

**Overall Performance**

2020 2021

69% 81% ▲

# Pfizer Inc

Large R&D-based pharmaceutical company

Stock exchange: NYSE • Ticker: PFE • HQ: New York, NY, United States • Employees: 78,500

## PERFORMANCE

Pfizer performs well overall in its evaluated Research Areas compared to the other large research-based pharmaceutical companies in scope.

**R&D:** Pfizer performs strongly in R&D. Its 13-project pipeline includes five vaccines. Seven of its projects target critical and/or urgent pathogens. It has a novel antifungal in clinical development. Pfizer reports access and stewardship plans for all eight of its late-stage projects.

**Responsible Manufacturing:** Performs strongly. Reports comprehensive environmental risk-management strategy for own sites and suppliers; quantifies discharge levels at all its own and supplier sites.

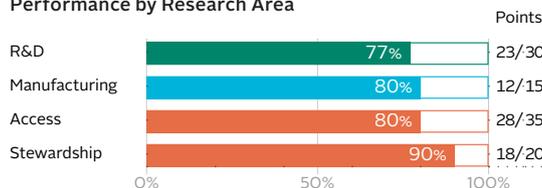
**Appropriate Access:** Performs strongly. Files some of its on-off-patent products for registration in access countries. Reports several strategies to expand access and ensure continuous supply of its relevant products.

**Stewardship:** Is the leader. It publicly shares raw data of its ATLAS surveillance programme. It fully decouples incentives for sales agents from antibacterial sales volumes in the UK. It reports comprehensive conflict of interest mitigation for its educational programmes. It adapts packaging for patients.

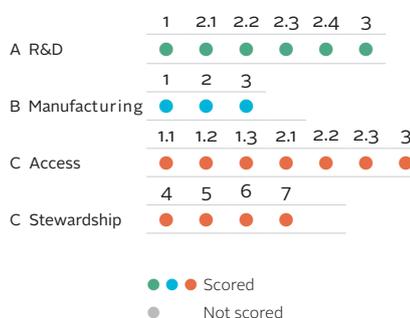
### Performance in the Benchmark



### Performance by Research Area



### How Pfizer was evaluated



## OPPORTUNITIES FOR PFIZER

**Fully decouple incentives for sales agents from sales volumes.** Pfizer fully decouples incentives for sales agents from sales volumes of antibacterial medicines in the UK. It can expand this practice to all countries it operates in and to all antibacterial and antifungal medicines.

**Expand breadth of R&D pipeline into more pathogens.** Pfizer has the largest late-stage clinical pipeline compared to peers in the AMR Benchmark. It has made a series of acquisitions of small biotech companies to increase the size of its pipeline. Pfizer can expand the focus of its pipeline to target resistant pathogens for which R&D is limited, such as *Campylobacter* spp. and *H. pylori*.

**Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites.** Pfizer tracks the compliance of all own sites with set discharge limits. It can also track such compliance of all its suppliers' sites since Pfizer reports all suppliers have quantified discharge levels and it can publicly disclose the results. The company currently publishes information on compliance of own and suppliers' sites with the guidelines of the AMR Industry Alliance but it is unclear whether this includes compliance to discharge limits.

**Expand registration of Trumenba® and NeisVac-C®.** Pfizer can file its vaccines Trumenba® and NeisVac-C® for registration in more countries, including low-income countries with a high burden of disease.

**Expand accessibility of its antibacterial and antifungal medicines in access countries.** Pfizer can implement new programs and partnerships to expand access to its antibacterial and antifungal medicines in access countries while demonstrating how it improves the availability and affordability of its medicines, including in low-income countries. For example, it can expand access to Zavicefta® and Zinforo® in Sub-Saharan Africa while taking ability-to-pay into account.

## CHANGES SINCE 2020

- In February 2021, BSAC, the European Bank for Reconstruction and Development, EBRD, and Pfizer co-created a global digital learning network for HCPs addressing AMR, antimicrobial stewardship (AMS), and COVID's impact on AMR and pandemic planning.
- Pfizer is addressing antimicrobial stewardship health disparities through multiple efforts. As part of its efforts, Pfizer and the Wellcome Trust launched the Surveillance Partnership to Improve Data for Action on Antimicrobial Resistance (SPIDAAR) in July 2020, which is a new collaboration with the governments of Ghana, Kenya, Malawi and Uganda to track resistance patterns and better understand the burden of AMR in LMICs.
- Pfizer purchased shares of ContraFect's common stock for approximately USD 3 mn. ContraFect intends to use the capital to fund its R&D activities, including a Phase III candidate targeting *S. aureus*.
- In the last year, Pfizer acquired Arixa Pharmaceuticals and Amplyx Pharmaceuticals, Inc., two companies focused on developing antibacterial and antifungal treatments, respectively.

**SALES AND OPERATIONS**

**Therapeutic areas:** Hospital, Inflammation & immunology, Internal medicine, Oncology, Rare diseases, Vaccines

**Business segments:** Biopharmaceutical products

**Product categories:** Biosimilars, Generic medicines, Innovative medicines, Vaccines

**M&A since 2020:** In July 2019, Pfizer and GSK combined their consumer health care business into a joint venture, with Pfizer controlling an equity interest of 32%. In November 2020, Pfizer spun its Upjohn Business off to combine it with Mylan N.V. to form Viatrix Inc. In October 2020, Pfizer acquired Arixa Pharmaceuticals, a company focused on developing next-generation oral antibiotics for drug-resistant Gram-negative infections. In April 2021, Pfizer acquired Amplyx Pharmaceuticals, Inc., including their lead drug fosmanogepix, a potentially first-in-class antifungal treatment.

**PIPELINE for pathogens in scope**

**Pipeline size:** 13 projects targeting pathogens in scope\* (7 antibacterial medicines; 5 antibacterial vaccines; 1 antifungal medicine).

**Development stages:** 6 clinical projects, including a Phase III vaccine candidate for *C. difficile* infections and a Phase II clinical vaccine candidate for the prevention of group B *Streptococcus* infections; and 5 discovery/pre-clinical projects.

**Novelty:** 1 project, potential first-in-class Phase II antifungal: fosmanogepix.

**'Critical' and/or 'urgent' pathogens:** 7 projects, with the focus on resistant *Enterobacteriaceae*, *C. auris* and *C. difficile*. Pfizer has a Phase III vaccine candidate for *C. difficile*. Its Phase II antifungal fosmanogepix targets *C. auris*.

**Regulatory approvals:** 4 approvals. In September 2019, the FDA gave a supplemental approval for ceftaroline fosamil (Teflaro®/Zinforo®)\*\* to treat Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in neonatal populations (from birth to less than 2 months of age). In June 2021, the FDA approved Prevnar20™, a pneumococcal 20-valent conjugate vaccine for adults. Avycaz®/Zavicefta®\*\*\* received two label extensions by the EMA in October 2020.

**PERFORMANCE BY RESEARCH AREA**

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

**A.1 Investments in R&D**

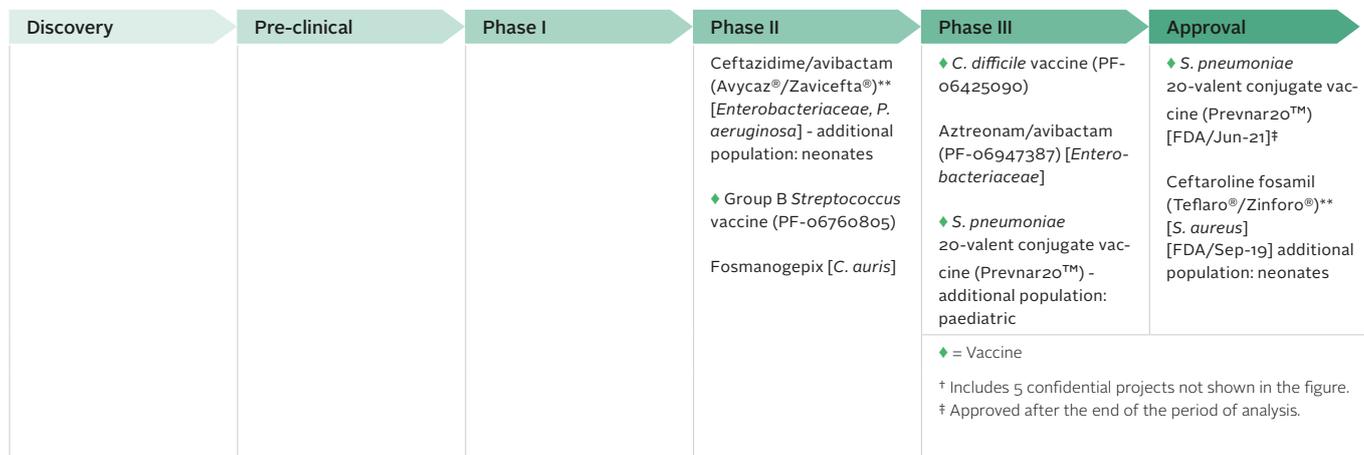
Pfizer does not disclose publicly, or to the Benchmark, its R&D investments during 2019 and 2020 in antibacterial and antifungal medicines and/or vaccines for pathogens in scope.

Pfizer has pledged USD 100 mn to the AMR Action Fund over the next ten years.

**A.2.1 Pfizer nearly doubles the size of its pipeline**

The company reports 13 projects targeting pathogens in scope: eight medicines and five vaccines.

Pipeline targeting priority pathogens: 13† As at 24 September 2021

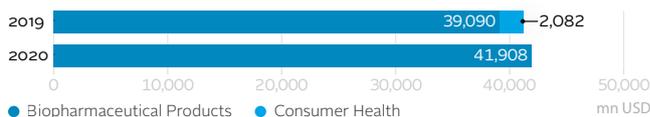


\* See Appendix V for information about eligibility for R&D projects and Appendix VII for eligibility criteria of products.

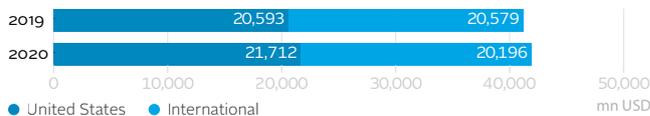
\*\* Avycaz® and Teflaro® are marketed by Allergan in the USA.

\*\*\* Listed on the 2019 WHO EML.

**Revenue by business segment**



**Revenue by region**



**PORTFOLIO for pathogens in scope**

**Comparatively large portfolio:** At least 116 products: 98 antibacterial medicines; 4 antibacterial vaccines; 14 antifungal medicines

**On-patent medicines:** 5 (anidulafungin, ceftazidime/avibactam, ceftaroline, isavuconazole, tavaborole)

**On-patent vaccines:** 4 (Trumenba®, NeisVac-C®, Nimenrix®, Prevnar 13®)

**Off-patent/generic medicines:** 10 of 107 were selected for analysis\* (amoxicillin [A], azithromycin [W], chloramphenicol [A], ethambutol/isoniazid/pyrazinamide/rifampicin [T], ethambutol/isoniazid/rifampicin [T], fluconazole [F], minocycline [W], polymyxin b [R], tigecycline [R], voriconazole [F])

**AWaRe medicines\*\*\*:** 26 Access group; 31 Watch group; 8 Reserve group

**Anti-TB medicines\*\*\*:** 11

**Pipeline for priority pathogens**



**Products on the market**



cines. Twelve targeting bacterial pathogens and one targets fungal pathogens. Out of the 13 projects, five are in discovery/preclinical stage, six are in clinical development and two received marketing approval.

#### A.2.2 Both innovative and adaptive medicine clinical candidates

Pfizer's clinical-stage medicine pipeline consists of both innovative and adaptive R&D projects. Pfizer is working on extending the indications of ceftazidime/avibactam (Avycaz®/Zavicefta®)\*\* and ceftaroline fosamil (Teflaro®/Zinforo®)\*\*. It is developing the combination of aztreonam/avibactam (PF-06947387) against MDR gram-negative infections. In April 2021, Pfizer acquired Amplyx Pharmaceuticals Inc and is now taking over the clinical development of its novel antifungal, fosmanogepix.

#### A.2.3 Five vaccine candidates

Pfizer reports five vaccine projects in its pipeline. It includes three innovative and two adaptive projects. Pfizer's vaccines in clinical stages of

development include candidates targeting *C. difficile*, group B *Streptococcus* and *S. pneumoniae*. In June 2021 Prevnar20™, a 20-valent pneumococcal vaccine was approved by the FDA. Pfizer is conducting Phase III trials to extend the use of this newly approved vaccine to paediatric populations.

#### A.2.4 Seven candidates targeting critical and/or urgent priorities

Pfizer has seven 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, Pfizer has medicine candidates against Carbapenem-resistant/ESBL-producing *E. coli* and *C. auris*, and a vaccine candidate targeting *C. difficile*.

#### A.3 Comprehensive planning for access and stewardship

Pfizer has eight late-stage R&D projects targeting pathogens in scope, the highest number across all the R&D-based companies evaluated,

four of them are vaccines. Three are in Phase II, three in Phase III and two have obtained marketing approval.

For seven out of eight of its projects in late-stage development, Pfizer has ongoing clinical trials or aims to file the successful products in access countries<sup>5</sup>. The plans for this projects include a wide range of access components such as filing for registration in access countries<sup>5</sup>, equitable pricing and measures to strengthen supply. Furthermore, its late-stage R&D medicine projects are covered by portfolio-wide stewardship plans, including initiatives for surveillance (ATLAS) and research and education on AMR (via unrestricted grants). For its recently acquired Phase II antifungal, fosmanogepix, Pfizer plans to continue the Expanded Access Programme that Amplyx Pharmaceuticals Inc had in place.

## 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

Pfizer 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. It reports that compliance of own sites with discharge limits is tracked.

Pfizer requires third-party suppliers of antibacterials to follow the same standards, including limits based on PNECs. It reports conducting on-site audits at least every five years. It requests and reviews the discharge levels of its suppliers. All supplier sites have quantified discharge levels.

Pfizer expects external private waste-treatment plants to comply with its general environmental standards. It audits these plants every 3-6 years which includes the suitability of technologies used for processing waste and pro-

ocols for preventing contamination. It also employs conservative measures for effluents sent to external private and public wastewater treatment plants.

### B.2 Publicly discloses some information on environmental risk management and commitment to set limits

Pfizer publishes some components of its environmental risk-management strategy. It is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Pfizer publishes its commitment to setting these targets. It also publicly discloses that it is developing a, AMR Industry Alliance sponsored, consensus-based standard to demonstrate responsible manufacturing of antibiotics. Pfizer publicly discloses that >90% of own sites are compliant with the guidelines of the AMR Industry Alliance, and that >80% suppliers are assessed against these guidelines. It is unclear whether such compliance also includes compliance with discharge limits. Pfizer 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; (2) a list of these suppliers and plants; or (3) the levels of antibacterial discharge

from its own or suppliers' sites.

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

Pfizer 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. Pfizer also requires its suppliers to audit their own suppliers. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Pfizer'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<sup>5</sup>

### C.1.1 Filed to register on-patent medicines in 14 access countries on average

Pfizer performs above average, filing four of its five relevant on-patent medicines for registration in 14 access countries<sup>5</sup> on average. Its most widely filed relevant product is the antifun-

gal anidulafungin (Eraxis; Ecalta®) used to treat invasive candidiasis, filed in 22 access countries. Its reserve antibiotic, ceftazidime/avibactam (Zavicefta®), was filed for registration in 20 access countries, including three LICs. Its antifungal isavuconazole (Cresemba®) was filed for

registration in nine access countries.

### C.1.2 Filed to register off-patent/generic medicines in 17 access countries on average

Pfizer performs above average, filing eight of ten relevant off-patent/generic medicines for reg-

\*\* Avycaz® and Teflaro® are marketed by Allergan in the USA.

<sup>5</sup> 102 low- and middle-income countries where better access to medicine is most needed.

istration in 17 access countries on average. Its most widely filed relevant product is the antifungal fluconazole, filed in 52 access countries. Six of its sample products are filed in less than 10 access countries. Four of its sample products are filed for registration in at least one LIC.

### C.1.3 Filed to register on-patent vaccines in 24 access countries on average

Pfizer has an average performance, filing three of its four relevant on-patent vaccines for registration in access countries. Its most widely filed relevant vaccine is the Pneumococcal Conjugate Vaccine (13-valent) (Pevnar 13<sup>®</sup>) filed in 65 access countries. Pevnar 13<sup>®</sup> is followed by the meningococcal vaccine Nimenrix<sup>®</sup>, filed for registration in 23 access countries, including LICs.

### C.2.1 Several strategies to expand access to on-patent medicines

Pfizer performs above average, with access strategies reported for three of five relevant on-patent medicines. It aims to expand access to its on-patent medicines in access countries through equitable pricing policies, one price per patient capitation model, and patient assistance programs. To set the prices of ceftazidime/avibactam (Zavicefta<sup>™</sup>) and isavuconazole (Cresemba<sup>®</sup>), Pfizer takes into account local economic conditions, the average income, and GDP growth. It allows for net price flexibility for specific procurement requests. Pfizer provides evidence of patient reach and geographic reach

for all its reported approaches. It estimates to have ensured access to ceftaroline (Zinforo<sup>®</sup>) ceftazidime/avibactam (Zavicefta<sup>™</sup>) and isavuconazole (Cresemba<sup>®</sup>) for 51,000 cumulative patients in low- and middle-income countries in 2020.

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

Pfizer performs above average, with access strategies reported for four of its ten relevant off-patent/generic medicines. It aims to expand access in low- and middle-income countries through donations and public/private partnerships. It provides evidence of patient and geographic reach for all its reported approaches. Pfizer takes part in the International Trachoma Initiative (ITI) and donated 31 mn azithromycin treatments to 12 countries in 2020. It extended its donation program until 2025. Through its Diflucan<sup>®</sup> Partnership Program, Pfizer distributed 7mn doses of fluconazole to nine access countries through governments and NGOs in 2019 and 2020.

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

Pfizer performs above average, with access strategies reported for one of its four relevant on-patent vaccines. It aims to expand access in access countries through equitable tiered pricing, public/private partnerships, humanitarian emergency assistance settings and tenders.

It has set a six-tiered pricing policy for Pevnar 13<sup>®</sup>. The tiers are defined by several criteria such as countries' GNI per capita. Pfizer partners with Gavi to provide Pneumococcal Conjugate Vaccine (13-valent) (Pevnar 13<sup>®</sup>) to Gavi-eligible and Gavi-transitioned countries at a public price of USD 2.90 per dose until 2027. Pfizer provides evidence of patient reach and geographic reach for all its reported approaches. It commits to supply 930 mn doses of its Pneumococcal Conjugate Vaccine (13-valent) (Pevnar 13<sup>®</sup>) by 2027 through its partnership with Gavi.

### C.3 Several strategies to ensure continuous supply

Pfizer performs above average, with strategies reported in all four areas assessed. Pfizer ensures accurate demand planning and data analytics by forecasting on a monthly and 24-month rolling basis. Pfizer mitigates against shortage risks by keeping buffer stocks for its finished products at country-level, for APIs at a global-level, and manufactures some of its APIs in-house. Pfizer reports one technology transfer initiative. Since 2014, it has engaged in a public/private partnership in South Africa to enable a local partner to manufacture Pneumococcal Conjugate Vaccine (13-valent) (Pevnar 13<sup>®</sup>). To mitigate against sub-standard and falsified products, Pfizer maintains a Disruption Program which identifies and disrupts online illicit sales. Pfizer uses serialisation with unique products identifiers and has a public counterfeit awareness page.

## C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

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

Pfizer performs strongly in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. To mitigate COI for all five programmes, it provides financial resources to independent third parties (BSAC, the University of Dundee, EBRD, ISID and Micron) to develop the programme.

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

Pfizer performs above average 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 is capped at 30% and sales targets are set at the national level. Its incentives for sales agents in emerging markets in Asia are provided on the basis of confidentiality. However, Pfizer does not reward its sales agents based on antibacterial volumes sold in the UK.

Pfizer engages in marketing practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines consistent with the approved indication. Its marketing materials reflect emerging resistance trends

and/or include treatment guidelines for healthcare professionals: for all antibacterial medicines and isavuconazole (Cresemba<sup>®</sup>), by using data from its ATLAS surveillance programme in the materials.

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

Pfizer adapts packaging to facilitate the appropriate use of azithromycin (Zithromax<sup>®</sup>) by patients. Pfizer performs strongly in this measure, taking account of adherence to treatment, paediatric use and language. It adapts the packaging of azithromycin, named the Z-Pak, which facilitates patient adherence by organising the pill intake for each day, so that the patient knows exactly which pill(s) to take on which day until the Z-Pak is completed. Moreover, Pfizer includes a QR code on the packaging of azithromycin as an oral suspension that directs patients to a video explaining how to administer the oral suspension properly for adults and children. This is applied in Vietnam and the Philippines and the video will be played in the local language. Finally, Pfizer has translated instructions on the packaging to the local language in Japan.

### C.7 Active in multiple AMR surveillance programmes; one openly shares raw data

Pfizer leads in this area. It is active in multiple AMR surveillance programmes. It runs the multinational ATLAS programme, which is focused on resistance against its antibacterial and antifungal medicines in 81 countries and has been running since 2004. Pfizer shares the raw data on the AMR Register, an open-access data platform, as well as the aggregated results on the ATLAS website and through peer-reviewed open-access journal articles. For the remaining programmes, only the aggregated results are shared through peer-reviewed open-access journal articles, as well as on open-access data platforms for the SENTRY programme (an antifungal resistance programme managed by JMI laboratories) and the CANWARD programme (a national programme managed by the Canadian Antimicrobial Resistance Alliance).