

RANK	SCORE
<b>1=</b>	<b>4.01</b>
1 (2016)	

# GlaxoSmithKline plc

Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, United Kingdom • Employees: 98462

## PERFORMANCE

Retains 1<sup>st</sup> place. It continues to outpace peers by building on a strong foundation of strategies that are applied to both R&D projects and products on the market. GSK leads in five out of seven Technical Areas.

**Management:** Retains third place. Access strategy is clearly linked to business rationale, with incentives for senior management aimed at long-term objectives.

**Compliance:** New to 1<sup>st</sup> place, it discloses all components of an internal control system looked for by the Index.

**R&D:** Retains top place, by creating an integrated Global Health R&D unit, and the largest number of projects targeting priority R&D gaps.

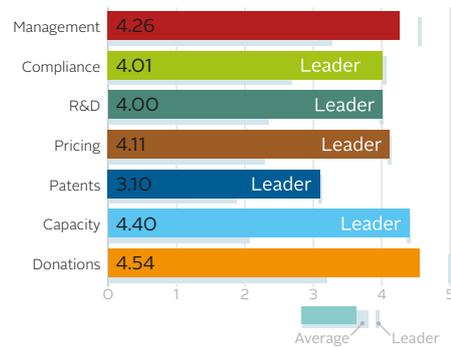
**Pricing:** Holds top place, with one of the highest proportions of equitable pricing strategies being applied to priority countries.

**Patents:** A new leader, with its voluntary licence for dolutegravir (Tivicay®) having the largest geographic spread.

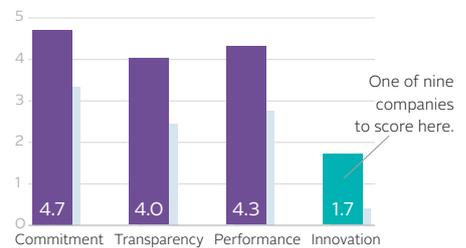
**Capacity:** Leads for the first time with the highest number of initiatives meeting all good practice standards.

**Donations:** Falls to 2<sup>nd</sup> place. Maintains strong performance, but falls short compared to the leader in endemic country-coverage.

Performance by technical area



Performance by strategic pillar



## OPPORTUNITIES

**Ensure sustainability of established access systems while shifting to a distributor-led model.** During the period of analysis, GSK reviewed and restructured its product deployment strategy for its pharmaceuticals business to a distributor-led approach in several countries within the scope of the Index, including sub-Saharan Africa. GSK should ensure that access to products is maintained and response to need and supply are addressed.

**Continue to register key HIV products in countries in scope.** GSK should work through ViiV Healthcare to register HIV/AIDS products in all priority countries, for example abacavir/dolutegravir/lamivudine (Triumeq®), dolutegravir/rilpivirine (Juluca®), and Dolutegravir (Tivicay®). Dolutegravir (Tivicay®) is GSK's most widely registered new product, registered in 50% of the possible priority countries. GSK can also file its paediatric formulation of dolutegravir (Tivicay®), for broad registration in priority countries. To help improve registration of HIV/AIDS medicines in priority countries, GSK can consider participating in the WHO Collaborative Registration Procedure.

**Expand HIV voluntary licensing agreements.** GSK can look to expand its non-exclusive voluntary licence for dolutegravir (Tivicay®) for HIV/AIDS, which currently covers 70% of middle-income countries in scope with the highest burden of HIV/AIDS. Middle-income countries with a high burden of HIV/AIDS excluded from the licence agreement are: Brazil, China, Mexico and Suriname.

**Develop equitable pricing strategies prior to Phase III.** GSK can work to ensure that all R&D projects have access plans during Phase II and continue to refine this process to allow for the earlier establishment of these provisions. In particular, it can work to establish equitable pricing strategies at Phase II of clinical development.

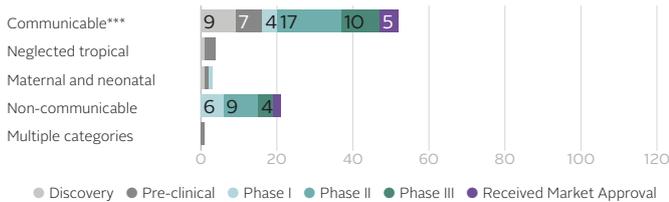
## CHANGE SINCE 2016

- Partially reverses company ban on payments to healthcare professionals as of October 2018.
- Joined Access Accelerated with its Africa NCD Open Lab initiative. It has also committed to measure impact and share results publicly via Access Observatory for two of its projects.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Improved its access planning process to consider all R&D projects in scope, with access plans in place, after proof of concept, during Phase II of clinical development.
- Established a Global Health R&D Unit (part of the new Global Health Unit) that encompasses GSK's open innovation initiatives for maternal and neonatal health, non-communicable diseases in Africa and neglected tropical diseases while systematically incorporating access into these projects.
- Shifts to distributor-led model in key regions (e.g. Sub Saharan Africa, Southeast Asia) within the Index scope.

**PIPELINE** for diseases and countries in scope

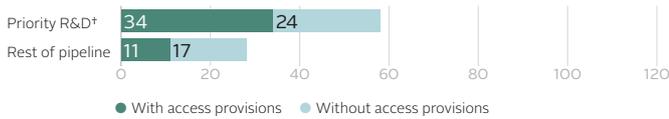
**Comparatively large pipeline:** 86\* R&D projects for diseases in scope (59 medicines; 26 preventive vaccines; 1 diagnostic; 1 therapeutic vaccine; 1 vector control product).  
**Clinical candidates:** 53, including tafenoquine for the treatment of *Plasmodium vivax* malaria in children and adults and a paediatric indication for dolutegravir/rilpivirine (Juluca®) for the treatment of HIV/AIDS.  
**Regulatory approvals:** 7, including influenza H5N1 pre-pandemic vaccine (Prepandrix™) for paediatric usage.  
**R&D focus:** communicable diseases (HIV/AIDS, malaria and lower respiratory infections) and non-communicable diseases (cancer, asthma and COPD).  
**Access provisions:** for 45 projects, most commonly registration commitments.

**Projects in the pipeline: 86\*\***



Tafenoquine (Krintafel™) was approved by the FDA three weeks after the 2018 Index's period of analysis closed. It is the first treatment for *P. vivax* malaria in over 60 years, and GSK continues to develop the drug for paediatric usage.

**Projects for R&D priority targets with access provisions: 34**



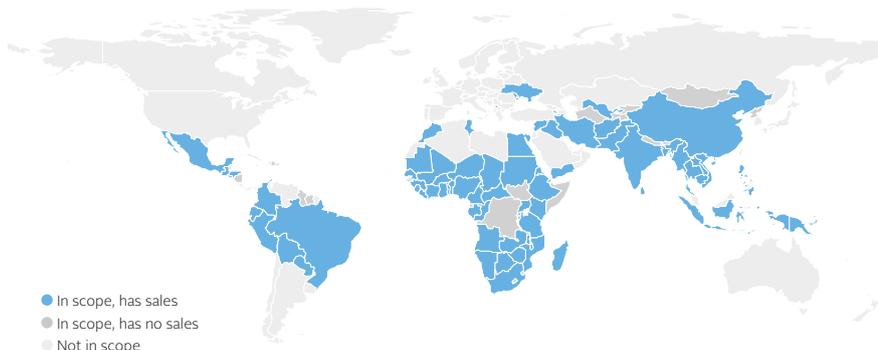
Of GSK's 86 R&D projects, 45 are supported by access provisions: e.g., the antimalarial tafenoquine includes not-for-profit pricing, patent waivers and a registration strategy. 32 of its 47 late-stage projects have provisions.

**BUSINESS CONTEXT**

**Three business units:** Pharmaceuticals; Vaccines; and Consumer Healthcare. Its pharmaceutical business segment has five therapeutic areas (respiratory; HIV/AIDS; oncology; rare diseases; and immuno-inflammation). Its vaccine portfolio focuses on traditional childhood vaccines (e.g., DTaP-containing combination vaccines) and newer vaccines with few other suppliers (e.g., HPV, pneumococcal disease and rotavirus). GSK holds a 78.3% equity share in ViiV

Healthcare - a joint HIV/AIDS medicine venture with Pfizer and Shionogi.  
**M&A news:** 2018 buyout of Novartis 36.5% stake in its Consumer Healthcare joint venture.  
**Presence in emerging markets:** In 2018, GSK reports sales in 74 countries in scope; 18 less countries than in the 2016 Index. It reports that a large portion of its sales in 2017 came from regions outside of Europe and the USA.

**Sales in countries in scope**



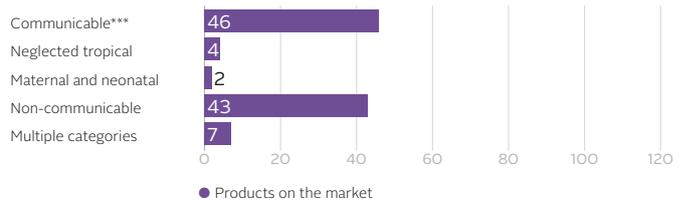
Statistics relate only to diseases and countries in scope.

\*Projects that target multiple product types are counted more than once.  
 \*\*Figure excludes 5 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control

**PORTFOLIO** for diseases and countries in scope

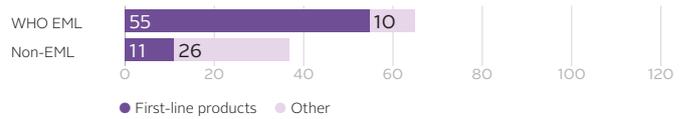
**Comparatively large portfolio:** 102 products for diseases in scope (77 medicines; 25 preventive vaccines).  
**Portfolio focus:** communicable diseases (lower respiratory infections and HIV/AIDS) and non-communicable diseases (asthma and hypertensive heart disease).  
**Essential medicines:** 64% of GSK's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).  
**First-line treatments:** 65% of GSK's medicines and vaccines have first-line indications for diseases in scope.

**Products on the market: 102**



GSK's portfolio includes products such as dolutegravir/rilpivirine (Juluca®) and several preventive vaccines including an expanded indication for its Fluarix® quadrivalent influenza vaccine in children six months and older.

**Essential medicines with first-line indications: 55**

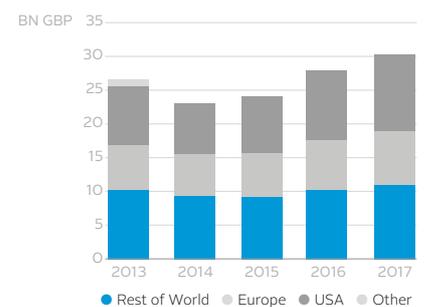


75% of GSK's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., the pneumonia and *H. influenzae* vaccine Synflorix®, the HPV vaccine Cervarix® and dolutegravir (Tivicay®).

**Turnover by segment (2017) - GBP**

Pharmaceuticals	17,276 MN
Vaccines	5,160 MN
Consumer Healthcare	7,750 MN
<b>Total</b>	<b>30,186 MN</b>

**Turnover by geographic region**



products, investigator sponsored trials and Phase IV projects.  
 \*\*\*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.  
 \*See Appendix IV for definition.

# GlaxoSmithKline plc

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 3 SCORE 4.26

**Has a strong access-to-medicine strategy with board-level responsibility.** GSK is one of 14 companies that performs strongly with regards to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around improving access to medicine and strengthening health systems in countries in scope by developing partnerships focused on access, such as ViiV Healthcare. The highest level of responsibility for access sits with a board-level committee.

**Financial and non-financial access-related incentives to reward employees.** GSK performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include a variable pay system linked to long-term results, bonuses and rewards. Senior management has a separate incentive that supports the company's long-term access oriented objectives.

**One of the 16 companies working on impact measurement.** GSK measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets and performance information. For example, for its partnerships with Amref Health Africa, CARE International and Save the Children, GSK reports reaching its goals on helping underserved people by training 65,000 front-line health workers. Furthermore, it is one of the companies that is measuring impact by reporting on the progress of its Save the Children partnership.

**Clear stakeholder engagement approach that includes local stakeholders.** GSK performs well when it comes to the disclosure of its stakeholder engagement. It publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with. It does incorporate local stakeholder perspectives into the development of access strategies. It has some policies covering responsible interactions with stakeholders, namely to operate with integrity and transparency with local stakeholders, following its standard for interacting with patient organisations.

### MARKET INFLUENCE & COMPLIANCE

RANK 1 SCORE 4.01

**Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards.** GSK leads in the area of ethical marketing and anti-corruption governance. It has a code of conduct relating to ethical marketing and anti-corruption, and provides annual compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities such as technical knowledge and quality of service.

**Internal control framework meets all Index criteria.** GSK has all the components of an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system in place to track compliance in the workplace; it conducts audits involving both internal and external resources—that also applies to third parties. GSK also demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

**Above average transparency regarding access-related practices.** GSK publicly discloses its policy positions on access-related topics. For example, it has a policy on intellectual property and access to medicine for developing countries. It is one of the few companies in scope to have a policy that prohibits political contributions. GSK discloses its membership of relevant institutions and whether it provides financial support. It discloses its policies for responsible engagement, including responsible lobbying. During the period of analysis, GSK was the only company to have a policy prohibiting payments to healthcare professionals to attend and speak at conferences.

### RESEARCH & DEVELOPMENT

RANK 1 SCORE 4.00

PROJECTS: 86 IN CLINICAL DEVELOPMENT: 53

**Publicly commits to R&D to meet public health needs.** GSK has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale with each commitment developed in response to public health needs in these countries. Further, it has time-bound strategies for

completing R&D projects for diseases in scope and evaluates progress toward these targets. GSK has one of the largest pipelines in the Index with 86 projects. For diseases in scope where priorities exist, GSK is active in 60 projects; 58 of these target priority R&D gaps.

**Access provisions in place for 68% (32/47) of late-stage candidates.** GSK has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope when possible. In general, GSK develops access plans for R&D projects in Phase II of clinical development, and it develops equitable pricing strategies in Phase III. To date, GSK has the highest number of project-specific access provisions, with 32 in place for its late-stage R&D projects. Of these, 19 are being conducted in partnership.

**Public policy to ensure post-trial access; commits to registering trialed products.** GSK has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, GSK commits to registering it in all countries where clinical trials for the product have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 1 SCORE 4.11

PRODUCTS: 102

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY 61

**Commits publicly to equitable pricing and reports a commitment to file to register new products in scope.** GSK commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It also publicly commits to implement inter-country equitable pricing strategies for the majority of its products for diseases in scope. However, this does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies.

**Some new products in scope filed for registration in the majority of priority countries.** Although GSK newly commits to filing its newest products for registration in countries in scope within one year of first market approval, it has

filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it publicly shares some registration information for the majority of its products.

**60% of products have equitable pricing strategies targeting priority countries.** GSK's overall performance is strong compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 60% of its products for diseases in scope. These strategies apply to an average of 35% of priority countries. The majority of these strategies apply both inter- and intra-country pricing; these take into account an average of four socioeconomic factors. GSK also applies equitable pricing strategies to 19 further products informed by a public health rationale.

**Has both globally consistent recall guidelines for countries in scope and processes to track products.** GSK has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING

RANK 1 SCORE 3.10

**Publicly discloses detailed information on patent statuses.** Like most of its peers, GSK publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

**Uses licensing to enable generic supply.** GSK performs strongly in this area. The company has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for dolutegravir (Tivicay®), encompasses 102 countries including 71 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

**Shares some IP assets with 3<sup>rd</sup>-party researchers.** Compared to its peers, GSK shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with UK research institutions such as the University of Keele and the University of Dundee. The assets shared include molecule libraries.

**Public commitment not to enforce patents in countries in scope.** GSK commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

## CAPACITY BUILDING

RANK 1 SCORE 4.40

**23 initiatives included for evaluation.** GSK has 23 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; GSK submitted the maximum.

**Strong focus on local manufacturing and strengthening health systems.** GSK has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least two initiatives in each area which meet all good practice standards. GSK performs strongest in manufacturing capacity building and health system strengthening.

**18 initiatives meet all applicable good practice standards:**

- Water Scarcity in India and Bangladesh
- Academic Research Chair
- Comic Relief – GSK malaria partnership
- STEP (Strategic Training for Executives Programme)
- Positive Action programmes

A full list of GSK's capacity building initiatives which meet all good practice standards can be found online.

Out of GSK's five remaining included initiatives, three are in the area of pharmacovigilance. These initiatives typically fall short on having good governance structures in place and processes for mitigating conflicts of interest.

**Timely approach to confirming and reporting substandard or falsified medicines.** GSK provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

## PRODUCT DONATIONS

RANK 2 SCORE 4.54

STRUCTURED DONATION PROGRAMMES: 2

**Responds to emergencies and humanitarian crises and tracks delivery.** GSK donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products such as amoxicillin/clavulanic acid (Augmentin™) in response to the 2016 hurricane in Haiti. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with Save the Children, Direct Relief, Amicares and Map International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

**Two donation programmes covering diseases and countries in scope.** GSK's programmes are focused on neglected tropical diseases (NTDs), namely lymphatic filariasis (LF) and soil-transmitted helminthiases (STH). Both programmes are carried out in partnership with WHO. Its programme for STH supplies albendazole (Zentel®) in 50 countries and has been ongoing since 2011. In 2017, GSK reported donating 123.7 million albendazole (Zentel®) tablets for STH and 770 million albendazole (Zentel®) tablets for LF.

**Addresses long-term access by aiming to eliminate disease.** GSK commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its albendazole (Zentel®) donation programme aims to eliminate lymphatic filariasis in 39 countries.

## BEST PRACTICES

**The Africa Non-Communicable Disease (NCD) Open Lab advances NCD research**

A notable number of collaborations with African institutions to support and improve NCD research.

**Extensive initiative to improve child healthcare**  
A wide range of projects through a global partnership with Save the Children.

**mVacciNation improves vaccine stock issues**

A successfully scaled-up mobile technology platform that tracks vaccine stock data.

**Dolutegravir (Tivicay®) licence has widest geographic potential for improving access**

The non-exclusive voluntary licence for dolutegravir (Tivicay®) covers 95% of low- and middle-income countries in scope.

**Continued commitment to combat NTDs**

One of five companies running donation programmes to eliminate or eradicate NTDs.

**Largest proportion of pipeline dedicated to priority R&D projects**

More than 60% of GSK's and Sanofi's pipelines focus on diseases for which products are urgently needed.

**Plans ahead for largest proportion of pipeline**  
GSK leads in planning ahead to make future products accessible.

**Three companies incorporate framework of strict guidelines to reduce non-compliance**

Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.

## INNOVATIVE PRACTICES

**HALOW partnership to improve worker's health**

Cross-sector partnership to address the health and wellbeing of workers in the textile industry  
**Live Well social enterprise model builds and supports local distributor networks**

Network of local outlets for health products run by community members.

**Global Health R&D Unit to stimulate collaboration**

Targeted open innovation incubators and research units with focus on R&D for conditions unique or endemic to low- and middle-income countries.