PERFORMANCE IN THE 2021 INDEX

5th place. Sanofi takes a place among the top five companies of the Index. The company performs strongly in two of the Technical Areas, but has an average performance in Governance of Access.

Governance of Access: 11th place. Sanofi performs below average in this area. The company has an access-to-medicine strategy incorporated within its overall corporate strategy and a robust set of compliance controls, but was faced with a settlement of a breach during the period of analysis.

Research & Development: 4th place. Sanofi performs strongly in this area. Its R&D pipeline consists of ten late-stage priority R&D projects, with six of them covered by an access plan. The company has an access planning process that covers all projects in the pipeline and engages in some high-quality R&D capacity building initiatives.

PRODUCT DELIVERY: 3rd place. Sanofi performs strongly in this area. The company has access strategies in place for the majority of its products and leads in its approach to access strategies for supranationally procured products. The company has a strong approach to donations, monitoring delivery to end users and committing itself to achieving elimination. Yet, there is no evidence of new products in scope filed for registration in the majority of high-burden countries.

OPPORTUNITIES FOR SANOFI

Review sales incentive structures. Sanofi could consider adopting a balanced scorecard approach consistently, thus not solely promoting sales volumes as a performance target for its sales agents in countries in scope of the Index.

Disclose patent status of products. Sanofi has 80 products in scope, including 34 medicines on the 2019 WHO Model List of Essential Medicines (WHO EML). Sanofi can clearly show which products are on- and off-patent. Sanofi can improve standard of disclosure by including jurisdiction, patent number and expiry date. Sanofi can disclose patent information via the Pat-INFORMED platform or elect to self-disclose patent statuses.

Expand registration of dupilumab (Dupixent®) to more countries with a high burden of asthma. Sanofi could endeavour to register this product broadly in more asthma high-burden countries.

Expand access plans to R&D projects. Sanofi implements access plans (registration and WHO prequalification) to 60% of its late-stage priority R&D projects. The company can apply access plans to all late-stage R&D projects. Furthermore, Sanofi can include affordability and supply in its access plans. These plans can be based on an intra-country tiered pricing strategy. Specific examples include the respiratory syncytial virus vaccine for infants and nirsevimab, a respiratory syncytial virus monoclonal antibody.

Expand access to insulin in LICs. Sanofi is one of the three companies in scope that supply insulin. For insulin glargin (Lantus®), the company can apply equitable pricing strategies in low-income countries to improve access and affordability.

CHANGE SINCE THE 2018 INDEX

• New agreement with Unitaid and the Global Fund for reduced price of USD 15.00 per rifapentine treatment course for public sector use in 100 low- and middle-income countries.
• Publishes its post-trial access plan.
• Has multiple new initiatives for supply chain, vaccines capacity building and product packaging in Vietnam and India.
• Joined the COVID-19 Therapeutics Accelerator.
• Expanded Good Clinical Practice (GCP) training initiative from China to include South Africa.
• Newly discloses patent status information for its EML products.
• Newly incorporated access planning for the whole pipeline.
• Expanded FAST initiative on mental health to three more countries, Mali, Myanmar and South Africa.
• Signed two sustainability-linked revolving credit facilities with social (e.g. for polio) and environmental targets.

The term LMIC is used to denote all low- and middle-income countries in the 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.
SALES AND OPERATIONS

Business segments: Pharmaceuticals; Consumer Healthcare; Vaccines

Therapeutic areas: Immunology; Rare Diseases; Rare Blood Disorders; Multiple Sclerosis / Neurology; Oncology; Diabetes; Cardiovascular; Vaccines

Product categories: Innovative medicines; Generic medicines; Vaccines; Consumer health products

M&A news: Acquired Synthorx (oncol-

ogy) for USD 2.5 billion, Principia Biopharma (immune-mediated diseases) for USD 3.7 billion and Kiadis (immunotherapy) for USD 308 million in 2020.

Sanofi’s products are sold in 92 out of 106 countries in scope. Sanofi has sales offices in 34 countries, sells via suppliers in 55 countries and via pooled procurement into 3 additional countries.

Sales in countries in scope

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Sanofi has a total of 43 R&D projects, featuring an average-sized priority R&D pipeline compared to its peers: 21 projects. Remarkably, the priority pipeline constitutes half of Sanofi’s R&D projects. The other 22 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory tract infections (7 projects) and COVID-19. Of the projects targeting other diseases in scope, the focus is on oncology (9).

23 R&D projects are in late-stage development that target either a priority disease (10) or address a public health need in LMICs (13). Evidence of access planning was in place for 39% of these projects: 6 targeting a priority disease and 3 addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

Sanofi has 65 medicines in scope (13 on patent) and 15 vaccines. 52% of these medicines (34) are on WHO’s EML. The off-patent medicines target mainly non-communicable diseases (NCDs) (34) such as mental health (11), communicable diseases (CDs) such as tuberculosis (7) and malaria (3) and neglected tropical diseases (NTDs) such as Human African Trypanosomiasis (HAT) (3) and leishmaniasis. Furthermore, one product targets neonatal sepsis and one is for missed abortion. The on-patent medicines mainly target NCDs (12) such as diabetes (4). In addition, one patented medicine is for HAT. (The fenixinidazole (Fenixinidazole Winthrop) patent expired in November 2020 after the period of analysis). The company’s vaccines (15) target mainly CDs (13) such as meningitis (4) and two vaccines target the NTDs rabies and dengue. In addition, the company markets 4 platform technologies for diabetes. Access strategies were analysed for 14 products on Sanofi’s portfolio – supranationally procured (5) or nationally procured HCP-administered (4) and self-administered products (5).

85 products as selected for analysis by the Index *

Breakdown of products

Breakdown of projects*

Fexinidazole was developed in partnership with DNDi for treatment of Tb. gambiense and approved in the Democratic Republic of Congo in 2019.

*52 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

***Other includes platform technologies. See Appendix i for definitions.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix i for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Net sales by segment (2019) – EUR

Pharmaceuticals 25,708 bn
Sanofi Pasteur (Vaccines) 5,731 bn
Consumer Healthcare 4,687 bn
Total 36,126 bn

Sales by geographic region

Emerging Markets
Rest of world
Europe
USA
Sanofi

**GOVERNANCE OF ACCESS**

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Sanofi performs strongly in this area. Its access to healthcare strategy is integrated in the activities of its three Global Business Units: Sanofi Pasteur, Sanofi Genzyme and General Medicines. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, namely with the Corporate Social Responsibility (CSR) committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Sanofi performs strongly in this area, too. 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 based on CSR goals.

Publicly discloses outcomes of its access-to-medicine activities. Sanofi performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, with reporting on its Access to Healthcare programmes.

Has an average performance in responsible promotional practices. Sanofi’s sales agents performance incentives are mostly sales driven. More details on how the company addresses sales incentives for agents are unavailable. It has a policy on service engagement with scientific experts, however, except for Ukraine where it discloses to EFPIA, Sanofi does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities).

Publicly pledges not to enforce patents. This commitment applies in all least Developed and low-income countries and in a subset of lower-middle income countries. Sanofi publicly discloses on its website information regarding the status of its patents for products on the WHO Model Lists of Essential Medicines. The only information disclosed is the patent status. No further information is publicly available.

Shares some IP assets with third-party researchers. During the period of analysis Sanofi newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes four IP assets shared with drug discovery initiatives, such as COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries and clinical-stage unpublished data.

**RESEARCH & DEVELOPMENT**

Access planning processes encompass all projects in 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 for diseases in scope. In general, Sanofi begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 60% of the late-stage candidates. Sanofi has 21 projects, including ten late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including lower respiratory tract infections and coronaviral diseases. Of Sanofi’s ten 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 some countries in scope. Notable is the diphtheria, tetanus, pertussis, hepatitis B, polio and haemophilus influenzae type b paediatric hexavalent vaccine (Shan 6), especially developed for lower income countries. Sanofi commits itself to WHO prequalification to ensure access to GAVI countries and plans to register the product in some additional countries in scope.

Some projects address a public health need in LMICs, with 23% of these 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 the 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 and/or are first-in-class molecules. Most target cancer. Sanofi provides evidence of access plans for three of these projects. These access plans prioritise registration in several LMICs and LMICs.

Public policy to ensure post-trial access; commits itself to registering trialled products. Sanofi has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threatening condition. Once a product is approved, Sanofi commits itself to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

**PRODUCT DELIVERY**

Publicly pledges not to enforce patents. Sanofi publicly pledges to neither file for nor enforce patents. This commitment applies in all least developed and low-income countries and in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status. Sanofi publicly discloses on its website information relating to the status of its patents for products on the WHO Model Lists of Essential Medicines. The only information disclosed is the patent status. No further information is publicly available.

Shares some IP assets with third-party researchers. During the period of analysis Sanofi newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes four IP assets shared with drug discovery initiatives, such as COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries and clinical-stage unpublished data.

1 Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare professionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

2 Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiatives align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.
No use of non-assert or licensing arrangements. Sanofi does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Sanofi did not disclose evidence of filing for any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, ‘Toujeo®’ (insulin glargine) for diabetes mellitus is registered/have been filed for registration in 24 countries in scope, including Ecuador and Mexico.

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 demonstrated 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 products for Unitaid-eligible countries. Sanofi is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Sanofi performs below average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for only one of the four products assessed. It makes efforts to reach additional patients through donations. For example, in Indonesia and Thailand, it participates in public-sector tenders to increase access to Verorab®, a rabies vaccine, while strengthening the health system via healthcare practitioner trainings and awareness raising campaigns. Between 255,000 and 375,000 patients per year access the vaccine in Thailand and 100,000 in Indonesia. Sanofi is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for some of its self-administered products for countries in scope of this analysis. Sanofi has an average performance in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. It makes efforts to reach additional patients through equitability pricing strategies and donations. For example, in Brazil, the company participates in state and municipality tenders and offer a patient support program to increase access to insulin glargine (Lantus®). Sanofi is able to provide evidence of how patient reach has been increased through the approaches used.

Four manufacturing capacity building initiatives meet all Good Practice Standards. Sanofi performs above average in this area. The company submitted five initiatives, which met all criteria for inclusion. Three of the five initiatives take place in Vietnam. Two initiatives met all Good Practice Standards. Both initiatives are aimed at improving vaccine supply in Vietnam by improving forecasting and cold chain distribution. For two of its initiatives, the cold chain management training in hospitals in India and pharmacies and supporting the Vietnamese manufacturer to expand its activities to include distribution, Sanofi only reports on measuring output but not outcomes.

Two supply chain capacity building initiatives meet all Good Practice Standards. Sanofi performs above average in this area. The company submitted five initiatives, which met all criteria for inclusion. Three of the five initiatives take place in Vietnam. Two initiatives met all Good Practice Standards. Both initiatives are aimed at improving vaccine supply in Vietnam by improving forecasting and cold chain distribution. For two of its initiatives, the cold chain management training in hospitals in India and pharmacies and supporting the Vietnamese manufacturer to expand its activities to include distribution, Sanofi only reports on measuring output but not outcomes.

Five health system strengthening initiatives meet all Good Practice Standards. Sanofi is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear, measurable goals or objectives; measure outcomes; have a governance structure in place and aim for sustainability/integration in the local health system. For example, through the Kids and Diabetes in Schools (KiDs) programme, Sanofi has raised awareness among approximately 189,000 children, 13,750 teachers and other school staff and more than 15,000 parents in 345 schools in nine countries, of which four are in scope of the Index.

Has contributed to the development and implementation of a new inclusive business model. Sanofi has improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has contributed to the development of one new model: Ngao ya Afya, focused on non-communicable disease (NCD) care in Kenya.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Sanofi performs well in this indicator, disclosing multiple strategies to ensure continuous supply in countries in scope of the Index. For example, as part of their supply de-risking strategy the company has a system in place to ensure the availability of API. In addition to internal production of API, the company has a dual/multiple sourcing arrangement for their Established Products range. Sanofi has signed Rapid Supply Mechanisms with UNICEF and Gavi to ensure availability of their medicines in emergency situations.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days. Sanofi has a policy for reporting SF medicines to national health authorities or WHO within 7 days, with the Central Anti-Counterfeit Laboratory conducting the assessment. It does not, however, distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end users. Sanofi has a policy in place to ensure ad hoc donations are carried out in response to an expressed need. It monitors the delivery until the end user.

For example, it donated ibuprofen/paracetamol and metformin for diabetes mellitus in 2019 in response to cyclone Vayu in three countries.

Publicly commits itself to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Sanofi publicly commits itself to eliminating Human African Trypanosomiasis by donating pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole-Winthrop®) in 21 countries since 2001.