The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies’ access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

GlaxoSmithKline plc

Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, United Kingdom • Employees: 99,437

1st place. GSK outpaces peers by building on a strong foundation of strategies applied to both R&D projects and products on the market. GSK leads in two of the three Technical Areas.

Governance of Access: 1st place. GSK leads in this area. It has a clear access-to-medicine strategy embedded in its overall corporate strategy, with access-related objectives tied to the CEO remuneration.

Research & Development: 1st place. GSK leads in this area. Its R&D pipeline consists of 25 late-stage priority R&D projects with the majority covered by access plans. It also performs well in R&D capacity building and has an access planning process that covers all projects in the pipeline.

Product Delivery: 2nd place. GSK performs strongly in this area. It applies access strategies to the majority of its products and has the highest number of capacity building initiatives (i.e., manufacturing, supply and health system strengthening) meeting all Good Practice Standards. It filed to register some of its products in the majority of high-burden countries and has multiple mechanisms in place to ensure continuous supply.

OPPORTUNITIES FOR GSK

Expand depth and breadth of access planning. GSK has a process in place to develop access plans for all R&D projects in its pipeline. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, such as GSK3902986A / GSK3536852A for Shigella. Further, it could strengthen its post-trial access policy to commit to registration and affordability in countries where it conducts clinical trials.

Apply access strategies in poorest countries. GSK has access strategies for nationally procured products, such as for mepolizumab (Nucala®), a treatment for asthma, and for umeclidinium bromide (Incruse®), a treatment for COPD. The company can scale these strategies to more LMICs and to LICs with high burden of pulmonary diseases, such as Central African Republic, Bangladesh, Myanmar and Nepal.

Expand manufacturing capacity building to sub-Saharan Africa. GSK performs well in manufacturing capacity building with initiatives in East and Southeast Asia (India, Pakistan, China, Thailand), Latin America (Mexico, Brazil) and northern Africa (Morocco, Egypt). It can expand its manufacturing capacity building to more geographic areas, including sub-Saharan African countries.

Expand albendazole donation to control soil-transmitted helminthiasis. Since 2011, GSK’s albendazole (Zentel®) donation programme in partnership with WHO is aimed at controlling the soil-transmitted helminthiasis (STH) in at-risk populations (school-aged children). The company publicly committed to donating until 2020. GSK can extend its public commitment indefinitely until STH is controlled in at-risk populations.

CHANGE SINCE THE 2018 INDEX

• Pledged to ramp up HPV vaccine supply for Gavi-supported countries.
• Supports the clinical development of novel antibiotics via the AMR Action Fund.
• Joined the COVID-19 Therapeutics Accelerator.
• Engages in technology transfer and development support for paediatric formulations of dolutegravir.
• Set up a local protocol to ensure continued provision of dolutegravir (Tivicay®) to participants in clinical studies, in countries where local availability after market authorisation is uncertain.
• Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative.
• Supported the VNCV’s Vietnam Paediatric Vaccine Supply Chain Initiative since July 2019.
• Expanded initiative STEP from 14 to 21 countries.
• Formed a supranational organisation service platform for supply planning, launches and route set-up for global health products for its pharmaceutical portfolio.
• Licensed its tuberculosis (TB) vaccine candidate to the Gates MRI for development and use in low-income countries.
• Collaborates with WHO and PATH to implement the new RTS,S vaccine for malaria in three countries (Ghana, Kenya, Malawi).
SALES AND OPERATIONS

Business segments: Pharmaceuticals; Vaccines; and Consumer Healthcare

Therapeutic areas: Pharmaceuticals:
- Respiratory, HIV, Immuno-inflammation,
- Oncology: Vaccines: Meningitis, Shingles, Influenza

Product categories: Innovative medicines, Vaccines, Consumer health products

M&A news: Combined consumer health business into a JV (68% stake) with Pfizer in 2019;

acquired Tesaro (oncology) for USD 5.1 billion in 2019.

GSK’s products are sold in 89 out of 106 countries in scope. GSK has sales offices in 22 countries, sells via suppliers in 43 countries and via pooled procurement into 24 additional countries.

Turnover by segment (2019) – GBP

<table>
<thead>
<tr>
<th>Segment</th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>17.554 bn</td>
</tr>
<tr>
<td>Vaccines</td>
<td>7.157 bn</td>
</tr>
<tr>
<td>Consumer Healthcare</td>
<td>8.995 bn</td>
</tr>
<tr>
<td>Corporate and other unallocated</td>
<td>0.048 bn</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>33.754 bn</strong></td>
</tr>
</tbody>
</table>

Sales by geographic region

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

**PIPELINE** as for diseases and countries in scope

GSK has a total of 117 R&D projects featuring the largest priority R&D pipeline compared to its peers: 81 projects. Remarkably, two thirds of GSK’s total R&D projects target priority diseases. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (16 projects) and COVID-19 (16). Of the projects targeting other diseases in scope, the focus is on oncology (22). 40 R&D projects are in late-stage development that target either a priority disease (25) or address a public health need in LMICs (15). Evidence of access planning was in place for 80% of these projects: 20 targeting a priority disease and 12 addressing a public health need in LMICs.

**PORTFOLIO** as selected for analysis by the Index

GSK has 39 medicines in scope, 21 of which are on patent, and 22 vaccines. 49% of these medicines (19) are on WHO’s EML. In addition, the company markets 1 platform technology. The off-patent medicines target communicable diseases (CDs) (7) such as HIV (4) and hepatitis B (2); non-communicable diseases (NCDs) (9) such as mental health (3) and cardiovascular diseases (4); the neglected tropical disease leishmaniasis and neonatal sepsis and infections. The on-patent medicines target the CDs HIV (8) and malaria and NCDs such as pulmonary diseases (9) and mental health (1). GSK’s preventative vaccines (22) target CDs such as meningitis (3) and rotavirus diarrhoea. The platform technology targets COVID-19. Access strategies were analysed for 12 products on GSK’s portfolio – supranationally procured (5) or nationally procured HCP-administered (2) and self-administered products (5).

62 products as selected for analysis by the Index†

Breakdown of products**

ViiV Healthcare & Janssen’s long-acting injectable formulation of cabotegravir and rilpivirine (Cabenuxa). It is the first complete long-acting regimen for the treatment of HIV-1 infection in adults. The product is currently only approved in Canada.

Vaccines, Consumer health products

Breakdown of projects††

*50 diseases and 271 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

***Other includes a platform technologies. See Appendix I for a full breakdown of the criteria. 

Projects in the discovery phases and/or other drug development phases were not included in this breakdown.
GlaxoSmithKline plc

### Governance of Access

**Rank 1**  **Score 4.59**

- Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. GSK performs strongly, as it has a comprehensive access to medicines and vaccines strategy. 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 (CRC) which is responsible for global health and access strategies.

- 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.

- Publicly discloses outcomes of its access-to-medicine activities. GSK performs strongly in transparency regarding access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities for example with its ESG Performance Summary.

- Performs above average in responsible promotional practices. For countries in scope GSK’s sales agents are not solely incentivised on sales volume targets. In addition, GSK does not set sales incentives at the individual level for agents in these countries. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope, 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 acknowledges that the flexibilities can allow countries to address their public health needs. GSK has a policy to dissent from industry association positions on these, if it does not agree with a public policy position, it will not participate in related advocacy activity.

### Research & Development

**Rank 1**  **Score 3.67**

- Access planning processes encompass all projects in 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 for diseases in scope. In general, GSK begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

- GSK has the largest priority R&D pipeline compare to peers, with access plans in place for 80% of the late-stage candidates. GSK has 81 projects including 25 late-stage candidates in its pipeline that target a priority product gap. The company focuses mainly on HIV/AIDS and other infectious diseases. Of GSK’s 25 late-stage candidates targeting a priority product gap, 20 have evidence of having an access plan in place. These plans range from commitments to ensure access; to product registration in several countries in scope; to equitable pricing strategies where prices are linked to the country’s ability to pay (i.e. GNI per capita). GSK (as ViiV Healthcare) applies a non-profit pricing approach in lower-income countries, least-developed countries and sub-Saharan Africa for its antiretroviral products. ViiV Healthcare plans for a broad registration plan for this product and considers where appropriate, local manufacturing partnerships. Notably, ViiV Healthcare's paediatric dolutegravir dispersible is the first integrase inhibitor available as a dispersible tablet for oral suspension for children.

- Many projects address a public health need in LMICs*, with 80% of the late-stage projects covered by access plans. In this analysis, GSK has 15 late-stage R&D projects 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 are first-in-class molecules and/or clinical trials are conducted in countries in scope. Most target cancer. GSK provides evidence of access plans for 12 of these projects.

- Public policy to ensure post-trial access; commits itself to registering trialled products. GSK has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy applies on a case-by-case basis. GSK does not conduct clinical trials in countries where, at the time of the trial, GSK knows it will not pursue registration and make the product available for use. The policy considers affordability for the wider population in the country where the trial(s) took place.

- Four R&D capacity building initiatives meet all Good Practice Standards. GSK leads in this area. GSK submitted the maximum of five initiatives. Four initiatives met all criteria for inclusion and all Good Practice Standards:
  - Africa NCD Open Lab, providing funds and additional in-kind support for research into Non-Communicable Diseases in sub-Saharan Africa.
  - Institute for Infectious Diseases and Public Health.
  - Trust in Science, enabling scientific exchange with and supporting research organisations in Latin America and Asia.
  - PENTA’s EPICAL Consortium, advancing the science of HIV remission in children for clinicians and researchers and enabling technology and expertise transfers.

### Product Delivery

**Rank 2**  **Score 4.36**

- Public commitment not to enforce patents in the majority of countries in scope. GSK publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

- Publicly discloses detailed information on patent status. Like most of its peers, GSK discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

- Shares some IP assets with third-party researchers. During the period of analysis GSK has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes five IP assets shared with research institutions, including sets of target-specific compounds in discovery stage and molecule libraries. GSK also joined the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda

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*Addresses local needs, priorities and/or skills gap; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiative goals align with or support institutional goals; measures outcomes; has long term aims/aims for sustainability.
GSK has access strategies for all supranationally procured products in scope of this analysis. GSK performs well in this area. The company provides examples of access strategies which consider affordability in UMICs and LMICs for the two products assessed in this category. It makes efforts to reach additional patients through equitable pricing strategies and patient assistance programmes. For example, in Colombia, for mepolizumab (Nucala®), a treatment for asthma, the company uses equitable pricing strategy and patient assistance programmes. For example, in Thailand, the company reduced the price of fluticasone propionate/salmeterol xinafoate (Seretide®), a treatment for asthma, the company does so in GAVI-eligible countries.

Has access strategies for both of the healthcare practitioner administered products in scope of this analysis. GSK performs well in this area. The company provides examples of access strategies which consider affordability in UMICs and LMICs for the two products assessed in this category. It makes efforts to reach additional patients through equitable pricing strategies and patient assistance programmes. For example, in Colombia, for mepolizumab (Nucala®), a treatment for asthma, the company uses equitable pricing strategies and implemented a patient support programme to increase access, while strengthening the health system by providing nurse home visits for patients. GSK forecasts that access to this medicine will have increased by 100% by the end of 2020. GSK is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. GSK performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for two of the five products assessed. For the other products the company falls short to provide example for LMICs and/or LICs. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Thailand, the company reduced the price of fluticasone propionate/salmeterol xinafoate (Seretide®), a treatment for asthma, for inclusion for reimbursement on the national list of essential medicines and launched a second discounted brand to increase affordability and access for patients. 380,000 patients access this medicine every year in Thailand. GSK is able to provide evidence of how patient reach has been increased through the approaches used.

Four manufacturing capacity building initiatives meet all Good Practice Standards. GSK is a leader in this area, with five manufacturing capacity building initiatives included for analysis. GSK submitted the maximum of five initiatives, which all met all criteria for inclusion. Four initiatives met all Good Practice Standards. GSK has submitted a variety of initiatives, which were all included for analysis and met all Good Practice Standards. GSK has submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards. GSK has submitted a variety of initiatives, which were all included for analysis and met all Good Practice Standards. GSK has submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards. GSK has submitted a variety of initiatives, which were all included for analysis and met all Good Practice Standards. GSK has submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards.

Five health system strengthening initiatives meet all Good Practice Standards. GSK is one of the leaders in this area. The company submitted the maximum of five initiatives, which all met the criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- GSK and Save the Children partnership, reaching nearly 3 million children under the age of five between 2013 and 2018.
- Frontline Health Worker Programme, strengthening health infrastructure and improving access to healthcare in Least Developed Countries. Since 2010, GSK’s investment has reportedly enabled the training of more than 100,000 health workers and reached over 16 million people in 44 countries.

Has engaged in the development and implementation of scaled up inclusive business models. GSK performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope of the Index. During the period of analysis, it has scaled up its Live Well social enterprise model aiming at building and supporting local distributor networks in Zambia.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. GSK performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in scope. For example, GSK manages global and regional supply & demand hubs, overseeing forecasts of countries including some Least Developed Countries. GSK maintains a dual sourcing policy which supports supply of key medicines. In 2019, it set up a supranational organisation service platform to improve forecast accuracy and supply planning.

Has a policy for reporting substandard and falsified (SF) medicines in index countries in less than 10 days. GSK has a policy for reporting SF medicines to national health authorities and WHO within 5 days. It distinguishes 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 enables GSK to respond quickly.

Donates in response to an expressed need and monitors delivery to end user. GSK has a policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors how it is delivered the end user. For example, it donated antibacterial medicine in 2018 in response to the conflict in Syria.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, GSK publicly commits itself to eliminating lymphatic filariasis by donating albendazole (Zentel®) in 39 index countries since 1998.