

GSK plc

Stock exchange: LSE • Ticker: GSK • HQ: Brentford, UK • Employees: 90,096

Governance of Access

Product Delivery

Research & Development

PERFORMANCE IN THE 2022 INDEX

1st place. GSK leads by ensuring its overarching access to medicine strategy is applied broadly to encompass both R&D and delivery of products on the market. GSK leads in the Research & Development Technical Area and performs strongly across all assessment criteria measured by the Index.

Governance of Access: 2nd place. GSK has a strong performance in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access-to-medicine and incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 1st place. GSK leads in this area. The company has the largest priority pipeline of all companies in scope with access plans in place for the majority of latestage pipeline candidates. It also performs strongly in R&D

Average

How score was achieved

capacity building and has an access planning framework that covers all projects in the pipeline.

Product Delivery: 2nd place. GSK performs strongly in this area by applying tailored access strategies across different country income classifications in all product categories. The company also excels in high-quality capacity building initiatives, leading in manufacturing and supply chain capacity building. Through ViiV Healthcare, the company engages in non-exclusive voluntary licensing to enable generic supply, with three such licensing agreements in place for one compound.

OPPORTUNITIES FOR GSK

Ensure all late-stage R&D projects have comprehensive access plans with a wide geographic scope. GSK has access plans in place for 89% of late-stage candidates analysed. It can expand these plans and apply them to all projects in the pipeline from Phase II onwards. Furthermore, it can broaden the geographic scope of existing plans to include more countries in scope of the Index.

Apply access strategies for its COPD product, umeclidinium bromide (Incruse®), in lower-income countries. GSK has access strategies in place across all country income classifications for two of its three products targeting chronic obstructive pulmonary disease (COPD), fluticasone propionate/salmeterol xinafoate (Seretide®) and salbutamol sulfate (Ventolin®). However, strategies for umeclidinium bromide are focused on upper-middle income countries and lower-middle income countries, such as Brazil and El Salvador. The company can expand these strategies to lowincome countries and countries with the highest disease burden of COPD, such as Nepal and India.

Expand albendazole (Zentel®) donation and other efforts to control soil-transmitted helminthiasis. Since 2011, GSK's albendazole donation programme, carried out in partnership with WHO, has been targeted at controlling soil-transmitted helminthiasis in at-risk populations. During the 2022 Index cycle, the company extended the donation programme to include pre-school aged children as an additional at-risk group and expanded its public commitment to donating until 2025. GSK can further expand its public commitment by including other at-risk populations (e.g., women of child-bearing age).

CHANGES SINCE THE 2021 INDEX

- Established a new, dedicated Global Health Group, a non-commercial group aimed at enhancing pipeline progression of needed medicines and vaccines in low and lower-middle income countries.
- ViiV Healthcare, a global specialist HIV company majority owned by GSK, established a Global Health & Access forum which provides focus on and governance for access-related discussions across its portfolio.
- Signed two agreements with Gavi and UNICEF to supply the RTS,S/ASon malaria vaccine (Mosquirix) for routine child immunisation in endemic countries following a recommendation by the WHO.
- Received regulatory approval for tafenoquine paediatric dose in March 2022, representing the first new relapse prevention treatment for P. vivax malaria in over 60 years.
- ViiV Healthcare signed a non-exclusive voluntary licensing agreement relating to dolutegravir in four countries within the scope of the Index, and (after the period of analysis) a new voluntary licensing agreement with the MPP to improve access to cabotegravir long-acting for HIV preexposure prophylaxis.
- GSK reaffirmed its long-term commitment to donate albendazole (Zentel®) until the elimination of lymphatic filariasis as a public health problem is achieved globally. In addition, 200 million tablets a year will be donated until 2025 to treat soil-transmitted helminthiases.
- GSK expects to positively impact health of more than 2.5 billion people within the next ten years, with an ambition of 1.3 billion people in lowand lower middle- income countries.
- A generic formulation of Tivicay paediatric dose, a child-friendly dispersible tablet formulation, reached children in 29 Index countries less than a year after US FDA approval.

SALES AND OPERATIONS

Business segments: Consumer healthcare*, pharmaceuticals and vaccines.

Therapeutic areas: Respiratory, HIV, Immunoinflammation, Oncology; Vaccines: Meningitis, Shingles and Influenza.

Product categories: Consumer health products*, innovative medicines and vaccines.

M&A news: GSK acquired Sierra Oncology in April 2022 for USD 1.9 billion.

GSK's products are sold in 92 out of 108 countries in scope of the Index. GSK has sales offices in 27 countries, and sells via suppliers and/or pooled procurement in an additional 65 countries.

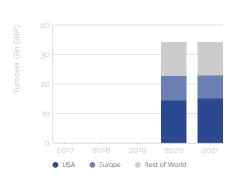
*As of July 2022, GSK no longer has a consumer healthcare business.

Turnover by segment (2021) - in GBP

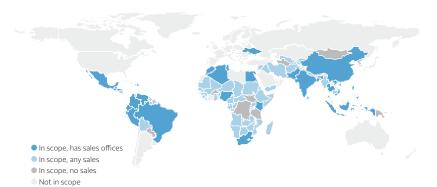
Pharmaceuticals	17.73 bn
Vaccines	6.78 bn
Consumer healthcare*	9.61 bn

Total 34.11 bn

Sales by geographic region



Sales in countries in scope

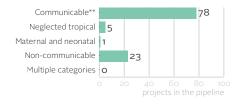


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

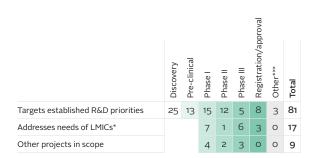
PIPELINE for diseases in scope

GSK has a total of 107 R&D projects in scope with 81 projects of these projects targeting priority diseases. The other 26 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (15 projects), COVID-19 (15), tuberculosis (14) and malaria (10). Of the projects targeting other diseases in scope, the focus is on oncology (14). Thirty-five R&D projects are in late-stage development that target either a priority disease (25) or address a public health need in LMICs (10).* Evidence of access planning was in place for 89% of these projects: 23 targeting a priority disease and eight addressing a public health need in LMICs. Additionally, GSK provides evidence of access plans for two projects in Phase I of clinical development.

107 projects in the pipeline



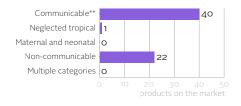
Breakdown of projects



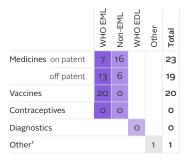
PORTFOLIO as selected for analysis by the Index

GSK has 42 medicines in scope, 23 of which are on patent, and 20 vaccines. 48% of the medicines (20) are on the WHO EML. In addition, the company markets one platform technology. The off-patent medicines target communicable diseases (CDs) (9) such as HIV/AIDS (4) and hepatitis B (2); non-communicable diseases (NCDs) (9) such as mental health (3) and cardiovascular diseases (4); and neglected tropical disease such as leishmaniasis (1). The on-patent medicines target CDs such as HIV/AIDS (10) and NCDs such as pulmonary diseases (6) and cancer (1). GSK's preventative vaccines (20) target CDs such as meningitis (6), rotavirus diarrhoea and malaria. The platform technology targets COVID-19.

63 products as selected for analysis by the Index†



Breakdown of products



se of development were low a different development cycle (e.g.

‡Other includes vector control products.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in the clinical phase of development were included for this analysis.

[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.

^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.

^{***}Other includes projects that have a technical lifecycle and projects that fol-

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GOVERNANCE OF ACCESS

access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Annual Report and ESG Performance Report.

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. GSK performs strongly. It has a comprehensive access-to-medicines and vaccines strategy, along with ViiV Healthcare, dedicated to HIV/AIDS. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with its Corporate Responsibility Committee responsible for global health and access strategies.

Performs well in responsible promotional

fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Provides evidence of financial and non-financial access-related incentives at the executive level. GSK performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives included in its annual bonus plan.

practices. GSK's sales agents are not solely incentivised on sales volume targets. In addition, it sets a capped variable pay component of incentives based on individual sales targets. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index, unless required by law or by local regulations, but it has a policy limiting such transfers, i.e. prohibiting payments for promotional activities in certain countries based on their scores in the Transparency International Corruption Perceptions Index.

Publicly supports the Doha Declaration on TRIPS and Public Health. GSK publicly shares support of the Doha Declaration on TRIPS and Public Health and states that there are flexibilities which can allow countries to address their public health needs. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, GSK, like all other member companies in scope of the Index, is by default connected to this activity.

Publicly discloses outcomes of its access-to-medicine activities. GSK performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

GSK performs strongly, demonstrating evidence of all components looked for by the Index:

RESEARCH & DEVELOPMENT

SCORE 3.78

Access planning processes encompass all projects in the pipeline. GSK has a structured process to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, GSK begins developing access plans for R&D projects in Phase II of clinical development.

GSK has the largest priority R&D pipeline com-

ViiV Healthcare's cabotegravir extended-release injectable suspension (Apretude) became the first long-acting injectable for pre-exposure prophylaxis of HIV to receive stringent regulatory authority (SRA) approval, following its approval by the US FDA.

pared to its peers, with access plans in place for (92%) 23/25 of late-stage candidates. GSK has 81 projects including 25 late-stage candidates in the pipeline that target a priority gap. The priority pipeline focuses mostly on HIV/AIDS, COVID-19, tuberculosis and malaria. Of GSK's 25 late-stage candidates targeting a priority product gap, 23 have evidence of an access plan in place. Additionally, it has access plans in place for two Phase I projects. These plans contain a range of components that are conducive to access, including commitments to register in countries in scope

of the Index, applying for WHO prequalification

and plans to ensure sustainable supply. Notably,

Many projects address a public health need in LMICs,* with 80% (8/10) of late-stage projects covered by access plans. In this analysis, GSK has ten late-stage candidates in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials conducted in countries in scope of the Index or are being developed for paediatric indications. The projects focus on several disease areas including cancer, asthma and kidney diseases. GSK provides evidence of access plans for eight of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, GSK does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. GSK leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, in collaboration with Novartis, the GRADIENT project researches genetic diversity across different regions in Africa and its potential impact on response to therapeutics. Local researchers are supported to explore responses to drugs used to treat several diseases, including malaria and tuberculosis.

PRODUCT DELIVERY

RANK 2 SCORE 4

Public commitment not to enforce patents in countries in scope. GSK publicly pledges to neither file for nor enforce patents in Least Developed Countries and LICs. For non-G20 LMICs, GSK may file for patents but can allow licenses to supply generic versions of its medicines.

Publicly discloses information on patent status.

Like most of its peers, GSK discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. GSK discloses patent information, including filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property assets with third-party researchers. GSK engaged in new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. ViiV

Healthcare has three non-exclusive voluntary licensing agreements in place for one compound (for diseases in scope). Its adult licence, its UMIC license, and its paediatric licence for dolutegravir (Tivicay® and Tivicay PD), which encompasses 104 countries relevant to the Index, including 82 low-income and lower-middle income countries. For abacavir, ViiV Healthcare has a paediatric licence that covers 104 countries in scope. After the period of analysis, ViiV Healthcare has announced a voluntary licensing agreement for cabotegravir long-acting for HIV PrEP, that will allow selected generic manufacturers to develop, manufacture and supply generic versions of the product.

Filed to register new products in 11 countries in scope on average. GSK filed one of its new products in more than half of the top ten high burden countries. Dolutegravir (Tivicay PD), a new product indicated for paediatric HIV/AIDS, is filed in seven high burden disease countries and six of the 27 low-income countries in scope of the Index. Abacavir/dolutegravir/lamivudine (Triumeq®), indicated for HIV/AIDS, is widely filed in 27 countries relevant to the Index, including in three high burden disease countries.

Has access strategies for all supranationally procured products in scope of this analysis.

GSK performs above average in securing access for products procured supranationally. For the five products assessed in this category, GSK demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, GSK supplies its MMR vaccine (Priorix®) through tenders

in the private sector in Tunisia, a country not eligible to benefit from UNICEF supranational procurement. The price is defined using a tiered pricing policy model that considers patients' ability to pay. According to GSK, 49,000 vaccinations were procured.

Has access strategies for all its healthcare practitioner administered products in scope of this analysis. GSK performs above average in this area. The company provides examples of affordable access strategies in all assessed income levels (UMIC, LMIC, LIC) for its hepatitis B vaccine (Engerix® B), one of the three products assessed in this category. It makes efforts to reach additional patients through pricing strategies that consider relevant payers' ability to pay and patient assistance programmes (PAPs). For example, the company extended the PAP for mepolizumab (Nucala®) in India by offering further discounts for patients completing the first month of treatment. GSK provides evidence that the strategy has been able to increase patient reach and treatment adherence.

Has access strategies for its self-administered products for some countries in scope of this analysis. GSK has an above average performance in this area. For three of the five products assessed, GSK provides examples of access strategies that consider affordability in all assessed income levels (UMIC, LMIC, LIC). GSK also provides evidence of additional access strategies such as a non-exclusive voluntary licensing and health systems strengthening. For example, in Colombia, GSK implemented 'parity pricing's and competitor-based pricing for abacavir/dolutegravir/lamivudine (Triumeq®). GSK reports that, in the current analysis period, it supplied the treatment to 7,350 people in Colombia living with HIV/AIDS.

All five manufacturing capacity building initiatives included meet all Good Practice

Standards. GSK is a leader in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. Since 2017, ViiV Healthcare in partnership with Clinton Health Access Initiative has established public-private partnerships that benefit generic manufacturers. These partnerships build capacity to manufacture dispersible tablets for paediatric dolutegravir and Triumeq®. This initiative meets all GPS.

All five supply chain capacity building initiatives included meet all Good Practice Standards.

GSK is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, through the Strategic Training for Executives Programme (STEP 2.0), GSK invested GBP 1.4 million to train 78 immunisation supply chain managers in 15 Gavi countries.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards. GSK's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the Frontline Health Worker Programme, GSK has invested over GBP 10 million in the Index period to support frontline health services in lower income countries providing education, skills and capacity building for local healthcare systems.

Has engaged in piloting one inclusive business model (IBM) and has scaled up two existing IBMs during the current analysis period. GSK performs above average in the use of IBMs aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. In one example, GSK's Project Respire is supporting patients with uncontrolled asthma in low-income counties in Lagos State, Nigeria through a multi-pronged approach including educating general practitioners and offering discounts on medication.

Performs above average in terms of ensuring continuous supply of medicines in LMICs.

GSK is involved in technology transfers with thirdparty manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. GSK has a policy for reporting SF medicines to national health authorities and the WHO within five days. It provides evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed. In urgent situations where there is a significant risk of patient harm, the policy is designed to enable GSK to respond quickly.

Donates in response to expressed need and monitors delivery. GSK has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. GSK has publicly committed itself since 1998 to contribute to the elimination of lymphatic filariasis by donating albendazole (Zentel®) in 38 countries in scope of the Index until goals are reached.