

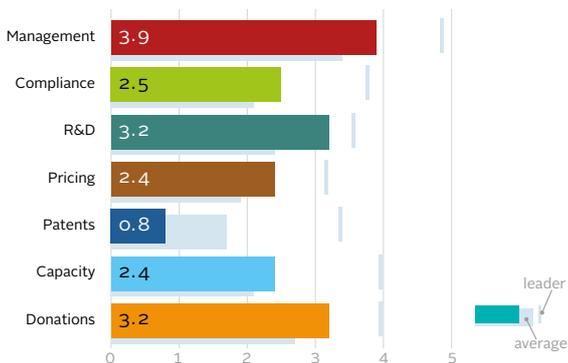
RANK	SCORE
6 [▲]	2.58
8 (2014)	

Sanofi

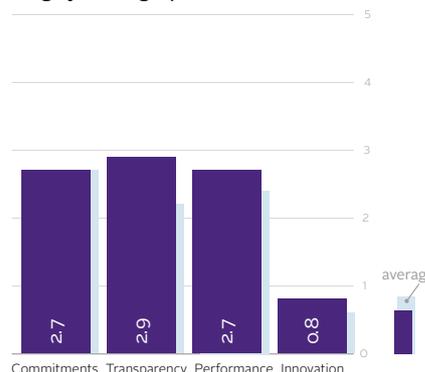


Stock Exchange: XPAR • Ticker: SAN • HQ: Paris, France • Employees: 115,631

Ranking by technical area



Ranking by strategic pillar



PERFORMANCE

Sanofi rises two positions, following improvements in several areas. It takes a clear approach to access management, which includes exploring the link between climate change and health. It performs well in compliance, certifying its sales agents and auditing its operations according to risk. It has expanded its relevant pipeline and is comparatively open with regards to its clinical trial data. It improves in equitable pricing,

with more products with equitable pricing strategies. It has recently agreed not to file for or enforce patent rights in Least Developed Countries and low-income countries, and is actively working (via donations) toward the elimination of Human African Trypanosomiasis (HAT). In Capacity Building, Sanofi has been outperformed by peers, despite maintaining its performance overall.

CHANGE SINCE 2014

- Innovates in the area of health and climate change, investigating and addressing health- and access-related issues linked to climate change.
- Is developing more relevant products, including several new fixed-dose combinations for treating TB and a paediatric formulation of primaquine for malaria.
- Has moved a greater proportion of its R&D projects from one stage of development to another than in the previous reporting period.
- Has expanded equitable pricing to significantly more products.
- Has newly committed to not filing for or enforcing patents in Least Developed Countries or low-income countries.
- Has launched a programme with the South African National Department of Health to improve the early detection and management of patients with concomitant diabetes and TB.
- Has recently revised its donation policy to take account of additional stages of the donation process (last-mile delivery, safety and quality, etc.)

OPPORTUNITIES

Expand strong capacity building approach. Sanofi can further improve its strong performance in capacity building in low- and middle-income countries: to target local needs more strategically, including in its ongoing programmes. It can also share more information with relevant stakeholders (e.g., regulatory authorities and distributors) to strengthen supply chains further.

Continue to develop work on climate change and health. Sanofi is encouraged to continue investigating the link between climate change and health. It can incorporate health needs linked to climate change in its R&D priorities, and develop an appropriate implementation strategy. It has already identified disease areas targeted by its products likely to be influenced

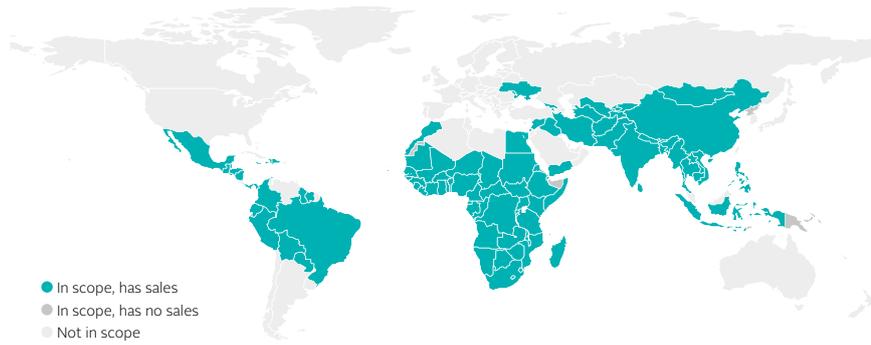
by climate change: malaria, dengue, cholera, leishmaniasis and animal health.

Consider equitable pricing and licensing more broadly. Sanofi can consider using non-exclusive voluntary licensing to improve access to its products, including those still in development. Likewise, it can extend equitable pricing to more disease areas (e.g., diarrhoeal diseases, lower respiratory infections, ischaemic heart disease, stroke and hypertensive heart disease). Sanofi is currently piloting equitable pricing in some of these areas: it can commit to always considering equitable pricing for products in these disease areas.

Continue to target known needs through innovative and adaptive R&D. Sanofi can continue to target defined, high-priority product R&D needs for low- and middle-income countries, including a range of product types and, in particular, leveraging its strengths in product adaptations.

Prioritise access to products on the WHO EML. Sanofi has the most products on the WHO Model Essential Medicines List (EML). It can assess access barriers to these products in all low- and middle-income countries that need them. It can ensure their availability and affordability, aligning with demand and the availability of alternative products in specific countries.

Sales in countries in scope



SALES AND OPERATIONS

Sanofi consists of five business units: Vaccines (Sanofi Pasteur); Diabetes and Cardiovascular; General Medicines and Emerging Markets; Specialty Care; and Animal Health. The Specialty Care unit is focused on: rare diseases, multiple sclerosis, oncology and immunology. In June 2016, Sanofi announced an assets swap with Boehringer Ingelheim, concerning Sanofi's Animal Health division and Boehringer

Ingelheim's consumer healthcare business. Sanofi has sales in 96 countries in scope. Approximately one third of its sales are generated in emerging markets.

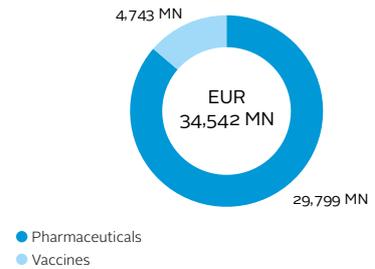
PORTFOLIO AND PIPELINE

Sanofi has the largest portfolio of relevant products in the Index, with 157 products. It has a large pipeline of 28 R&D projects that address the needs of people in countries in scope.

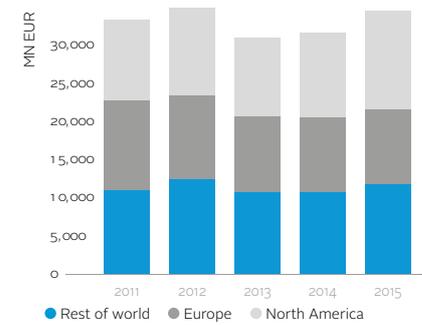
Sanofi's portfolio includes medicines and preventive vaccines, medical devices for diabetes, and vector control products for communicable and neglected tropical diseases (NTDs). Its portfolio has a strong focus on diabetes and cardiovascular diseases.

Its pipeline focuses on medicines and vaccines for communicable diseases (nine diseases). It is developing products for several NTDs and diabetes. Sanofi has a new project with the Bill and Melinda Gates Foundation to explore the use of Micropellet technology to develop thermostable, cost-effective, novel combination vaccines. Over half of Sanofi's R&D projects target high-priority product gaps with low commercial incentive. Several of its products have been approved since 2014: e.g., Dengvaxia® gained regulatory approval in several countries in scope in 2015 (including in Brazil, Mexico and the Philippines).

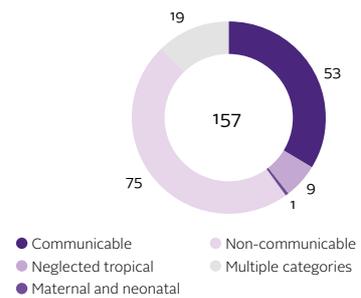
Net sales by segment (2015)



Net sales by geographic region

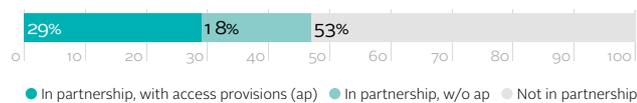


Products per disease category



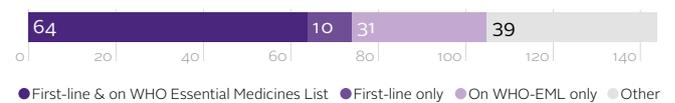
Sanofi has the most medicines in its portfolio in the Index. It is most active in infectious diseases, ischaemic heart disease and diabetes.

Pipeline projects



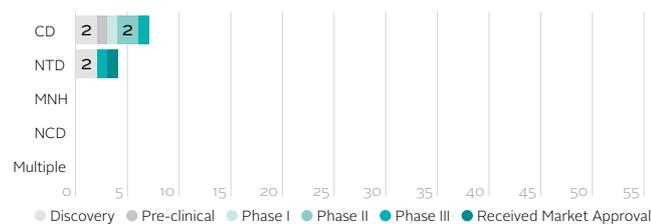
Over half of Sanofi's R&D partnerships include provisions to ensure access. Fexinidazole, in phase III trials for HAT, will be part of its donation programme with WHO.

First-line treatments and essential medicines



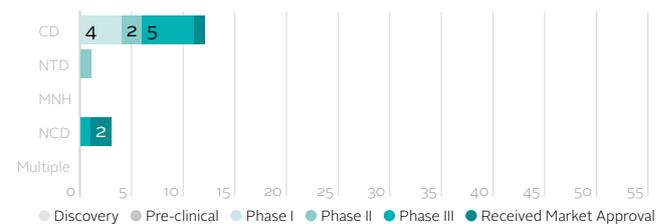
A comparatively high proportion of Sanofi's relevant products are listed on the WHO EML and/or as first-line treatments: e.g., Shan5®, Menactra®, meglumine antimoniate (Glucantime®), and melarsoprol (Arsobal®).

Pipeline by stage of development



Sanofi has several innovative vaccines in clinical development, including a trivalent pneumococcal protein vaccine, an HIV/AIDS vaccine, an adjuvanted subunit TB vaccine and a Clostridium difficile vaccine.

Adaptive medicines and vaccines



Sanofi's pipeline focuses on product adaptations, including four projects to develop fixed-dose combinations for TB, and 2nd-generation vaccines for rabies and meningitis (to extend its use in infants up to 6 months old).

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 7 SCORE 3.9

Retains top ten position, staying firm in 7th place. Sanofi retains its position, with a clear approach to access management and an investigation into the link between climate change and health.

Integrated approach to access spanning all stages of healthcare. Sanofi's access approach aims to optimise patient outcomes, covering prevention, detection, early diagnosis, treatment, care and disease management. This approach is designed to focus on innovation, affordability, quality care and patient support and is fully integrated into the company business strategy.

Transparent regarding access-related objectives and performance. The company publishes its access-related commitments, objectives and quantitative and qualitative targets, as well as its performance in access activities. It publishes a dashboard tracking its progress against key access objectives.

Clear stakeholder engagement approach. Sanofi's approach focuses on providing reliable information, building formalised dialogue and consultation processes, and on forging partnerships for patient support and humanitarian aid programmes. Sanofi is transparent about its stakeholder engagement activities, but does not publish its stakeholder selection process.

Dedicated access award for employees. To incentivise its staff, Sanofi organises biennial CSR Awards to recognise high-impact access-to-healthcare programmes. Several criteria are used to identify the best programmes, such as: level of innovation; added value for the stakeholder; added value for Sanofi; sustainability and replicability.

► **Innovation: exploration of link between health and climate change.** Sanofi's starting point is that climate change will have an impact on health, especially in the most vulnerable countries with weak infrastructure and weak resilience. The company has established an advisory board, composed of international experts, that regularly meets to discuss the topic and inform company strategy.

MARKET INFLUENCE & COMPLIANCE

RANK 5 SCORE 2.5

Biggest riser in the area, with advances in transparency and compliance. Sanofi is the biggest riser in this area, climbing 13 places into the top five. This is due to its above-average transparency and comprehensive compliance system.

Certification system for managing ethical marketing practices. Sanofi's marketing code is consistent with industry standards. It has developed a certification system for regularly testing and updating the skills of its sales agents. The company discloses general information about its marketing activities in some countries in scope, but provides no information about payments made to healthcare professionals.

Transparency of lobbying practices is limited. Sanofi discloses its policy positions on several access-related topics, including counterfeit medicines and the Sustainable Development Goals. It states that political contributions are prohibited, unless expressly approved by the CEO, without specifying whether or not they have occurred. The company provides a list of associations of which it is a member and discloses financial contributions made. Its conflict of interest policy is not publicly available.

Annual audits of high-risk third parties. The company conducts annual audits in its priority markets and rotational audits in other countries sensitive to risk. External experts may be used on specific tasks. For high-risk third parties, Sanofi conducts an annual targeted evaluation of their CSR performance.

Evidence of misconduct in marketing. Sanofi was found to have been the subject of settlements related to three breaches of codes of conduct during the period of analysis, for cases related to unethical marketing practices.

► **Innovation: invoice management system to track expenses.** EASYDAY/EASYFOOD is a collaborative web-based project being piloted in China that aims to anticipate the risk of unethical behaviour in relation to events and dining expenses. The project includes a payment and invoice management system to track the expenses of invitees attending promotional events.

RESEARCH & DEVELOPMENT

RANK 4 SCORE 3.2

Rises five places into the top five. Sanofi rises five places in this area. It has a larger relevant pipeline than in 2014, and its policies for clinical trial conduct have improved, as has its openness with clinical trial data.

R&D commitments linked to public health rationale. Sanofi commits to R&D targeting diseases in scope and has a clear R&D presence in relevant countries. The company's R&D priorities focus on unmet health needs, informed by the company's teams in relevant countries.

No policy for ensuring R&D partnerships promote access. Sanofi does not commit to ensuring access-oriented terms (e.g., registration targets, affordable pricing strategies) are systematically included in its research partnerships.

High transparency in clinical trials. Sanofi upholds high standards of transparency regarding its clinical trial data: including providing scientific researchers with access to patient-level data upon request, via clinicalstudydatarequest.com.

► **Innovation: signing on to combat antimicrobial resistance.** Sanofi signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

Shares intellectual property with several partners. Sanofi shares intellectual property with several partners in order to accelerate research in TB, malaria and NTDs. Its partners include the Drugs for Neglected Diseases initiative, WIPO Re:Search, PreDiCT-TB, the Global Alliance for TB Drug Development and Cornell University.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 4 SCORE 2.4

Rises four places due to improved equitable pricing. Sanofi moves from 8th into the top five, due to its improved performance in equitable pricing, and disclosure of volume-of-sales and price-point information.

Equitable pricing for significantly more products. Sanofi has implemented equitable pricing for significantly more products than in 2014. Its equitable pricing strategies cover a wide range of diseases, including diabetes, malaria, schizophrenia and dengue, among others. Some (22%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these strategies reach just some (25%) corresponding priority countries. The company only considers affordability in its inter-country equitable pricing strategies, overlooking other socio-economic factors. However, it does consider the needs of rural populations in its intra-country equitable pricing.

Comprehensive product tracking for recalls. Sanofi has traceability systems in place for its products at each step of the supply chain, which allows products to be tracked. In the case of a recall, its quality management department uses this system to follow up on the quantities of products that should be returned.

Monitors prices but does not set pricing guidelines. Sanofi does not set pricing guidelines for its sales agents: its affiliates are responsible for defining the sales practices of regional agents and distributors, and for monitoring them on a monthly basis. Sanofi monitors the prices set by its own agents.

Mixed performance in registration. Sanofi commits to registering products for a sub-set of relevant diseases in some low-income countries but provides no time-frame. In practice, it has filed to register all (100%) of its newest products in at least some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These products were first launched between 1999 to 2016. Sanofi has already registered products launched in 2014 and 2016 in some priority countries.

Adapts brochures and packaging to limited extent. Sanofi adapts brochures and packaging materials to address language and environmental needs, but does not consider cultural, literacy or demographic needs.

PATENTS & LICENSING

RANK 16 SCORE 0.8

Low ranking, but with a clearer stance. Sanofi holds a low position in Patents & Licensing, with no indication that it considers engaging in licensing, and low overall transparency. However, it has now disclosed a clearer stance on where it promises not to file for or enforce its patents.

Clarity over patents: will not file for or enforce patents in LDCs and LICs. Sanofi has not published its patenting strategy. It has disclosed to the Index that it will not file for nor enforce pat-

ents in Least Developed Countries and low-income countries.

No transparency on patent status. Sanofi does not publish the status of its patents.

Does not engage in licensing. Sanofi does not engage in non-exclusive voluntary licensing, and has not stated whether it would consider doing so in the future.

Absence of competition-related breaches. Sanofi was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

Limited transparency regarding its view of Doha Declaration. Sanofi makes no clear public reference to the Doha Declaration on the TRIPS agreement and public health, but acknowledges that, in a public health crisis or emergency, IP rights should not be a barrier to access to medicine.

CAPACITY BUILDING

RANK 8 SCORE 2.4

Previously in the leading group, now outperformed in capacity building. Sanofi fell six places, from 2nd. It is strong in building capacities outside the pharmaceutical value chain, where it focuses on local needs, and supply chain management. Nevertheless, the company has been outperformed by peers in 2016.

Leader in building capacity outside the value chain. Sanofi's approach to philanthropy, through the Sanofi Espoir Foundation, is strong: it works toward long-term change based on local needs, and includes impact measurement. The company builds capacities outside the pharmaceutical value chain, focusing on NCDs (e.g., its Alerte Santé partnership in Cameroon).

Strong in building manufacturing capacity. Sanofi commits to assessing and building capacity in countries in scope for in-house manufacturers. In practice, the company undertakes a relatively large number of capacity building activities, including with third parties, in a range of countries in scope (e.g., Brazil, China and India).

Focus on Africa when strengthening pharmacovigilance systems. Sanofi has a relatively high number of activities for building local pharmacovigilance capacity, focusing on Africa. For example, the company supports health workers from sub-Saharan African countries with weak pharmacovigilance systems to undertake fellowships at WHO Collaborating Centres for pharmacovigilance in Morocco and Ghana.

No evidence of engagement in R&D capacity building. Sanofi did not disclose any relevant partnerships with local universities or other public research organisations in countries in scope to build R&D capacity.

► **Best practice: training to strengthen supply chains.** Sanofi developed and piloted a supply chain management training programme for national medicine purchasing centres, scaled up in partnership with the African Association of Essential Drugs National Purchasing Centres (ACAME). The programme has been rolled out in several countries, including Ghana and Sierra Leone.

PRODUCT DONATIONS

RANK 7 SCORE 3.2

Rises three positions. Sanofi moves from 10th to 7th position. Sanofi is involved in one WHO donation programme for NTDs: targeting Human African Trypanosomiasis (HAT).

Continues to eliminate Human African Trypanosomiasis. Sanofi has been supporting WHO in its efforts to eliminate HAT. During this Index period, Sanofi donated a combined total of 92,000 units of melarsoprol (Arsobal®), pentamidine (Pentacarinat®), and eflornithine (Ornidyl®).

Complies with WHO guidelines for donations. Sanofi disclosed its guidelines for donations, which are based on WHO Guidelines for Medicine Donations.

Monitoring is mainly the responsibility of partners. Sanofi works with international organisations to make ad hoc donations. These organisations conduct regular audits and send the results to Sanofi. The organisations are responsible for monitoring, reporting and auditing. Sanofi does not directly conduct audits on its donation programmes. For structured donation programmes Sanofi monitors and tracks the reception of donated products.

Involved in numerous emergency relief efforts. Sanofi donated over 3 million boxes of medicines and doses of vaccines in 11 countries during the period of analysis. The main destinations of humanitarian aid included Nepal and India. In addition, Sanofi has provided humanitarian aid to refugees in multiple countries.

Disclaimer

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