3.D **Risk Factors**

Principal risks and uncertainties

The principal risks discussed below are the risks and uncertainties relevant to our business, financial condition and results of operations that may affect our performance and ability to achieve our objectives. They are the risks that we believe could cause our actual results to differ materially from expected and historical results.

During 2019, we continued to embed changes to our risk management and reporting cycle to help us identify, manage and report our most important risks across the organisation in a more consistent and proportionate way. We completed Enterprise Risk Plans for all of our most important risks and ensured businesses adopted them and only adapted them with approval. We deployed confirmation across the organisation, reinforcing leader accountability for risk management, and measured how well the controls set out in the Enterprise Risk Plans had been implemented and gaps closed. We further evolved our risk management process by introducing new reports to the Board with more focus on data and key risk indicators, leading to better informed discussions on risk exposure and action needed. We introduced a new approach to the annual risk review to support CET decisions on any changes required to our most important risks.

We are required to comply with a broad range of laws and regulations which apply to research and development, manufacturing, testing, approval, distribution, sales and marketing of Pharmaceutical, Vaccines and Consumer Healthcare products.

These affect not only the cost of product development but also 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 change, the nature of a particular risk may change. Changes to certain regulatory regimes may be substantial. Any change in, and any failure to comply with, applicable laws and regulations could materially and adversely affect our financial results.

Similarly, our global business exposes us to litigation and government investigations, including but not limited to product liability litigation, patent and antitrust litigation and sales and marketing litigation. Litigation and government investigations, including related provisions we may make for unfavourable outcomes and increases in related costs such as insurance premiums, could materially and adversely affect our financial results.

More detail on the status and various uncertainties in our significant unresolved disputes and potential litigation is set out in “Note 46 – Legal proceedings” on pages 247 to 251 of the GSK Annual Report 2019.

Patient safety

Risk definition

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

The risk impact has the potential to compromise our ability to conduct robust safety signal detection and interpretation and to ensure that appropriate decisions are taken with respect to the risk/ benefit profile of our products, including the completeness and accuracy of product labels and the pursuit of additional studies/ analyses, as appropriate. Additionally, this risk could potentially negatively impact our ability to incorporate verified safety signals into local (country) labelling. This could lead to potential harm to patients, reputational damage, product liability claims or other litigation, governmental investigation, regulatory action such as fines, penalties or loss of product authorisation.

Context

Pre-clinical and clinical trials are conducted during the development of investigational Pharmaceutical, Vaccine and Consumer Healthcare products to determine the safety and efficacy of the products for use by humans. Notwithstanding the efforts we make to determine the safety of our products through appropriate pre-clinical and clinical trials, unanticipated side effects may become evident only when products are widely introduced into the marketplace.

Questions about the safety of our products may be raised not only by our ongoing safety surveillance and post-marketing studies but also by governmental agencies and third parties that may analyse publicly available clinical trial results. Constant vigilance and flexibility are required in order to respond to a varied regulatory environment which continues to evolve and diverge globally. Externally, developments in data interrogation present potential benefits for patient safety but the volume of data to be analysed presents a significant challenge which intensifies when coupled with fragmented regulatory requirements and privacy concerns. In the economic arena, mergers and acquisition activities introduce data integrity risks. Technology presents a significant opportunity for patient safety risk management by creating more reliable data interrogation tools and more accurate data collection mechanisms, even though the pace of Artificial Intelligence development has not been as great as once expected. Cyberattacks are an ever-growing concern given the volume of data and digital dependency.

The Group is currently a defendant in a number of product liability lawsuits, including class actions, that involve significant claims for damages related to our products. Litigation, particularly in the US, is inherently unpredictable. Class actions that seek to sweep together all persons who take our products increase the potential liability. Claims for pain and suffering and punitive damages are frequently asserted in product liability actions and, if allowed, can represent potentially open-ended exposure and thus, could materially and adversely affect the Group’s financial results.

Product quality

Risk definition

Failure 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 in terms of patient and consumer safety, delays in launching products, drug shortages, product recalls, as well as regulatory, legal, and financial consequences, which could materially and adversely affect GSK’s reputation and financial results.

Context

The external environment for product quality continues to be challenging. The single biggest change since 2018 is the political instability and uncertainty surrounding the delivery of Brexit and the implications for medicine supply continuity both into and out of mainland Europe. Two new sets of requirements are due to be implemented by EMA shortly and we are preparing for both. In the first quarter of 2020, there will be new reporting requirements on potential drug shortages and from May 2020 there are new regulations covering the licensing of medical devices.

Technological developments are increasingly used to both enhance manufacture and to support the inclusion of packaging features that help secure the legitimate supply chain e.g. serialisation. The threat of cyberattacks remains a key risk to the integrity of product quality data and its audit trail.

Significant changes are taking place in GSK as we implement the new organisational alignments and IPTc strategy. These changes are assessed by the Quality organisations to ensure our quality procedures and governance can facilitate the strategy whilst also ensuring that no unintended consequences increase our product quality risk.

Financial controls and reporting

Risk definition

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

Risk impact

Non-compliance with existing or new financial reporting and disclosure requirements, or changes to the recognition of income and expenses, could expose us to litigation and regulatory action and could materially and adversely affect our financial results. In the current period of significant political uncertainty especially in the USA and UK, there can be significant changes at short notice. Failure to comply with any changes in the substance or application of the governing laws covering transfer pricing, dividends, tax credits, and intellectual property could materially and adversely affect our financial results.

Significant losses may arise from inconsistent application of treasury policies, transactional or settlement errors, or counterparty defaults.

Context

The Group is required by the laws of various jurisdictions to disclose publicly its financial results and events that could materially affect the financial results of the Group. Regulators routinely review the financial statements of listed companies for compliance with new, revised or existing accounting and regulatory requirements. The Group believes that it complies with the appropriate regulatory requirements concerning our financial statements and disclosure of material information including any transactions relating to business restructuring such as acquisitions and divestitures. However, should we be subject to an investigation into potential non-compliance with accounting and disclosure requirements, this can lead to restatements of previously reported results and significant penalties.

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

The Group’s effective tax rate reflects rates of tax in the jurisdictions in which the Group operates that are both higher and lower than the UK rate and considers regimes that encourage innovation and investment in science by providing tax incentives which, if changed, could affect the Group’s tax rate. In addition, the worldwide nature of our operations means that our intellectual property, R&D and manufacturing operations are centered in several key locations. A consequence of this is that our cross-border supply routes, necessary to ensure supplies of medicines into numerous end markets, can be complex and result in conflicting claims from tax authorities as to the profits to be taxed in individual countries. Tax legislation itself is also complex and differs across the countries in which we operate. As such, tax risk can also arise due to differences in the interpretation of such legislation. The tax charge included in our financial statements is our best estimate of tax liability pending audits by tax authorities.

We expect there to be continued focus on tax reform driven by initiatives of the Organisation for Economic Cooperation & Development to address the taxation of the digital economy and European Commission initiatives including the use of fiscal state aid investigations. Together with domestic initiatives around the world, these may result in significant changes to established tax principles and an increase in tax authority disputes. These, regardless of their merit or outcomes, can be costly, divert management attention and may adversely impact our reputation and relationship with key stakeholders.

Anti-bribery and corruption (ABAC)

Risk definition

The ABAC risk comprises five sub-risk areas:

- Bribery of public officials by GSK
- Bribery of commercial and other non-public entities by GSK
- Bribery by third parties acting on behalf of GSK
- GSK employees receiving and/or requesting bribes and/or other undue personal benefit
- Other corruption-non-compliance with laws and regulations related to money laundering or facilitation of tax evasion by third parties/clients/partners.

Risk impact

Failure to mitigate this risk could expose the Group and associated persons to governmental investigation, regulatory action, and civil and criminal liability and may compromise the Group’s ability to supply its products under certain government contracts. In addition to legal and financial penalties, a failure to prevent bribery through complying with ABAC legislation and regulations could have substantial implications for the reputation of the company, the credibility of senior leaders, and an erosion of investor confidence in our governance and risk management.

Context

The macro risk level remains unchanged as we continue to see legal frameworks similar to the UK and US develop in emerging economies; high standards are expected of individuals and corporations aided by improved technology and increased enforcement.

The overall environment for ABAC in 2019 remained challenging. Divergence of legislation is making compliance harder and countries are increasingly holding individuals accountable as well as corporations, increasing the employer duty of care. Society is holding corporations to ever higher standards with technology providing a speedy and anonymous avenue for dissemination of previously privileged information or even damaging false reports. Enforcement actions and penalties have increased across the globe with focus on use of third-party intermediaries. Supportive aspects of new policies include Latin America moving towards compliance regimes like those established by the US and UK. In India there was an amendment of the Corruption Act (2018) which explicitly makes an offence to pay a bribe. China has introduced significant anti-bribery and anti-corruption/legislative and regulatory reforms.

The GSK exposure remains unchanged.

Commercial practices

Risk definition

Failure to engage in commercial activities that are consistent with the letter and spirit of the law, 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 manage risks related to commercial practices could materially and adversely affect our ability to deliver our strategy and long-term priorities. Failure to comply with applicable laws, rules and regulations may result in governmental investigation, regulatory action and legal proceedings brought against the Group by governmental and private plaintiffs which could result in government sanctions, and criminal and/or financial penalties. Failure to provide accurate and complete information related to our products may result in incomplete awareness of the risk/benefit profile of our products and possibly suboptimal treatment of patients and consumers. Any practices that are found to be misaligned with our values could also result in reputational harm and dilute trust established with external stakeholders.

Context

We continue to evolve our business operations (including acquisitions and joint ventures) to operate on a global basis in an industry that is both highly competitive and highly regulated. Our competitors may make significant product innovations and technical advances and may intensify price competition. In light of this competitive environment, continued development of commercially viable new products and the development of additional uses for existing products that reflect insights which help ensure those products address the needs of patients/consumers, HCPs, and payers are critical to achieve our strategic objectives.

As other pharmaceutical, vaccine and consumer companies, we face downward price pressure in major markets, declining emerging market growth, rapidly evolving digital landscape, and negative foreign exchange impact.

Developing new Pharmaceutical, Vaccine and Consumer Healthcare products is a costly, lengthy and an uncertain process. A product candidate may fail at any stage, including after significant economic and human resources have been invested. Our competitors' products or pricing strategies, or any failure on our part to develop commercially successful products, or to develop additional uses for existing products, could materially and adversely affect our ability to achieve our strategic objectives.

We are committed to the ethical and responsible commercialisation of our products to support our purpose to improve the quality of human life by enabling people to do more, feel better, and live longer. To accomplish this purpose, we engage the healthcare community in various ways to provide important information about our medicines.

Promotion of approved products seeks to ensure that HCPs globally have access to information they need, that patients and consumers have access to the information and products they need and that products are prescribed, recommended or used in a manner that provides the maximum healthcare benefit to patients and consumers. We are committed to communicating information related to our approved products in a responsible, legal and ethical manner.

Privacy

Risk definition

The failure to collect, secure, use and destroy personal information (PI) in accordance with data privacy laws can lead to harm to individuals and GSK, including fines and operational, financial and reputational risk.

Risk impact

Non-compliance can lead to harm to individuals and GSK. It can also damage trust between GSK and individuals, communities, business partners and government authorities.

The General Data Protection Regulation (GDPR), with other privacy legislation following suit, increased the enforcement powers of supervisory authorities, including the ability to impose fines and to suspend processing of PI. GDPR and other privacy laws also give individuals the right to bring collective legal actions against GSK for failure to comply with data privacy laws.

Context

Data privacy legislation is diverse with limited harmonisation or simplification, despite Europe's adoption of GDPR. It is challenging for multi-nationals to standardise their approach to compliance with data privacy laws due to the high-level of local variation. Governments are enforcing compliance with data privacy laws more rigorously. The focus on the ethical use of PI is growing, over and above compliance with data privacy laws, due to an increase in data volume processed and advancements in technology. Individuals are more aware of their rights under data privacy laws.

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: Non-clinical & laboratory research; Human subject research; Data integrity; Care, welfare and treatment of animals; Human biological samples management; Data disclosure; Regulatory filings and engagement; Scientific engagement; and Intellectual property.

Risk impact

The impacts of the risk include harm to human subjects, reputational damage, failure to obtain the necessary regulatory approvals for our products, governmental investigation, legal proceedings brought against the Group by governmental and private plaintiffs (product liability suits and claims for damages), loss of revenue due to inadequate patent protection or inability to supply GSK products, and regulatory action such as fines, penalties, or loss of product authorisation. Any of these consequences could materially and adversely affect our financial results and cause loss of trust from our customers and patients.

Context

Research relating to animals can raise ethical concerns however, in many cases, research in animals is the only method that can be used 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 whilst complying with regulatory requirements and reduce the impact on the animals used.

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. GSK is committed to ensuring that human biological samples are managed in accordance with relevant laws, regulations and ethical principles, in a manner that respects the interests of the sample donors.

The integrity of our data is essential to success in all stages of the research data lifecycle: design, generation, recording and management, analysis, reporting, storage and retrieval. Our research data is governed by legislation and regulatory requirements. Research data and supporting documents are core components at various stages of pipeline progression decision-making and form the content of regulatory submissions, publications and patent filings. Poor data integrity can compromise our research efforts and negatively impact company reputation.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Continually changing and increasingly stringent submission requirements continue to increase the complexity of worldwide product registration. The continued supply of GSK medicines to patients is dependent on the ongoing compliance and maintenance of these licenses across many geographies whose requirements and timelines differ. The secure management of the high volume of lifecycle changes to these licenses and their renewal is critical to enable compliant supply. Failure to maintain licenses will directly impact patients and company revenue.

Scientific engagement, defined as the interaction and exchange of information between GSK and external communities to advance scientific and medical understanding, including the appropriate development and use of our products, is an essential part of scientific discourse. Such non-promotional engagement with external stakeholder groups is vital to GSK's purpose and necessary for scientific and medical advance. Scientific engagement activities are essential but present legal, regulatory, and reputational risk if the sharing of data, invited media coverage or payments to HCPs have, or are perceived to have, promotional intent.

A wide variety of biological materials are used by GSK in discovery, research and development phases. Through the Convention on Biological Diversity (CBD) and the Nagoya Protocol, the international community has established a global framework regulating access to, and use of, genetic resources of non-human origin in R&D.

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

Patent rights are awarded to protect innovation and play an important role in providing GSK with a competitive advantage in the market for a limited period of time. Any loss of patent protection in a market for GSK's products developed through our R&D, including reducing the term, availability or scope of patent rights, could materially and adversely affect our financial results in that market. Absence of adequate patent or data exclusivity protection, which could lead to, for example, competition from manufacturers of generic or biosimilar pharmaceutical products, could limit the opportunity to rely on such markets for future sales growth for our products, which could also materially and adversely impact our financial results.

Following expiration of certain intellectual property rights, a generic or biosimilar manufacturer may lawfully produce a generic version of a product. Introduction of generic products typically leads to a rapid and dramatic loss of sales and reduces our revenues and margins for our proprietary products.

Third party oversight (TPO)

Risk definition

There is a risk that our third parties fail to meet their contractual, regulatory or ethical obligations resulting in significant operational, reputational, legal and financial risk for GSK (and in some cases our employees directly).

Put simply, there is a risk that third parties fail to deliver the goods and services we expect or fail to deliver them in a legal and compliant way.

Risk impact

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

Context

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

These business relationships present a material risk. For example, we share critical and sensitive information such as marketing plans, clinical data, and employee data with specific third parties who are conducting the relevant outsourced business activities. Inadequate protection or misuse of this information by third parties could have significant business impact. Similarly, we use distributors and agents in a range of activities such as promotion and tendering which have inherent risks such as inappropriate promotion or corruption. Insufficient internal compliance and controls by the distributors could affect our reputation. These risks are further increased by the complexities of working with large numbers of third parties across a diverse geographical spread.

Environment, health and safety & sustainability (EHS&S)

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 we operate in and harm the environment and its longer-term sustainability.

Risk impact

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

Context

GSK is subject to health, safety and environmental laws of various jurisdictions. These laws impose duties to protect people, the environment, and the communities in which we operate, as well as potential obligations to remediate contaminated sites. Overall, our control framework for managing EHS&S risk is effective and our frequency of serious events is similar to peers and lower than for high hazard industries e.g. petrochemicals.

Information security

Risk definition

The risk that unauthorised disclosure, theft, unavailability or corruption of GSK's information or key information systems may lead to harm to our patients, workforce and customers, disruption to our business and/or loss of commercial or strategic advantage, damage to our reputation or regulatory sanction.

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in loss of commercial or strategic advantage and could materially affect our ongoing business operations, such as scientific research, clinical trials and manufacturing and supply chain activities.

Further, inadequately applying controls that would be expected of GSK may result in regulatory fines or present a reputational risk to the organisation.

Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, intellectual property, manufacturing systems and trade secrets. There is the potential that our computer systems or information may be exposed to misuse or unauthorised disclosure.

GSK operates a highly 'connected' information network that exposes our confidential research and development, manufacturing, commercial, workforce and financial data to the risk of external attacks. GSK's Digital and Data Analytics Strategy also substantially increases the businesses dependency on digital assets and distributed data, while increasing the number of assets potentially impacted by a cyberattack. As threats evolve, we cannot provide broad assurances that the significant efforts we deliver in the protection and monitoring of our systems and information will always be successful in preventing compromise or disruption. Cybersecurity losses increasingly involve highly-resourced and organised threat actors such as nation-states and online criminal collectives targeting GSK's large and complex information technology (IT) and operational technology (OT) footprint, as well as the systems of our supply chain partners (including outsourced operations).

This means that our systems and information have been and will continue to be the target of cyberattacks. Additionally, extensive use of third parties to store and process our data increases GSK's reliance on suppliers to operate effectively. This dependence increases the complexity around security controls and practices. It also reduces GSK's ability to monitor controls and effectively investigate and respond to incidents involving GSK information or systems. While GSK stands at the ready to address cybersecurity incidents and risks as they occur, in the past year GSK has not experienced a material cybersecurity incident that would have resulted in substantial harm to GSK (e.g., injury to reputation, financial performance, and customer and vendor relationships).

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 that failure to supply our products can adversely impact consumers and patients who rely on them. A material interruption of supply or exclusion from healthcare programmes could expose us to litigation or regulatory action and financial penalties that could adversely affect the Group's financial results. The Group's international operations, and those of its partners, expose our workforce, facilities, operations and information technology to potential disruption from natural events (e.g. storm, earthquake), man-made events (e.g. trading barriers imposed at short notice, civil/political unrest, terrorism), and global emergencies (e.g. coronavirus outbreak, Ebola outbreak, flu pandemic). It is important that we have robust crisis management and recovery plans in place to manage such events.

Context

Our supply chain operations are subject to review and approval by various regulatory agencies that effectively provide our license to operate. Failure by our manufacturing and distribution facilities or by suppliers of key services and materials could lead to litigation or regulatory action such as product recalls and seizures, interruption of supply, delays in the approval of new products, and suspension of manufacturing operations pending resolution of manufacturing or logistics issues.

We rely on materials and services provided by third party suppliers to make our products, including active pharmaceutical ingredients, antigens, intermediates, commodities, and components for the development, manufacture and packaging of Pharmaceutical, Vaccine and Consumer Healthcare products. Some of the third-party services procured, such as services provided by contract manufacturing and clinical research organisations to support development of key products, are important to ensure continuous operation of our business.

Although we undertake risk mitigation, we recognise that certain events could nevertheless still result in delays or service interruptions. We use effective crisis management and business continuity planning to provide for the health and safety of our people and to minimise impact to us, by maintaining functional operations following a natural or man-made disaster, or a public health emergency.

Risks associated with the coronavirus outbreak

The potential impact of the coronavirus outbreak on GSK's trading performance and supply continuity remains uncertain.

Up to the date of this annual report on Form 20-F, the outbreak has not had a material impact on the trading results of the Group. However, we continue to monitor the situation closely, including the potential impacts on trading results, our supply continuity and our employees.

The situation could change at any time and there can be no assurance that the coronavirus outbreak will not have a material adverse impact on the future results of the Group.

Risks associated with the Consumer Healthcare Joint Venture with Pfizer

The legal completion of the transfer of certain assets or entities to the GSK consumer healthcare business in certain jurisdictions is subject to the satisfaction of regulatory approvals or other requirements agreed between the parties (including the passage of time to allow for additional integration preparation), which if not satisfied may result in the further delay of legal completion of such transfers in these jurisdictions

The acquisition of Pfizer's consumer healthcare business to form the Consumer Healthcare Joint Venture (the "Transaction") was completed on July 31, 2019. In a number of jurisdictions (the "Delayed Jurisdictions"), the transfer of certain assets or entities to the GSK consumer healthcare business is subject to the satisfaction of regulatory approvals (including antitrust clearances or satisfaction of related commitments) or other requirements agreed between the parties (including the passage of time to allow for additional integration preparation). In the event that such requirements are not satisfied in any of the Delayed Jurisdictions, the legal completion of the transfer of certain assets or entities in such jurisdictions may be further delayed, which could reduce the anticipated benefits of the Transaction (or result in additional difficulty in the integration of the business in such jurisdiction), including the realization of anticipated synergies, and could have an adverse impact on the results and operations of the GSK Group following the acquisition of the Pfizer consumer healthcare business (the "Enlarged Group").

The Enlarged Group may experience difficulties in integrating the Pfizer consumer healthcare business with the GSK consumer healthcare business

The future prospects of the Enlarged Group will, in part, be dependent upon the Enlarged Group's ability to integrate the Pfizer consumer healthcare business with the existing GSK consumer healthcare business, and the ability of the Enlarged Group to realize the anticipated benefits and cost savings from combining the respective businesses.

The key potential difficulties in integrating the businesses include the following:

- the complexity of transferring employees and assets (including intellectual property, third party contracts, real estate and marketing authorizations and other licenses/permits) and consolidating operations, infrastructure, procedures, systems, facilities, services and policies across many different countries, jurisdictions, regulatory systems and business cultures;
- maintaining employee engagement and retaining and incentivizing key employees;
- the diversion of management time and resources away from the day-to-day operations of the Enlarged Group;
- limiting disruption to the ongoing businesses of the Enlarged Group, including minimizing the risk of supply chain interruptions and ensuring that necessary transitional arrangements between Pfizer and the Enlarged Group function successfully;
- replacing and/or integrating IT systems used by the Pfizer consumer healthcare business with those used by the GSK consumer healthcare business and transferring relevant data from Pfizer IT systems to GSK IT systems;
- technical transfer of manufacturing and other processes and services, upon expiry of transitional manufacturing and services arrangements and/or in-sourcing of third party supply contracts;
- the delay of legal completion of the Transaction in the Delayed Jurisdictions; and
- maintaining business continuity throughout integration.

Difficulties experienced in the integration process could potentially lead to the interruption of operations of the businesses, or a loss of customers, suppliers or key personnel, which could have a material adverse effect on the business, results of operations or financial condition of the Enlarged Group.

Transaction-related costs may exceed GSK's expectations

GSK has incurred and expects to incur additional costs in relation to the Transaction, including integration and post-completion costs in order to implement the Transaction successfully and deliver anticipated costs savings. The actual costs may exceed those estimated and there may be additional and unforeseen expenses incurred in connection with the Transaction. In addition, GSK has incurred and will incur legal, accounting and transaction fees and other costs relating to the Transaction. Such costs could materially and adversely affect the realization of synergies and the results of operations of the Group or the Enlarged Group.

The Enlarged Group may fail to realize, or it may take longer than expected to realize, the anticipated benefits of the consumer healthcare joint venture

The expected benefits of the consumer healthcare joint venture with Pfizer, including any identified synergies, may not be achieved, or may take longer than expected to realize, and other assumptions upon which the terms of the transaction with Pfizer to form the consumer healthcare joint venture have been determined may prove to be incorrect. To the extent that GSK incurs higher integration costs, achieves lower margin benefits or fewer cost savings than expected, the results of operations and financial condition of the Enlarged Group may suffer, which may materially and adversely affect GSK's share price.

The Stock and Asset Purchase Agreement with Pfizer contains certain representations, warranties and indemnities, which could require GSK or GlaxoSmithKline Consumer Healthcare Holdings (No. 2) Limited ("GSK Consumer Healthcare") to make payments to Pfizer

The Stock and Asset Purchase Agreement with Pfizer in relation to the Transaction contains certain representations, warranties and indemnities given by GSK and GSK Consumer Healthcare in favor of Pfizer. Any payment required under those representations, warranties and indemnities may have a material and adverse effect on the cash flow and financial condition of the Enlarged Group.

The consumer healthcare joint venture with Pfizer and the Enlarged Group may not have full recourse to Pfizer under the Stock and Asset Purchase Agreement

Under the terms of the Stock and Asset Purchase Agreement, Pfizer provides GSK Consumer Healthcare and GSK with certain representations, warranties and indemnities. However, these representations, warranties and indemnities may not cover all potential liabilities associated with the Pfizer consumer healthcare business, and they are in certain circumstances limited in their scope, duration and/or the amount which may be claimed under them. Accordingly, GSK Consumer Healthcare and GSK may not have recourse against Pfizer, or may not recover in full from Pfizer, for losses which it may suffer in respect of a breach of those warranties, or in respect of the subject matter of any of the indemnities, or otherwise in respect of the consumer healthcare joint venture. This could materially and adversely affect the operations and financial results of the consumer healthcare joint venture and the Enlarged Group.

The successful completion of a separation of the consumer healthcare joint venture initiated by GSK may be dependent on a number of factors that are outside GSK's control, including favorable conditions in public equity markets and public or private debt markets and changes in applicable law and regulation

GSK's ability to exit the consumer healthcare joint venture through a listing and admission to trading of shares of GSK Consumer Healthcare on the London Stock Exchange, the Nasdaq Stock Market or the New York Stock Exchange (the "Separation") initiated by GSK may be dependent on a number of factors such as (i) the condition of public or private debt markets being such that the consumer healthcare joint venture is able to raise, on terms acceptable to the Group, sufficient levels of debt finance to undertake a pre-separation recapitalization and distribution of the proceeds to GSK and Pfizer and (ii) the condition of public equity markets being such as to enable a successful sale or demerger of shares in the consumer healthcare joint venture. Conditions in public equity markets and public or private debt markets are not within GSK's control and disruption in those markets may impede GSK's ability to exit the consumer healthcare joint venture at the desired time or in the desired way.

In addition, GSK's ability to implement a successful Separation initiated by GSK, including by way of a demerger of its equity stake and a listing of the consumer healthcare joint venture on the London Stock Exchange, the Nasdaq Stock Market or the New York Stock Exchange, may be impeded or prevented by any change of law, regulation or the rules of any authority to which GSK is subject (including, for example, any rules or guidance issued by the U.K. Financial Conduct Authority or H. M. Revenue & Customs) or any change to the way in which applicable law and regulation is interpreted and applied by the relevant authorities. Such changes are outside the control of GSK and there can be no guarantee that GSK's preferred strategy in relation to the Separation will be capable of being implemented.

If GSK is not able to execute a successful Separation, including by undertaking a pre-separation recapitalization of the consumer healthcare joint venture and completing a demerger of its equity stake, at a time and on terms acceptable to it, the Group may not be able to implement its preferred strategy, including in relation to its pharmaceuticals and vaccines business, the reduction of leverage associated with those businesses, and the support for those businesses' ongoing investment requirements (especially the Group's R&D pipeline). This may have a material and adverse effect on the business, financial condition, results and operations of the Enlarged Group.

The expected benefits of a successful completion of a Separation initiated by GSK of the consumer healthcare joint venture from the Group may not be realized and such a Separation may be detrimental to the consumer healthcare joint venture and/or the Group

Following a successful Separation, there can be no guarantee that the expected benefits of such a Separation will be realized. In particular, if such a Separation does proceed, both the consumer healthcare joint venture and the Group (excluding the consumer healthcare business) will form smaller, less diversified groups. As a result, each separate group may be more exposed to cyclical, sector-specific or other risks than the Group and, following completion of the Transaction, the Enlarged Group are currently. In addition, consistent with their smaller sizes, each separate group may not be able to obtain future debt or equity financing or put in place other contractual arrangements on terms as favorable as the Group and, following completion of the Transaction, the Enlarged Group are currently able to achieve. Were any of these risks to be realized following a Separation, this may have a material and adverse effect on the business, financial condition, results and operations of the consumer healthcare joint venture and/or the Group (excluding the consumer healthcare business).

The completion of a Separation initiated by Pfizer, causing the consumer healthcare joint venture to become a listed, publicly traded company, would reduce GSK's control over the consumer healthcare joint venture

Under the terms of the Shareholders' Agreement between GSK and Pfizer in relation to the consumer healthcare joint venture, in the event that GSK has not exercised its exit rights in respect of the consumer healthcare joint venture within five years following completion of the Transaction, Pfizer will be entitled to initiate a Separation from that point in time. While GSK would not be required to sell or demerge any of its shares in the consumer healthcare joint venture as part of such a Separation initiated by Pfizer and could therefore retain its proportionate equity stake, GSK's rights to appoint directors to the board of directors of the joint venture and other control rights would be reduced to a customary level for a company listed on the same exchange as the primary listing of the consumer healthcare joint venture, such that GSK would lose overall control of the board of directors of the consumer healthcare joint venture and its control rights under the Shareholders' Agreement would cease to apply. In that event, GSK may not be able to direct the business and operations of the consumer healthcare joint venture in accordance with the strategy and objectives of the Enlarged Group, which could have a material and adverse effect on the business, financial condition and results of the Enlarged Group.