Sanofi

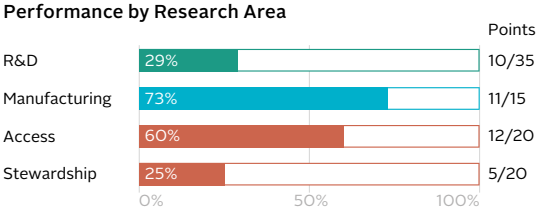
Large R&D-based pharmaceutical company
Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 104,226

PERFORMANCE

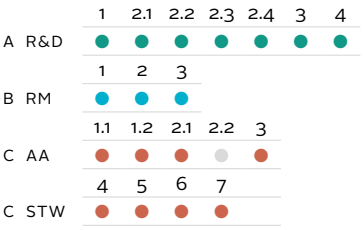
Sanofi performs less well in its evaluated Research Areas when compared to other large R&D-based pharmaceutical companies in scope.
R&D: Performs less well. Transferred its infectious diseases R&D unit to Evotec in 2019 but maintains a pipeline of six medicines and vaccines projects that target priority pathogens. Reports access plans for two late-stage vaccine projects.
Responsible Manufacturing: Performs well. Reports comprehensive environmental risk-management strategy for own sites and suppliers, however reports less information than the leaders on the progress in the implementation of discharge limits.
Appropriate Access: Middle-performing. Files its relevant vaccines in access countries. It discloses limited information regarding the access countries in which it has filed its relevant off-patent antibacterial and antifungal medicines for registration. It discloses several strategies on how it ensures the continuous supply of its products including forecasting and safety stocks.
Stewardship: Performs less well. Its educational programmes have some conflict of interest (COI) mitigation. It is active in surveillance in France, but does not share data publicly. It does not adapt its brochures or packaging to facilitate appropriate use.

Performance in the Benchmark

Performance by Research Area



How Sanofi was evaluated

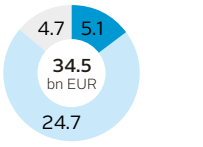


Each indicator is worth a max score of 5. Indicators are not applicable to every company. See Appendix for full overview.

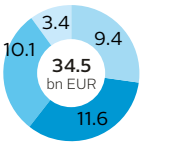
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular diseases; Diabetes; Infectious diseases; Neurology; Rare diseases; Urology
Business segments: Sanofi Pasteur; Primary Care; Consumer Healthcare; Sanofi Genzyme; Winthrop
Product categories: Consumer healthcare; Generic medicines; Innovative medicines; Vaccines
Manufacturing & supply: No information available
M&A since 2018: In July 2018, Sanofi completed the transfer of its infectious diseases R&D unit, including licensing, to Evotec for USD 70 million cash and guaranteed financial commitment for five years. In October 2018, Sanofi completed the divestment of its European generic business Zentiva to Advent International for USD 2.38 billion.

Revenues by product (2017-18)



Revenues by region (2017-18)



PIPELINE *for diseases in scope*

Pipeline size: 6 projects for priority pathogens* (2 antibacterial medicines and 4 antibacterial vaccines)
Development stages: 6 clinical projects, including a Phase III clinical trial to create a shorter and simpler rifapentine dosing regimen for the treatment of latent and active tuberculosis (TB) compared to existing six-month treatments
Novelty: No novel clinical-stage medicine projects
Regulatory approvals: 0 approvals for priority pathogens
Access plans: 2 of 4 late-stage R&D projects with project-specific access plans, both of which include plans for WHO prequalification for vaccine projects.
Stewardship plans: Its 1 late-stage R&D medicine project lacks a project-specific stewardship plan.

PORTFOLIO *for diseases in scope*

Mid-sized portfolio: At least 102 products (53 unique INNs): 86 antibacterial medicines; 13 antibacterial vaccines; 3 antifungal medicines
Essential medicines: 50% (51) products are on the 2019 WHO EML
AWaRe medicines:** 9 Access group; 13 Watch group; 2 Reserve group
Anti-TB medicines:** 12 products

Pipeline for priority pathogens

Products on the market

* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

** Listed on the 2019 WHO EML (Section 6).

All companies were assessed based on data available in the public domain, including information the companies have made publicly available. This was supplemented by data submitted directly to the Benchmark by the companies. Sanofi declined to submit data to the 2020 AMR Benchmark.

OPPORTUNITIES FOR SANOFI

Maintain engagement on AMR and increase disclosure of AMR strategies and activities. While Sanofi transferred its infectious diseases R&D unit to Evotec in July 2018 and did not submit data for the Benchmark, it is a key player to limit drug-resistant infections, with an active R&D pipeline of vaccines and 51 marketed antibacterial and/or antifungal medicines on the 2019 WHO EML. Sanofi can disclose more information (publicly and/or through the Benchmark) about its strategies to improve access and stewardship to the medicines within its portfolio, including their availability in access countries and its steps to mitigate the risk of inappropriate use.

Follow up to public commitments and increase public disclosure on environmental risk management. Following up on its commitments as a signatory to the Industry Roadmap for Progress on Combating AMR, Sanofi can work with stakeholders to develop a practical mechanism to publicly disclose (1) a list of its suppliers and waste-treatment plants and (2) the results of environmental audits and the levels of antibacterial discharge from its own sites and the sites of its suppliers.

Decouple sales incentives from sales volumes and/or avoid deploying sales agents. In order to mitigate the risk of inappropriate use, Sanofi can decouple sales incentives from sales volumes and/or avoid deploying sales agents, as appropriate, for its antibacterial and/or antifungal medicines.

CHANGES SINCE 2018

- Transferred its infectious diseases R&D unit, including the majority of R&D assets and 100 employees, to Evotec in July 2018.

PERFORMANCE BY RESEARCH AREA

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

A.1 No information on relevant R&D investments

Sanofi does not report publicly, or to the Benchmark, how much it invested in R&D for antibacterial medicines, antifungal medicines and/or vaccines in 2017 and 2018.

A.2.1 Pipeline size small compared to peers

Among the large research-based pharmaceutical companies evaluated, this pipeline is small in size. Sanofi reports six projects targeting priority pathogens in its pipeline, all of which target bacterial pathogens, including four vaccine and two medicine projects. All six projects are in clinical development.

A.2.2 No clinical-stage novel projects

Sanofi's clinical-stage medicine pipeline for priority pathogens consists entirely of adapted R&D projects. It does not currently include candidates that are considered novel. However, Sanofi is developing a water-dispersible fixed-dose combination of isoniazid/rifapentine for the treatment of latent TB infection in children.

A.2.3 Four vaccines in the pipeline

Sanofi reports four vaccine projects in its pipeline, including two new projects: one next-generation pneumococcal conjugate vaccine being co-developed with SK Bioscience; one TB recombinant subunit vaccine being co-developed with Statens Serum Institute, Valneva, and the International Aids Vaccine Initiative (IAVI); and two adapted projects. All vaccine candidates are in clinical development.

A.2.4 No candidates targeting critical and/or urgent priorities

Sanofi does not have any candidate targeting pathogens considered critical and/or urgent R&D priorities for limiting AMR, as defined by WHO and/or the US Centers for Disease Control and Prevention (CDC).

A.3 No intellectual capital sharing practices

The company does not report any intellectual capital sharing initiatives.

A.4 Access plans for two of four projects

Sanofi has four late-stage R&D projects targeting priority pathogens, of which two have access plans. It is applying for WHO prequalification for its TB vaccine and its DTP-HepB-Polio-Hib vaccine. Submitting products to WHO's prequalification process allows for UN procurement and accelerates registration processes in countries with weak national regulatory authorities. Its one medicine candidate does not have an access or stewardship plan in place.

Pipeline targeting priority pathogens: 6 *As at 16 October 2019*

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Approval
		Rifapentine/isoniazid** - *M. tuberculosis* - Adaptation (FDC water-dispersible formulation for paediatric patients)	♦ *M. tuberculosis* recombinant subunit vaccine (H4-IC31®)	Rifapentine - *M. tuberculosis* - Adaptation (shorter and simpler dosing regimen)	
		♦ Next-generation pneumococcal conjugate vaccine (Skypac) - *S. pneumoniae*		♦ DTP-HepB-Polio-Hib paediatric hexavalent vaccine (Shan 6) - *H. influenzae* type B	
				♦ DTP-Polio-Hib paediatric pentavalent vaccine - *H. influenzae* type B	

♦ Vaccine
FDC = Fixed-dose combination
DTP = Diphtheria, tetanus and pertussis
HepB = Hepatitis B
Hib = *Haemophilus influenzae* type B

** After the period of analysis, the project has moved to Phase II.

* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

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

B.1 Comprehensive environmental risk-management with less information on discharge limits for own sites and suppliers

Sanofi has a comprehensive strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, with an aim to limit AMR. This includes audits every three years. The company reports setting discharge limits for antibacterials manufactured at its sites based on PNECs to limit AMR (or more stringent PNECs), having first covered API sites and currently moving into drug product sites.

Sanofi expects third-party suppliers of antibacterial APIs and drug products to follow a specified set of standards. Its suppliers are covered by a programme that aims to review management practices with respect to discharge of antibacterials to the environment. Sanofi prioritised these suppliers for auditing in 2017 and 2018, and reports that corrective action plans were issued. There is limited information on whether Sanofi requires suppliers to set antibacterial discharge limits. It expects external private waste-treatment plants to comply with its environmental standards, but there is limited information on how plants are audited. The company does not report whether it requires the wastewater plants to set antibacterial discharge limits.

B.2 Publicly discloses some information on environmental risk management

Sanofi publishes some components of its environmental risk-management strategy. Further, it is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. The underlying methodology was summarised in an open-access journal article co-authored by Alliance members including Sanofi. Sanofi does not publish: (1) the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private waste-treatment plants; (2) a list of these suppliers and waste-treatment plants; or (3) the levels of antibacterial discharge from its own sites.

B.3 Has system to maintain production quality for own and suppliers' sites: no requests for official corrective action

Sanofi reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards. This includes risk-based internal audits and tracking of corrective and preventive actions. The company reports requiring suppliers to abide by regulatory and company quality standards. This includes submitting suppliers to a qualification process, after which a quality technical agreement is established and routine audits are conducted. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Sanofi's own sites or any subsidiaries.***

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

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

C.1.1 Filed to register two of its five on-patent products in 10+ access countries

Sanofi is one of the leaders when it comes to filing relevant on-patent products‡ for registration. It files its products in 20.4 access countries on average. Overall, 40% of its relevant on-patent products are filed in 10+ access countries (2/5). Its most widely filed relevant on-patent products are the vaccines Hexaxim® (for DTP-Hib-Polio-Hep B) and Shan5™ (for DTP-Hib-Hep B), filed for registration in 59 and 43 access countries, respectively.

C.1.2 Limited information on registration filings for off-patent products

Sanofi performs less well than its peers in this area, as it discloses limited information regarding the access countries in which it has filed its relevant off-patent products (antibacterial and antifungal medicines) for registration.

C.2.1 Takes socioeconomic factors into account when setting prices

When setting prices for on-patent products, Sanofi considers socioeconomic factors, including Gross National Income (GNI) per capita. Five products were included for analysis, all vaccines. Sanofi has tiered pricing policies through which its vaccines are made available to pooled-procurement agencies, including WHO, Gavi the Vaccines Alliance and the United Nations Children's Fund (UNICEF). Sanofi has made a general commitment to ensuring the prices of its vaccines are sustainable and equitable. Sanofi does not disclose how it plans to increase the affordability of these products over the next five years.

C.2.2 Pricing strategies for off-patent products
Companies were not scored for this indicator as the available data was insufficient for a comparative analysis. Sanofi reports that it aims to consider unequal living conditions in its pricing strategies. It does not disclose whether it considers affordability or socioeconomic factors when setting prices for off-patent antibacterial or antifungal medicines or vaccines.

C.3 Several strategies to ensure the continuous supply of relevant products

Sanofi is a middle-performing company compared to other large research-based pharmaceutical companies evaluated when it comes to taking steps to ensure the continuous supply of its relevant products to access countries. It has short-term (up to 36 months) and long-term (36 months to 5/10 years) forecasting for demand planning and inventories of finished goods to last between two and three months in order to avoid stockouts. It has developed a Procurement Risk Management Model to address the full range of procurement risks and to guarantee appropriate risk assessment and mitigation. Sanofi engages in capacity building through the training and employment of local staff in line with International GMP. It has strategies in place to reduce distribution of falsified medicines and an Anti-Counterfeiting Laboratory.

*** Including only wholly-owned direct subsidiaries of the company. More information in Appendix I.

† 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.

‡ See Appendix VII.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Some COI mitigation for all educational programmes

The Benchmark analysed two AMR-related educational programmes for healthcare professionals (HCPs) from Sanofi. Sanofi reports some COI mitigation for these two programmes. Both programmes have two of three COI mitigation strategies looked for by the Benchmark: (1) a pledge not to provide financial or material incentives to participants; and (2) it does not use branded materials. However, it is unclear whether content for these programmes is developed independently from Sanofi's marketing department.

C.5 No information on marketing or sales practices that aim to address appropriate use

There is no information regarding Sanofi's engagement in practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines, either regarding its marketing materials or its sales practices.

C.6 No information on brochure and/or packaging adaptations to facilitate appropriate use

There is no information regarding Sanofi's adaptations in its brochures and/or packaging to facilitate appropriate use of its antibacterial and/or antifungal medicines by patients beyond regulatory requirements.

C.7 Active in one AMR surveillance programme

Sanofi is active in one long-term AMR surveillance programme. The programme is run by the National Reference Centre for Pneumococci (NRCP) with the French Regional Pneumococcal Observatories. It runs periodically and focuses on *S. pneumoniae* in France. The NRCP only shares the results of the programme through peer-reviewed journal articles. However, these articles are not open access. The programme covers 10 antibacterials and includes 400 health facilities. Sanofi does not report making antibacterial and/or antifungal consumption data available to national governments or other public health authorities.