

Overall Performance

2020 2021

86% **84%**▼

GlaxoSmithKline plc

Large R&D-based pharmaceutical company

Stock exchange: LSE • Ticker: GSK • HQ: Brentford, UK • Employees: 94,066

PERFORMANCE

GSK is the leader among the large research-based pharmaceutical companies in scope and performs well in its evaluated Research Areas.

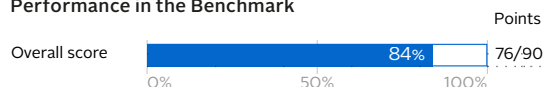
R&D: With 31 R&D projects, about half of them vaccines, GSK leads in R&D. Eleven of its projects target critical and/or urgent pathogens. Two of its medicine candidates in clinical development are novel. GSK reports access and/or stewardship planning for all five of its late-stage projects.

Responsible Manufacturing: Performs strongly. Reports comprehensive environmental risk-management strategy for own sites and suppliers; co-leads in reporting compliance with limits at own sites and suppliers; publicly discloses this compliance.

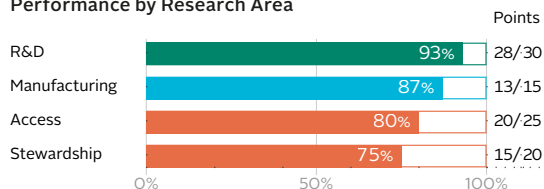
Appropriate Access: Performs strongly. Files some of its on- and off-patent products for registration in access countries. Reports several strategies to expand access and ensure continuous supply to its on-patent antibacterial vaccines in access countries.

Stewardship: Performs well. It partly decouples incentives for sales agents from sales volumes. It publicly shares aggregated results of its SOAR surveillance programme. It reports broad conflict of interest mitigation for its educational programmes. It adapts brochures and packaging for patients.

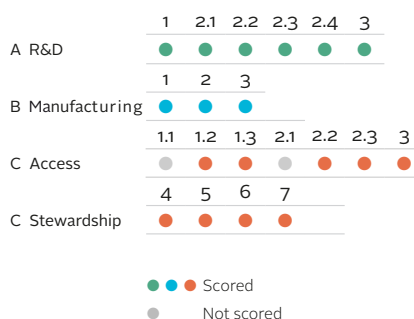
Performance in the Benchmark



Performance by Research Area



How GSK was evaluated



OPPORTUNITIES FOR GSK

Expand and tailor access and stewardship plans for critical late-stage R&D projects. As a leader in antibacterial and antifungal R&D with the largest pipeline, GSK can further strengthen their company-wide policies and project-specific plans to ensure new medicines are swiftly available to those in critical need but also to prevent excessive use. GSK maintains policies and plans for their late-stage R&D projects and can make plans more wide-reaching and timely. As an example, for its vaccine Bexsero®, that is in phase III targeting *N. gonorrhoeae*, GSK can define the access countries where it plans to file for registration, based on burden of disease and where resistance for *N. gonorrhoeae* is highest and where it considers ability-to-pay in its pricing strategy. In addition, GSK can expand its stewardship plans for its medicine R&D projects through more comprehensive surveillance activities by covering more priority pathogens and countries, as well as re-evaluating its sales practices for when these medicines reach the market to safeguard them from overuse and misuse.

Increase public disclosure on environmental risk management. GSK publishes information on some of the components of its environmental risk-management strategy including compliance percentages of its own and suppliers' sites with discharge limits. While it reports 100% compliance at its own sites, it can disclose more information to provide clear evidence of its progress publicly. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency. GSK can also apply limits directly in effluent to fully mitigate AMR risk.

Comprehensively mitigate COI for educational programmes. GSK organises medical education programmes for healthcare professionals on responsible use of antimicrobial medicines. It ensures that branded materials are not used in most educational programmes. It can ensure that this is applied in all educational programmes.

Fully decouple incentives for sales agents from sales volumes. GSK links part of its sales agents' incentives to sales volumes of antibacterial and antifungal medicines. It can fully decouple incentives for sales agents from sales volumes again.

Publicly share raw data from surveillance programme. GSK runs the multinational Survey of Antibiotic Resistance (SOAR) programme, which is focused on community-acquired respiratory-tract infections. It can publicly share raw data from this surveillance programme, following through on clear commitments to share this with the University of Washington (as part of the GRAM project) and on the AMR Register.

CHANGES SINCE 2020

- In February 2020, GSK joined the Project to Accelerate New Treatments for Tuberculosis (PAN-TB), a collaboration among philanthropic, non-profit and sector partners that aims to develop an investigational drug regimen capable of treating all forms of TB.
- Compared to 2020 Benchmark analysis, GSK tracks the compliance of its own and suppliers' sites with discharge limits. All of GSK's own sites and 95% of its suppliers' sites are reportedly compliant with discharge limits.
- Since 2020, GSK has publicly shared information on compliance percentages of own and suppliers' sites, specific to antibacterial production.
- GSK received funding from CARB-X, up to USD 18 mn, to support the development of two unique vaccine projects that target the prevention of group A streptococcus (Strep A) infections and infections caused by *Salmonella enterica* which cause invasive nontyphoidal salmonellosis (INTS) disease and typhoid fever. Currently there are no vaccines available against these infections.

SALES AND OPERATIONS

Therapeutic areas: Respiratory, HIV, Immuno-inflammation, Oncology
Business segments: Pharmaceuticals, Consumer healthcare, Vaccines
Product categories: Innovative medicines, Vaccines, Consumer health products

M&A since 2020: In July 2019, GSK and Pfizer combined their consumer health care business in a new joint venture, with GSK having the majority and controlling an equity interest of 68%. In February 2021, GSK signed an agreement to sell the cephalosporin antibiotic business to Sandoz (Novartis division) for USD 350 mn in addition to milestone payments up to USD 150 mn.

PIPELINE for pathogens in scope

Pipeline size: 31 projects targeting pathogens in scope* (15 antibacterial medicines; 15 antibacterial vaccines; 1 antifungal vaccine)
Development stages: 10 clinical projects, 5 in Phase I, 2 in Phase II and 3 in Phase III, including a Phase III project for an expanded indication of its serogroup B meningococcal vaccine (Bexsero®) for the prevention of gonorrhoea; and 19 discovery/preclinical projects.
Novelty: 2 novel projects, GSK-3036656, for the treatment of *Myobacterium tuberculosis*, that meets all four WHO innovativeness criteria; and gepotidacin, for the treatment of infections caused by *Enterobacteriaceae* and *Neisseria gonorrhoeae*, and which belongs to a new chemical class and has a new mode of action.
'Critical' and/or 'urgent' pathogens: 11 projects, with the focus on carbapenem-resistant *Escherichia coli* and drug-resistant *N. gonorrhoeae*. GSK has one vaccine against *C. difficile* in Phase I of clinical development.
Regulatory approvals: 0 approvals for products targeting pathogens in scope.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT Evaluated: medicine & vaccine pipelines for priority* bacteria & fungi

A.1 Largest amount invested in R&D
 GSK reports to the Benchmark the amount invested during 2019 and 2020 in R&D for antibacterial and antifungal medicines and/or vaccines for pathogens in scope. Specific investment figures were provided under confidentiality. GSK reports above average R&D investments relative to its revenues among the companies assessed. GSK reports the largest abso-

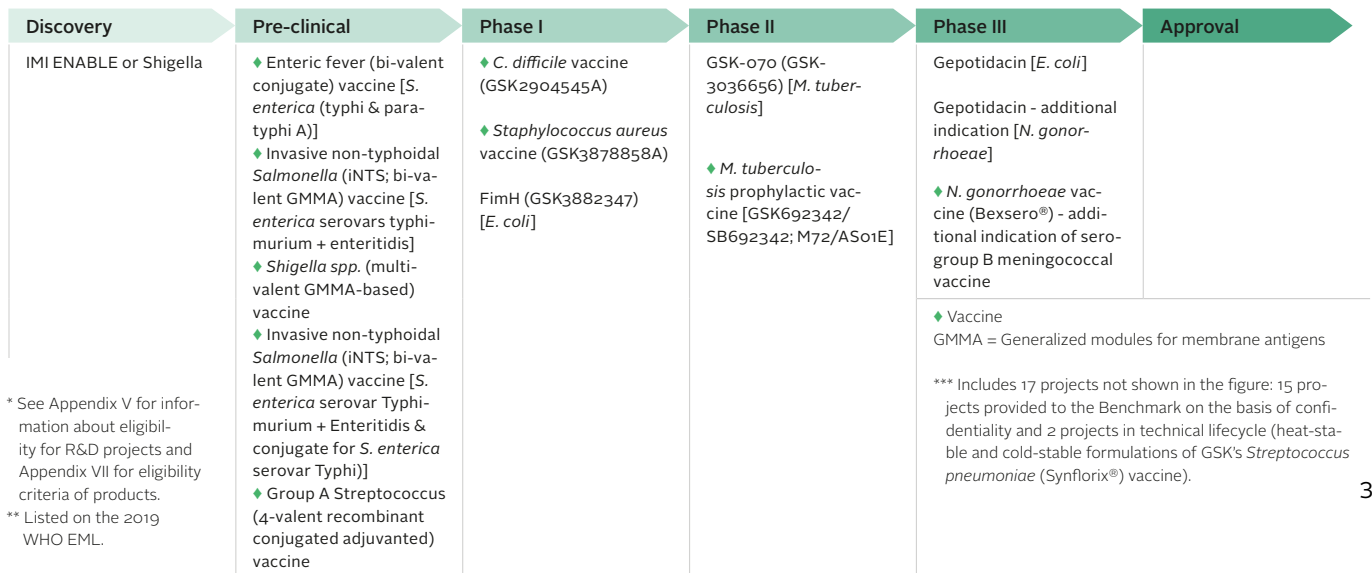
lute R&D investment figure compared to the other companies who reported investments to the Benchmark. GSK is a contributor to the AMR Action Fund.

A.2.1 GSK has the largest R&D pipeline among the large R&D-based companies

The company reports 31 projects targeting pathogens in scope: 15 medicines and 16 vaccines,

targeting bacterial and fungal pathogens. Out of the 31 projects, ten are in clinical development, 19 are in discovery/preclinical stage and 2 projects are in technical lifecycle. GSK did not obtain marketing approval for any of its products during the period of analysis.

Pipeline targeting priority pathogens: 31*** As at 24 September 2021

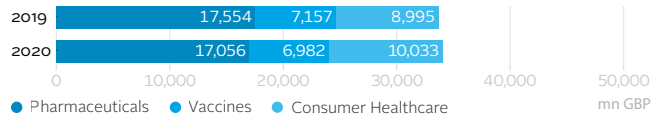


* See Appendix V for information about eligibility for R&D projects and Appendix VII for eligibility criteria of products.

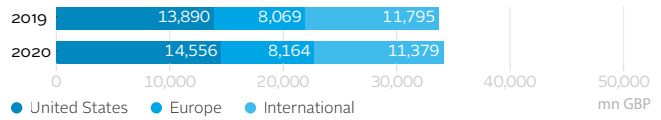
** Listed on the 2019 WHO EML.

*** Includes 17 projects not shown in the figure: 15 projects provided to the Benchmark on the basis of confidentiality and 2 projects in technical lifecycle (heat-stable and cold-stable formulations of GSK's Streptococcus pneumoniae (Synflorix®) vaccine).

Turnover by business segment



Turnover by region



PORTFOLIO for pathogens in scope

Mid-sized portfolio: At least 51 products: 28 antibacterial medicines; 19 antibacterial vaccines; 4 antifungal medicines
On-patent vaccines: 8 (Infanrix® IPV Hib, Infanrix® Hexa, Boostrix®, Infanrix® Hib, Boostrix® Polio, Menveo®, Bexsero®, Synflorix®)
Off-patent/generic medicines: 9 of 43 were selected for analysis* (amoxicillin [A], amoxicillin/clavulanic acid [A], cefadroxil [W], cefuroxime [W], clotrimazole [F], colistin [R], dapson [T], griseofulvin [F], polymixin B [R])
AWaRe medicines:** 8 Access group; 9 Watch group; 2 Reserve group
Anti-TB medicines:** 1

Pipeline for priority pathogens



Products on the market



A.2.2 Pipeline with highest number of innovative candidates

GSK's clinical-stage medicine pipeline consists of both innovative and adaptive R&D projects. GSK has four innovative medicine antibacterial candidates in clinical development, making the company's clinical pipeline the one with the highest number of innovative candidates among all companies evaluated in the Benchmark. This includes GSK-3036656, for the treatment of tuberculosis, which meets all four WHO's innovativeness criteria; and gepotidacin, for the treatment of infections caused by *Enterobacteriaceae* and *N. gonorrhoeae*, which belongs to a new chemical class and has a new mode of action. GSK also has a non-traditional medicine in clinical development.

A.2.3 Largest vaccine pipeline

GSK reports 16 vaccine projects in its pipeline. It is by far the largest vaccine pipeline of the six companies active in vaccine development. It includes 13 innovative and three adaptive pro-

jects. GSK's vaccines in clinical stages of development include candidates targeting *C. difficile*, *S. aureus* and *N. gonorrhoeae*. Moreover, GSK is developing M72/ASo1E in collaboration with the Bill & Melinda Gates Medical Research Institute, a Phase II tuberculosis vaccine candidate.

A.2.4 Largest number of projects targeting 'critical' and/or 'urgent' pathogens

GSK has 11 projects targeting pathogens defined as 'critical' by WHO's list of priority pathogens and/or characterised as 'urgent' threats by the US Centers for Disease Control and Prevention (CDC). In clinical development, GSK has medicine candidates against Carbapenem-resistant/ESBL-resistant *E. coli* and *N. gonorrhoeae*; and vaccine candidates against *C. difficile* and *N. gonorrhoeae*.

A.3 Company-wide commitments and project-specific plans for access and stewardship

GSK has five late-stage R&D projects target-

ing pathogens in scope. It reports having project-specific access plans for most of these projects. All five projects have ongoing trials in access countries.[†]

GSK reports that it has developed an equitable pricing strategy framework for low- and middle-income countries (LMICs) that applies across its portfolio and business units. Its access plans include equitable pricing strategies, registration filings, non-exclusive licensing and supply chain commitments. GSK states that it does not file patents in Least Developed or Low-Income countries nor does it enforce historic patents. GSK does not conduct clinical trials in countries where it does not intend to pursue registration and to make the product available for use. GSK commits to conducting global surveillance studies for its new antibacterials to enable appropriate use and support stewardship.

B RESPONSIBLE MANUFACTURING Evaluated: antibacterials manufacturing (APIs and drug products)

B.1 Comprehensive environmental risk-management for own sites and suppliers; tracks compliance with limits at own sites and suppliers

GSK reports a comprehensive strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every three years. It reports setting discharge limits in the receiving environment for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Discharge levels are quantified at all sites using a mass balance approach, verified by chemical analysis if applicable. GSK reports that all its 20 sites, or 100%, are compliant with discharge limits.

GSK requires third-party suppliers of antibacterials to follow the same standards, including limits based on PNECs. It reports conducting on-site audits every three years. It requests and reviews the discharge levels of its suppliers. It reports 37 of 39 supplier sites, or 95%, are com-

pliant with discharge limits.

GSK expects external private waste-treatment plants to comply with its general environmental standards. GSK audits these plants at least every 3 years (based on risk) which includes checking the suitability of technologies used for processing waste and protocols for preventing contamination. It requests external private and public wastewater treatment plants for dilution and flow rate data to inform the mass balance approach and employs conservative measures when needed.

B.2 Publicly discloses some information on environmental risk management and compliance with limits

GSK publishes some components of its environmental risk-management strategy and is a member of the AMR Industry Alliance. It discloses that all its 20 (100%) own sites manufacturing antimicrobials and 32 of 45 (71%) of supplier sites are compliant with discharge targets set by the AMR Industry Alliance.[‡] The discharge

levels themselves are not published. It also does not publish: (1) the results of environmental audits, conducted at its own sites, the sites of suppliers and/or external private and public waste-treatment plants; or (2) a list of these suppliers and plants.

B.3 System in place to maintain production quality for own and suppliers' sites; no requests for official corrective action

GSK reports that its own sites and suppliers have a system to maintain high-quality antibacterial production consistent with international GMP standards. This includes periodic risk-based audits and tracking of corrective and preventive actions. GSK does not require its suppliers to audit their own suppliers, but do encourage them to do so. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at GSK's own sites or any subsidiaries that manufacture antibacterials.

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries[†]

GSK is not eligible for indicators: C.1.1 and C.2.1. For more information, see Appendix VII.

C.1.2 Filed to register off-patent/generic medicines in 16 access countries on average

GSK performs above average, filing eight of its nine relevant off-patent/generic medicines for registration in 16 access countries on average. Its most widely filed relevant product is the antibiotic amoxicillin/clavulanic acid filed in 62 access

countries including 19 LICs. Seven of its relevant products are filed in less than 10 access countries.

C.1.3 Filed to register on-patent vaccines in 17 access countries on average

GSK has an average performance, filing seven of its eight relevant on-patent vaccines for registration in access countries. Its most widely filed relevant vaccine is the pneumococcal conju-

gate vaccine Synflorix[®], filed in 45 access countries followed by Infanrix[®] Hexa, its vaccine used to protect against diphtheria, tetanus, pertussis, hepatitis B, polio and bacterial meningitis (Hib), filed in 31 access countries. Two of its eight relevant vaccines are filed for registration in at least one LIC.

[†] 102 low- and middle-income countries where better access to medicine is most needed.

[‡] Discrepancy with compliance data in B.1 is explained by GSK's submission data

for the Benchmark being more up to date than publicly available data.

C.2.2 Several strategies to expand access to off-patent/generic medicines

GSK performs above average. It aims to expand access to its off-patent/generic medicines in access countries through donations, second-brands, patient support programs, tenders, and equitable pricing policies. GSK provides evidence of patient reach and geographic reach for all its reported approaches. For example, GSK donated more than 200,000 units of its branded amoxicillin/clavulanic acid antibiotic in 2020 through humanitarian partnerships, including one with Save the Children.

C.2.3 Several strategies to expand access to on-patent vaccines

GSK performs above average, with access strategies reported for all its eight relevant

on-patent vaccines in scope. It aims to expand access to its on-patent vaccines in access countries through tiered pricing policies and public or private partnerships. GSK partners with MSF and UNICEF to provide Synflorix® at the lowest price tier during humanitarian situations. GSK provides evidence of patient reach and geographic reach for some of its reported approaches. For example, it estimates that 56 mn doses of Synflorix® were supplied to Gavi-eligible countries in 2020, through its partnership with Gavi The Vaccine Alliance.

C.3 Leader in strategies to ensure continuous supply

GSK performs above average, with strategies reported in all four areas assessed. GSK ensures accurate demand planning and data

sharing by conducting 3-year forecasts and annual long-term demand forecasting (up to 10 years). GSK mitigates against shortage risks by keeping buffer stocks for both APIs and finished products. It ensures dual sourcing for critical APIs. GSK reports three capacity building or technology transfer initiatives in access countries, such as its support to the Strategic Training Executives Program (STEP) in GAVI-eligible countries. To mitigate against substandard and falsified products, GSK works closely with local law enforcement, conducts online and offline investigations or uses security features such as serialised barcodes and tamper-evident packaging.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Broad COI mitigation strategies in place for its educational programmes

GSK performs well in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. Four programmes have all three COI mitigation strategies looked for by the Benchmark: (1) content is developed independently from its marketing department; (2) a pledge not to provide financial or material incentives to participants; and (3) it does not use branded materials. The remaining programme has two COI mitigation strategies: in some countries where these programmes were presented the content could be branded.

C.5 Engages in sales and marketing practices to address appropriate use

GSK is middle-performing in sales practices. It reports that it partly decouples incentives for sales agents from sales volumes of its antibacterial and/or antifungal medicines. Its percentage of variable pay linked to sales volumes is 25%, and this is set at the smaller group level.

GSK engages in marketing practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines. Its marketing materials reflect emerging resistance

trends and/or include treatment guidelines for healthcare professionals. In some countries these include GSK SOAR surveillance data for the antibacterials amoxicillin/clavulanic acid (Augmentin™) and cefuroxime (Zinnat®).

C.6 Makes five types of brochure and/or packaging adaptations to facilitate appropriate use by patients

GSK adapts brochures and packaging to facilitate the appropriate use of amoxicillin/clavulanic acid (Augmentin™) by patients. GSK is the leader in this measure, taking account of language, adherence to treatment, literacy, the environment and paediatric use. For example, it has translated a Patient Knowledge Card into English, French and Portuguese. This card highlights information to improve adherence to treatment. Moreover, GSK has created blister packaging with a specific lidding foil that is sensitive to moisture for high humidity environments. Further, it has created oral suspensions and flavoured dosing syringes for paediatric patients in 35 countries.

C.7 Active in one AMR surveillance programme; openly publishes aggregated results

GSK runs the multinational Survey of Antibiotic Resistance (SOAR) programme, which is focused on community-acquired respiratory-tract infections in more than 30 countries and has been running since 2002. GSK only shares the aggregated results through peer-reviewed open-access journal articles. In addition, it will be sharing SOAR data with the University of Oxford and University of Washington (as part of the GRAM project) as well as on the AMR Register, an open-access data platform, with these projects aiming to complete in Q4 of 2021.