliance with data protection and privacy laws more rigorously. The approach and focus of data protection and privacy regulators also differs between regions and countries, which further creates challenges for global organisations seeking to implement a single harmonised global privacy programme.

Increases in the volume of data processed and advances in technology have resulted in a greater focus on data governance and the ethical use of personal information, over and above compliance with data privacy laws. Companies seeking to foster innovation in artificial intelligence and other new technologies are faced with evolving decisions from global policymakers on how best to promote trust in these systems and avoid unintended outcomes or harmful impacts.

Additionally, there are a number of emerging laws concerning the localisation of data, restrictions on international transfers and data security, which are changing existing frameworks that GSK has previously relied upon. This increasing trend for data sovereignty affects our ability to drive medical innovation and to effectively operate internationally.

Research practices

Risk definition

The risk that GSK or our third parties potentially fail to adequately conduct ethical and credible pre-clinical and clinical research, collaborate in research activities compliant with laws, regulations, and internal controls and requirements.

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 involving 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 evaluating our products once they have been approved. This research includes clinical trials in healthy volunteers and patients and adheres to 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 (EHS)

Risk definition

The risk that GSK or our third parties potentially fail to ensure appropriate controls and governance of the organisation's assets, facilities, infrastructure, and business activities, including execution of hazardous activities, handling of hazardous materials, or release of substances harmful to the environment that disrupts supply or harms employees, third parties or the environment.

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.

Information security

Risk definition

The risk that GSK or our third parties potentially fail to ensure appropriate controls and governance over unauthorised access, disclosure, theft, unavailability or corruption of GSK's information, key systems or technology infrastructure.

Risk impact

Failure to adequately protect our information and 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 external environment continues to be extremely challenging, making it hard to keep pace with increasingly sophisticated cyber threats. This is due to many factors including increased geopolitical conflict and digital nationalism, rising frequency and severity of data breaches and growing capability and sophistication of bad actors and cyber criminals. GSK's business relies on operating a highly connected information network of internal and external systems, which hold 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 cyber-attacks. Acceleration in the use of digital, data and analytics and cloud computing capabilities to drive GSK's pipeline and performance requires us to continuously adapt and strengthen our controls and defensive capabilities. GSK also relies on third-party contractors, partners and suppliers who face similar cyber threats and this continues to be a vector of risk to manage as well.

Supply continuity

Risk definition

The risk that GSK or our third parties potentially fail to deliver a continuous supply of compliant finished product or respond effectively to a crisis incident in a timely manner to recover and sustain critical supply operations.

Risk impact

We recognise how important the continuity of supply of our products is to the patients 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.

External factors continued to challenge supply continuity in 2022. In the early part of the year COVID-19 continued to disrupt our sourcing of biosciences materials across our Medicines and Vaccines supply chains (e.g. vials, syringes and single-use systems components). The Ukraine conflict has resulted in supply disruption to the region. To manage these disruptions, we deployed bespoke de-risking plans using crisis and continuity plans to manage the detail and mitigate the risk of supply continuity problems, e.g. by dual sourcing of materials or re-routing of shipments to avoid conflict zones. Keeping our patients supplied with their medicines is our priority.

New technology and modality platforms within supply chains are changing the requirements for the skillsets of people working in this field. We have implemented a new Chemistry, Manufacturing and Controls Operating Model in 2022. This brings cross-fertilisation of talent focus on the skills needed for the future for innovative manufacturing.

Industrial relations are also a current risk to supply continuity, with the threat of industrial action being averted in our UK manufacturing sites through successful dialogue with unions. Continued business monitoring is in place to assess the risk of the spread of

industrial relations challenges resulting from global cost of living pressures.

Climate-related risks

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. For example, risks from increasing levels of water stress could lead to interruptions to supply of water to our sites and third-party supply sites, and increasing frequency of extreme weather events may cause disruptions to our and third-party supply sites, affecting our ability to supply products to patients and consumers.

Current and future regulatory responses to address climate change may result in increased costs and compliance obligations, including restricting our ability to manufacture certain products and/or requiring us to find alternatives for the manufacture of certain products. For example, regulations governing the use of high global warming potential (GWP) substances are being updated in the EU and were recently updated in the US, which will lead to increasing costs and could restrict GSK's ability to manufacture its metered dose inhaler products that use a high GWP propellant. In addition, our ability to meet our target of reducing carbon emissions by 80% and 90% by 2030 and 2045, respectively, is based on our investment in an R&D programme to reduce greenhouse gas emissions from metered dose inhalers, including successful clinical trials and obtaining regulatory approvals. Limitations in the jurisdictions in which we operate may also limit our access to renewable energy sources and electric vehicles, which may affect our ability to achieve reductions in emissions across our operations. Failure to meet fast-evolving regulatory requirements and stakeholder expectations could also result in litigation or regulatory actions or lead to increasing demand for low carbon medicines and vaccines, affecting demand for our products, 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, such as carbon taxes in countries where GSK manufacturers and sources goods from third parties.

Risks associated with COVID-19

The potential impact of the COVID-19 pandemic on GSK's trading performance and all its principal risks is continually assessed. While GSK was encouraged by the uptake of its vaccines and medicines in 2022, the pandemic remains a dynamic ongoing risk, with the World Health Organization continuing to monitor the emergence of new variants. The current rate of infection is predominantly driven by the circulation of the BA.5 subvariant and its descendent lineages, which are still the dominant subvariants of Omicron globally. While COVID-19 vaccines are being updated with Omicron variants to provide broader immunity against circulating and emerging variants, these subvariants and potential future variants of concern could potentially impact GSK's trading results, clinical trials, supply continuity and its employees materially.

Risks relating to the separation of the Consumer Healthcare business

On 18 July 2022, GSK separated its Consumer Healthcare business from the Group to form Haleon, an independent listed company. Following the demerger, GSK continues to hold 6.0% of the shares of Haleon (including shares received by GSK's consolidated ESOP trusts) and 7.5% remains held by certain Scottish Limited Partnerships set up to provide collateral for a funding mechanism pursuant to which GSK will provide additional funding for its UK defined benefit pension schemes.

The realisation of the anticipated benefits of the separation is subject to a number of factors, including many which are outside the control of the Group. There can be no guarantee that the anticipated benefits of the 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 separation are realised, the market price of the GSK shares may not reflect such benefits.

Following the separation, GSK's business is smaller and less diversified than it was prior to the separation, with greater relative exposure to the global pharmaceuticals and vaccines markets and the risks associated with such markets. As a result of the reduction in GSK's size, should any part of its business underperform, this may have a greater adverse impact on the Group than would have been the case prior to the separation.

In addition, the value of GSK's retained investment in Haleon will be affected by changes in the market price of Haleon shares, and may decrease in value as a result of any decrease in the market price of Haleon shares.

The failure of GSK to realise any of the anticipated benefits of the separation, including the value of its retained investment in Haleon, could have a material adverse impact on the Group's business, financial condition, results of operations and/or prospects.