

RANK	SCORE
<b>8</b>	<b>3.47</b>
5 (2021)	

# Sanofi

Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 95,442

## PERFORMANCE IN THE 2022 INDEX

8<sup>th</sup> place. Sanofi ranks among the top ten companies in the Index. The company has strong policies governing access to medicine and patent transparency. It leads in applying access strategies for supranationally procured products and engages in R&D for neglected tropical diseases.

**Governance of Access:** 2<sup>nd</sup> place. Sanofi has a strong performance in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access-to-medicine and incentives for its senior executives, including the CEO, and in-country and regional managers. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

**Research & Development:** 8<sup>th</sup> place. Sanofi performs above average in this area. It has a structured access planning framework and applies this to most of its late-stage pipeline candidates. The company has an average-sized priority pipeline and performs well in R&D capacity building.

## OPPORTUNITIES FOR SANOFI

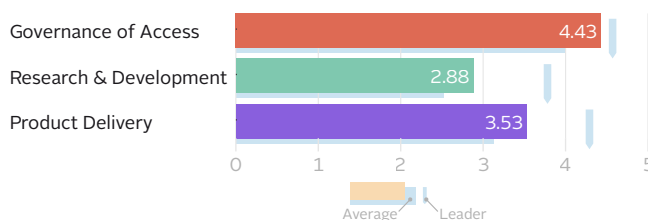
**Ensure all late-stage R&D projects have comprehensive access plans.** Sanofi has access plans in place for 81% of its late-stage projects. It can apply plans to all late-stage candidates from Phase II onwards, including the Pneumococcal Conjugate Vaccine (Skypac, SPO202).

**Expand registration of analogue insulins.** Sanofi has six analogue insulins in its portfolio. Insulin glargine (Toujeo®) has been filed in 30 countries within scope of the Index. Sanofi can expand the registration of this product as well as insulin lispro (Admelog®) and Insulin aspart Sanofi, especially in countries with a high burden of diabetes such as Sri Lanka, Guyana and Suriname.

**Expand access to insulin and diabetes products.** For insulin glargine (Lantus®), Sanofi implements access strategies considering payers' ability to pay in at least one upper-middle income country and one lower-middle income country. The company can apply access and pricing strategies in low-income countries (LICs) to improve the affordability of diabetes medicines such as glimepiride/metformin (Amaryl® M) and insulin glargine in LICs, following through on the commitments made through the company's Global Health Unit.

**Measure and share outcomes of Sanofi Global Health Unit.** In 2021, Sanofi launched its Global Health Unit, which will expand on the company's work with partners to increase access to 30 of its medicines for communicable and non-communicable diseases. To scale up this initiative and support integration into local health systems, Sanofi can track and share both short- and long-term patient outcomes as part of its impact evaluation of this programme, in addition to outcomes such as patient reach and product volumes sold.

How score was achieved



**Product Delivery:** 8<sup>th</sup> place. Sanofi performs well in this area. The company applies comprehensive access strategies for healthcare-practitioner administered products, with the majority covered by strategies across all country income classifications. However, the strategies for self-administered products tend to focus on upper-middle and lower-middle income countries. The company engages in high-quality health systems strengthening and manufacturing capacity building initiatives. It has strengthened its performance with respect to inclusive business models.

## CHANGES SINCE THE 2021 INDEX

- Established Sanofi Global Health Unit, a non-profit unit aimed at providing access to essential medicines and care through affordable prices and supporting local capacity building with programmes for specific low and lower-middle income countries.
- Through the Global Health Unit, Sanofi has shared a commitment to expand access to analogue insulins, namely glargine and glulisine, with the target to reach 300,000 insulin-dependent patients by 2030.
- Launched a new brand of standard care medicines called Impact®. These medicines are produced by Sanofi for non-profit distribution by the Sanofi Global Health Unit to at-risk populations in 40 LMICs.
- Integrated a new CSR strategy which places more focus on Access via its Affordable Access and Vulnerable Communities strategic pillars.
- Announced the development of a global access plan for all new products, with aims to make them available within two years post first launch wherever this can make an impact for patients (including in countries within scope of the Index).
- Sought regulatory authorisation alongside GSK for its COVID-19 vaccine.
- Renewed partnership with the World Health Organization (WHO) to fight neglected tropical diseases and eliminate sleeping sickness before 2030 through its long-term donation programme of pentamidine eflornithine, melarsoprol and fexinidazole.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- Issued EUR 1.5 billion bond linked to access to medicine.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

### SALES AND OPERATIONS

**Business segments:** Pharmaceuticals, Vaccines and Consumer healthcare.

**Therapeutic areas:** Oncology, Immunology & Inflammation, Neurology, Rare Blood Disorders, Rare Diseases, Diabetes and Cardiovascular Diseases.

**Product categories:** Innovative medicines, Vaccines and Consumer health products.

**M&A news:** Sanofi acquired Kiadis Pharma N.V., Kymab Group Ltd. and Tidal Therapeutics in

April 2021. Additionally it acquired Translate Bio in September 2021, Kadmon Holdings, Inc. in

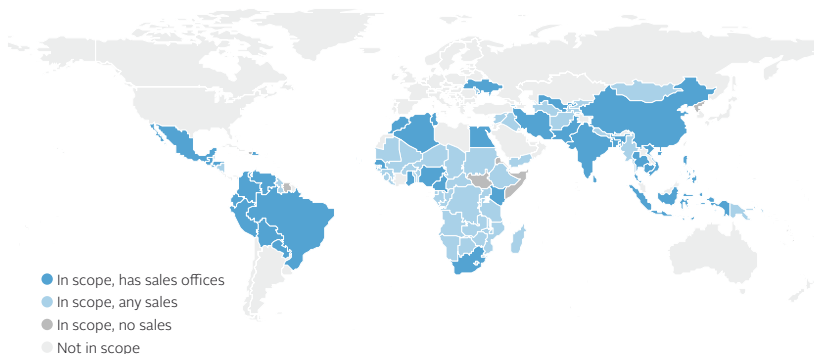
November 2021, Origimm Biotechnology GmbH in December 2021 and Amunix Pharmaceuticals, Inc. in February 2022.

**Sanofi's products are sold in 92 out of 108 countries in scope of the Index.** Sanofi has sales offices in 36 countries, and sells via distributors in an additional 56 countries.

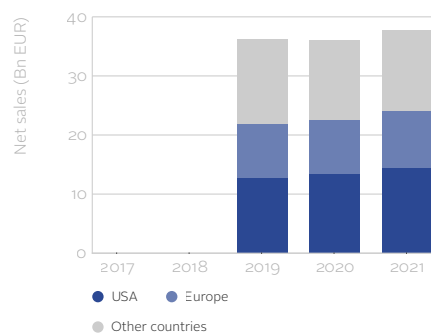
### Net sales by segment (2021) – in EUR

Pharmaceuticals	26.97 bn
Vaccines	6.32 bn
Consumer healthcare	4.47 bn
<b>Total</b>	<b>37.76 bn</b>

### Sales in countries in scope



### Sales by geographic region

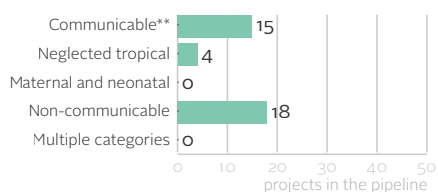


### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### PIPELINE for diseases in scope

Sanofi has a total of 37 R&D projects in scope, with 16 projects targeting a priority disease. The other 21 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory tract infections (seven projects). Of the projects targeting other diseases in scope, the focus is on oncology (14). Twenty-one R&D projects are in late-stage development that target either a priority disease (8) or address a public health need in LMICs (13).<sup>\*</sup> Evidence of access planning was in place for 81% of these projects: six targeting a priority disease and 11 addressing a public health need in LMICs.

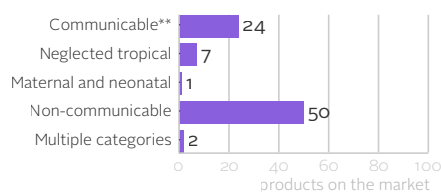
#### 37 projects in the pipeline



#### PORTFOLIO as selected for analysis by the Index

Sanofi has 65 medicines in scope, 12 of which are on patent, and 15 vaccines. 54% of the medicines (35) are on the WHO EML. In addition, the company markets four platform technologies. The off-patent medicines target communicable diseases (11) such as tuberculosis (6), malaria (3) and HIV/AIDS (1); non-communicable diseases (NCDs) (36) such as diabetes (6), cardiovascular diseases (10), mental health conditions (10); and certain neglected tropical diseases. The on-patent medicines target mainly NCDs such as cancer (3), diabetes (3) and kidney diseases (2). Sanofi's preventive vaccines (15) target diseases such as tetanus, meningitis and yellow fever.

#### 84 products as selected for analysis by the Index<sup>†</sup>



#### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	2	3	2	2	3	3	1	16
Addresses needs of LMICs*			0	3	5	5	0	13
Other projects in scope			5	3	0	0	0	8

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	10			12
off patent	33	20			53
Vaccines	14	1			15
Contraceptives	0	0			0
Diagnostics			0		0
Other <sup>†</sup>				4	4

\*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.  
 \*\*Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.  
 \*\*\*Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).  
<sup>†</sup>Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.  
<sup>‡</sup>Other includes vector control products.

# Sanofi

## GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

**Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.** Sanofi performs strongly. Its access to healthcare strategy, recently revamped in 2021, is integrated in the activities of its three core global business units: Sanofi Pasteur, Sanofi Genzyme and General Medicines and its standalone business unit, Consumer Healthcare. A fifth non-profit business unit was created, Sanofi Global Health. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with board-level members seated on the Corporate Social Responsibility (CSR) committee.

**Provides evidence of financial and non-financial access-related incentives at the executive level.** Sanofi performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives beyond CSR goals.

**Publicly discloses outcomes of its access-to-medicine activities.** Sanofi performs strongly in transparency of access activities. It publicly dis-

closes commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Access to Healthcare Programmes Report and in its quarterly results press release.

**Performs well in responsible promotional practices.** Sanofi's Sales Incentive Plan is primarily driven by sales volume, but qualitative components are adjusted depending on the specific situation. The company sets sales incentives at the national level for agents in most of the countries that are in scope of the Index. It has a policy on service engagement with scientific experts, but it does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations.

**Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.**

Sanofi performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

**Publicly supports the Doha Declaration on TRIPS and Public Health.** Sanofi publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that compulsory licensing should only be used in extraordinary and very limited circumstances. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Sanofi, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.88

**Access planning processes encompass all projects in the pipeline.** Sanofi has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Sanofi begins developing access plans for R&D projects in Phase II of clinical development.

**An average-sized priority R&D pipeline compared to its peers, with access plans in place for 75% (6/8) of the late-stage candidates.** Sanofi has 16 projects, including eight late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including lower respiratory tract infections, coronaviral diseases and human African trypanosomiasis. Of Sanofi's eight late-stage candidates targeting a priority product gap, there is evidence of an access plan for six. These plans prioritise WHO prequalification and registration

in countries in scope of the Index. Notably, Sanofi partners with Drugs for Neglected Diseases *initiative* (DNDi) for two projects using fexinidazole to treat for two different types of human African trypanosomiasis. These access plans include WHO prequalification, a donation programme managed by WHO and plans for registration in countries with a high burden of disease.

**Some projects address a public health need in LMICs,\* with 85% (11/13) of late-stage projects covered by access plans.** In this analysis, Sanofi has 13 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.\* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. Most target cancer. Sanofi provides evidence of access plans for 11 of these

projects. These plans mostly relate to planning registration in countries where it is conducting clinical trials.

**Publicly discloses disaggregated R&D investment data for phase of development.** In addition, Sanofi also discloses fully disaggregated R&D investment data to Policy Cures Research.

**Three of the four R&D capacity building initiatives included meet all Good Practice Standards.** Sanofi's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, through the Sanofi Global Site Partnership, Sanofi partners with over 80 institutes to build clinical trial capacity in countries in scope of the Index.

\*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

## PRODUCT DELIVERY

RANK 8

SCORE 3.53

**Publicly pledges not to enforce patents.** Sanofi publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries and LICs and in a subset of LMICs and UMICs.

**Publicly discloses information on patent status.**

Sanofi publicly discloses on its website information relating to the status of its patents for products on the WHO Model List of Essential Medicines (EML).

**Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers.**

Sanofi does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

**No use of licensing agreements.** Sanofi does not engage in voluntary licensing agreements for products in scope of the Index.

**Filed to register new products in 14 countries in scope on average.** Sanofi did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, its most widely filed is the booster vaccine (Tetraxim), indicated for tetanus and pertussis prevention, filed in 38 countries within the scope of the Index, including four high burden disease countries and eight LICs.

**Has access strategies for all supranationally procured products in scope for this analysis.**

Sanofi leads in securing access for products procured supranationally. For the five products assessed in this category, the company demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company offers the same terms to Brazil and Mexico for the influenza trivalent vaccine (Vaxigrip® TIV) as it does for PAHO-eligible countries. Sanofi provides evidence of how patient reach has been increased through these approaches.

**Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis.**

Sanofi performs above average in this area. For three of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients through pricing strategies considering relevant payers' ability to pay

for treatments. For example, Sanofi supplies its meningitis vaccine (Menactra®) via tenders run by international and local public authorities in 23 countries in scope of the Index, of which six are LICs. The company offers a price that is adjusted to local tenders' specifications and considers countries' ability to pay. In parallel, it supports local healthcare systems by providing training to public managers. This training includes cold chain management and vaccination surveillance. Sanofi provides evidence of how patient reach has been increased through these approaches.

**Has access strategies for its self-administered products for some countries in scope of this analysis.**

Sanofi has an average performance in this area. For one of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients through pricing strategies that consider local payers' ability to pay and disease management initiatives. For example, Sanofi ensured the inclusion of glimepiride/metformin (Amaryl® Min) in Colombia's mandatory national health plan which offers 100% coverage to eligible patients. The company has additional strategies to improve disease early diagnosis, treatment adherence and patient health outcomes. Sanofi provides evidence of patient reach, reporting that approximately 920 patients receive the treatment yearly.

**Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards.**

Sanofi's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, Sanofi has been working with the May & Baker manufacturing site since 2015. The company provides training on hygiene, on-site safety and good manufacturing practice. This initiative meets all GPS.

**One of the five supply chain capacity building initiatives included meets all Good Practice Standards.**

Sanofi's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. Sanofi partnered with the Vietnam Vaccine Joint Stock Co. to build capacity in supply chain planning. This includes improving forecasting and warehouse planning to meet vaccine demand. This initiative meets all GPS.

**Four of the five health systems strengthening initiatives included meet all Good Practice Standards.**

Sanofi's performance is above average in this area. The number of initiatives meeting

all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the My Child Matters programme was initiated by the Sanofi Espoir Foundation in 2006 in order to fight childhood cancer and reduce health inequalities worldwide. This initiative meets all GPS.

**Has engaged in both scaling up and piloting one inclusive business model.**

Sanofi performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Sanofi Global Health Unit is a new non-profit unit that sells and/or donates 30 of Sanofi's products at affordable prices to approximately 40 low and lower-middle income countries.

**Performs above average in terms of ensuring continuous supply of medicines in LMICs.**

Sanofi is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

**Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days.**

Sanofi has a policy for reporting SF medicines to national health authorities or the WHO within seven days. It does not provide evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed.

**Donates in response to expressed need and monitors delivery.**

Sanofi has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

**Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria.**

Sanofi publicly commits to contributing to the elimination of human African trypanosomiasis by donating pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole Winthrop®) in 21 countries in scope of the Index until goals are reached.