RANK	SCORE
7▼	2.49
6 (2016)	

Sanofi

Stock Exchange: EURONEXT Paris • Ticker: SAN • HQ: Paris, France • Employees: 100,000

PERFORMANCE

Falls 1 place to 7th. While the company is a top performer in R&D, it slips compared to peers in its overall approach to pricing and is amongst the few companies not to disclose patent statuses and clarify filing/enforcement policies.

Management: Holds 7th place, with limited public disclosure of the company's approach to stakeholder engagement.

Compliance: Holds 5th place, with a solid performance on mitigating the risk of non-compliance, but with sales agents remaining solely incentivised by sales targets.

R&D: Falls 1 place to 5th. Amongst the top performers in R&D for its priority R&D and access plans. However, pipeline progression is comparatively average.

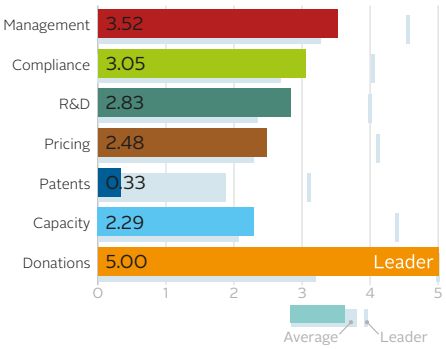
Pricing: Falls 2 places to 6th. Comparatively strong performance in registration, but pushed slightly down due to stronger performances from peers in both inter- and intra-country equitable pricing strategies.

Patents: Fall 2 places to 18th. Unlike many of its peers, it has no public position on patent filing and enforcement in low- and middle-income countries, or disclosure of patent status.

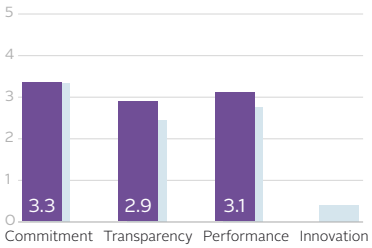
Capacity: Maintains 8th place with a strong focus on manufacturing and health systems strengthening.

Donations: Takes the lead, with a strong donation programme aiming to eliminate human African trypanosomiasis.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Review policies for access-oriented IP management. Sanofi is one of five companies that does not yet commit to not file for and/or not enforce patents in the poorest countries. Sanofi can look to adopt a general public stance to not filing for or enforcing patents related to diseases in scope in Least Developed Countries, low-income countries, and in a subset of middle income countries. Further, Sanofi can publicly disclose the status of its patents, clearly showing where products are on- and off-patent, and when patents are due to expire. Sixteen peers joined Pat-INFORMED, a platform to promote the accessibility of patent information for health agencies tasked with the procurement of medicines. Sanofi could disclose patent information via this platform, or also elect to self-disclose patent status.

Improve access plans for R&D projects during development. Although Sanofi has the third-highest proportion of late-stage R&D projects with access plans in place, its process to establish these provisions can be strengthened. For example, the company can go further than plans for WHO prequalification, and also implement equitable pricing strategies and registration targets. Sanofi can expand access planning to all R&D projects, regardless of product type and in-house or collaborative status, and implement a firmer timeline for developing these access provisions by Phase II of clinical development. Specific examples include developing access provisions for projects such as its Phase II clinical candidate preventive vaccine for respiratory syncytial virus (RSV) and its newly approved insulin lispro biosimilar, Admelog®.

Review sales incentive structures. Sanofi can work towards decoupling sales incentives from sales targets to better incentivise responsible practices. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for e.g, rational prescribing. This can be critical for a company like Sanofi that produces antibiotics and other products which are often inappropriately used.

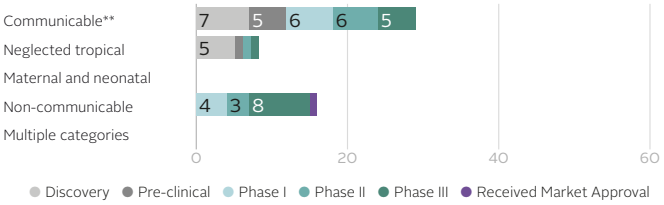
CHANGE SINCE 2016

- Entered into a technology transfer agreement with Moroccan manufacturer, Maphar, in 2017 to support the local production of Sanofi products and help improve supply in Africa.
- Joined Access Accelerated with multiple initiatives including its mental health programme, FAST (Fighting Against Stigma). It has also committed to measure impact and share results publicly via Access Observatory.
- Launched the Faster2Care drone delivery project to improve delivery of essential medicines in the Great Mekong Subregion to help control artemisinine resistance and contribute to malaria elimination in the region.
- Working since September 2016 with ACAME (Association des Centrales d'Achats Africaines de Médicaments Essentiels) to build supply chain capacity for central medical stores in the Western and Central African regions.
- Outsources research on antimicrobials to Evotec.

PIPELINE *for diseases and countries in scope*

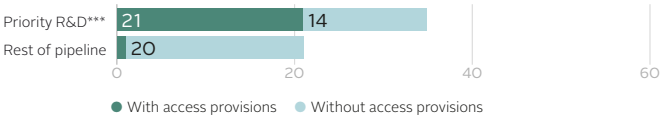
Mid-sized pipeline: 56 R&D projects for diseases in scope (36 medicines; 20 preventive vaccines).
Clinical candidates: 36, including fexinidazole for the treatment of human African trypanosomiasis and a preventive vaccine for rabies.
Regulatory approvals: 1, including a biosimilar for insulin lispro (Admelog®) for the treatment of diabetes mellitus.
R&D focus: communicable diseases (lower respiratory infections and TB) and non-communicable diseases (diabetes mellitus).
Access provisions: for 22 projects, most commonly plans to apply for WHO prequalification.

Projects in the pipeline: 56*



Over one-third of Sanofi's pipeline consists of preventive vaccine candidates including a paediatric vaccine for the prevention of diphtheria, hepatitis B, pertussis, poliomyelitis, tetanus and infections caused by *H. influenzae* (Hexaxim®).

Projects for R&D priority targets with access provisions: 21

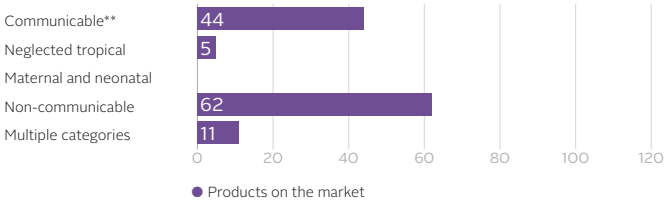


Of Sanofi's 56 R&D projects, 22 are supported by access provisions: e.g., Sanofi's oral cholera vaccine, Shanchol™, has received expanded WHO prequalification for storage at temperatures up to 40°C for up to 14 days before use. Ten of its 25 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

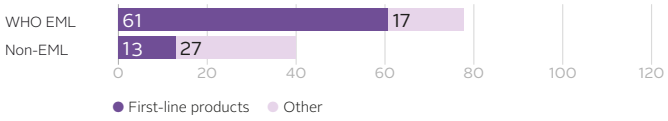
Comparatively large portfolio: 122 products for diseases in scope (102 medicines; 16 preventive vaccines; 4 platform technologies).
Portfolio focus: non-communicable diseases (diabetes mellitus and ischaemic heart disease) and communicable diseases (lower respiratory infections and diarrhoeal diseases).
Essential medicines: 66% of Sanofi's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 63% of Sanofi's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 122



Sanofi's portfolio includes products such as the antibiotics teicoplanin (Targocid®) and cefpodoxime (Orelox®); and melarsoprol (Arsobal®) and eflornithine (Ornidyl®) for the treatment of human African trypanosomiasis.

Essential medicines with first-line indications: 61



77% of Sanofi's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., recombinant human insulin (Insuman®) and its meningococcal quadrivalent A, C, Y and W-135 vaccine (Menactra®).

BUSINESS CONTEXT

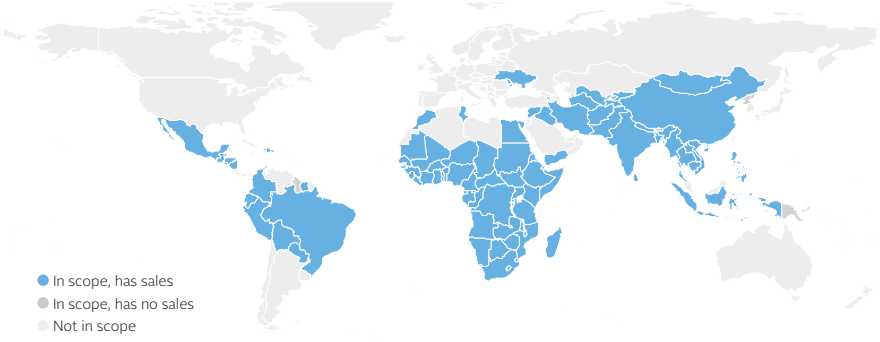
Five business units: Diabetes & Cardiovascular, Consumer Healthcare, Vaccines, Specialty Care (rare diseases, multiple sclerosis, oncology & immunology), General Medicines & Emerging Markets (established prescription products & generics). Its vaccines portfolio focuses on paediatric vaccines, influenza, adult and adolescent booster vaccines, meningitis, and travel and endemic vaccines.

M&A news: 2016 conclusion of joint vaccines venture with Merck & Co., Inc. in Europe to independently manage their product portfolios. 2018 acquisition of Ablynx, a biopharmaceutical company.
Presence in emerging markets: In 2018, Sanofi reports sales in 93 countries in scope; three less than in the 2016 Index. It is the company with the second highest number of countries in scope with sales. It reports that approximately 30% of its sales in 2017 came from emerging markets.

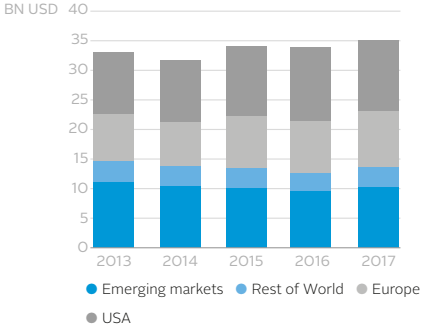
Net sales by segment (2017) - EUR

Pharmaceuticals	29,954 MN
Vaccines	5,101 MN
Total	35,055 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes 3 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control 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.

Sanofi

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 7 SCORE 3.52

Has a strong access-to-medicine strategy with executive level responsibility. Sanofi is one of the 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy centres around the development of new business models focused on developing medicines for unmet needs, affordability and strengthening healthcare systems. The highest level of responsibility for access sits with executive committee members.

Financial and non-financial access-related incentives to reward employees. Sanofi 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 salary increases, bonuses and awards.

One of 16 companies working on impact measurement. Sanofi measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its Global Polio Eradication initiative, the company is committed to adapt its production capacity based on needs, and to help provide vaccines to millions of children around the world, reporting a sustained reduction from 350,000 cases in 1988 to 22 in 2017. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Some transparency about stakeholder engagement approach. Sanofi publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 5 SCORE 3.05

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Sanofi has a code of conduct and policy relating to ethical marketing and anti-corruption. It provides regular compliance training for employees through e-learning tools. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Sanofi's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism, and performs regular evaluations that also apply to third parties. It reports that it regularly conducts fraud-specific risk assessments, and has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of a monitoring system for compliance in place.

Above average transparency regarding access-related practices. Sanofi publicly discloses its policy positions on access-related topics (e.g., its global medicine protection strategy includes its position on counterfeit medicines). It is one of the few companies to have a global policy that prohibits political financial contributions. The company publicly discloses its financial support and membership of relevant organisations. It publicly discloses its policies for responsible engagement in its Code of Ethics. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 5 SCORE 2.83

PROJECTS: 56 IN CLINICAL DEVELOPMENT: 36

Publicly commits to R&D to meet public health needs. Sanofi 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 based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Sanofi has a mid-sized pipeline in the Index with 56 projects. For diseases in scope where priorities exist, Sanofi is active in 38 projects; 35 of these target priority R&D gaps.

Access provisions in place for 40% (10/25) of late-stage candidates. Sanofi has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely vaccines. To date, Sanofi has project-specific access provisions in place for 10 of its late-stage R&D projects, eight of which are preventive vaccine candidates. Of these, four are being conducted in partnership with organisations including the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases initiative (DNDi).

Policy to ensure post-trial access; commits to conduct clinical trials only where it intends to make the product available. Sanofi has a 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. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Sanofi commits to only perform clinical studies in countries where it intends to make the product available.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 6 SCORE 2.48

PRODUCTS: 122

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 35

Does not publicly commit to equitable pricing or report a commitment to file to register products in scope. Sanofi does not commit to filing its newest products for registration in countries in scope within one year of first market approval. It also does not publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

Some new products in scope filed for registration in the majority of priority countries. Sanofi has filed 40% 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). It also publicly shares some registration information for the minority of its products.

29% of products have equitable pricing strategies targeting priority countries. Sanofi's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 29% of its products for diseases in scope. These

strategies apply to an average of 35% of priority countries. Some of these strategies apply both inter- and intra-country pricing strategies; these take into account an average of one and two socioeconomic factors, respectively. Sanofi also applies equitable pricing strategies to six further products informed by a public health rationale.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Sanofi 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 18 SCORE 0.33

Does not publicly disclose patent statuses. Unlike most of its peers, Sanofi does not disclose the status of its products for diseases and countries in scope.

No use of non-assert or licensing arrangements. Sanofi does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing long term commitment agreements. Sanofi reported existing agreements with product development partnerships, including DNDi, MMV and TB Alliance. During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. Sanofi does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries. However, Sanofi shares information via the Index that it does not file or enforce patents in Least Developed Countries or low-income countries.

CAPACITY BUILDING

RANK 8 SCORE 2.29

18 initiatives included for evaluation. Sanofi has 18 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; Sanofi submitted 23.

Strong focus on local manufacturing and strengthening health systems. Sanofi has initiatives which meet inclusion criteria in all five areas of capacity building. Most of these initiatives are focused on manufacturing and health system strengthening; it performs strongest in manufacturing capacity building with multiple technology transfers.

Six initiatives meet all applicable good practice standards:
- Technology transfer to Maphar (Morocco)
- Technology transfer to Abidi (Iran) for supplying Iranian market
- Vaccines manufacturing partnerships
- ACAME capacity building
- FAST (Fighting Against STigma)

A full list of Sanofi's capacity building initiatives which meet all good practice standards can be found at online.
Most of its other included initiatives have good governance structures in place, but it commonly falls short on setting clear, measurable goals & objectives and monitoring progress against them.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Sanofi has a policy for reporting cases of substandard or falsified medicines to relevant authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 1 SCORE 5.00
STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Sanofi donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to floods and landslides in Peru and heavy rains in India. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with the NGOs such as Cruz Roja Peruana, Tulipe Association and Americares to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Sanofi's programme is focused on neglected tropical diseases (NTDs). The programme is carried out in partnership with WHO and has been ongoing since 2001. Its NTD programme for human african trypanosomiasis supplies eflornithine (Ornidyl®), melarsoprol (Arsobal®) and pentamidine (Pentacarinat®) reaches 17 countries, and Sanofi reported reaching more than 2000 patients in 2016.

Addresses long-term access by aiming to eliminate disease. Sanofi commits to long-term structured donation programmes by aiming to eliminate the diseases in question. Its eflornithine (Ornidyl®), melarsoprol (Arsobal®) and pentamidine (Pentacarinat®) donation programme aims to eliminate human african trypanosomiasis (HAT) in 17 countries by 2020.

BEST PRACTICES

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.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.