OVERALL PERFORMANCE

38%

Sanofi

Research-based pharmaceutical company

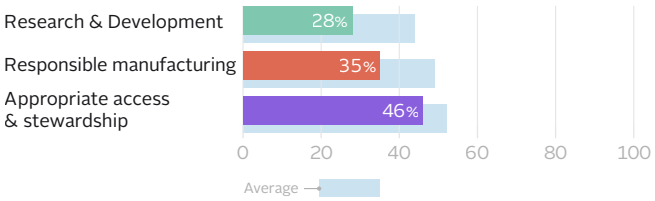
Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 82,878

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Sanofi has opportunities to strengthen its efforts across R&D and Responsible Manufacturing, as it has a small pipeline focused on vaccines and a basic environmental risk management strategy, where underlying quantification and compliance levels remain unclear. Its performance in Appropriate Access & Stewardship is uneven. It provides no evidence of ensuring access to any of the assessed off-patent medicines, either through registrations or access strategies, but it is ahead of its peers in ensuring access for its on-patent vaccines. Sanofi does not demonstrate involvement in AMR surveillance.

How Sanofi was evaluated

How score was achieved



OPPORTUNITIES FOR SANOFI

Expand breadth of R&D pipeline and access plans. Sanofi's AMR pipeline size has reduced by 50% since the last Benchmark. It can diversify its pipeline investing in vaccine development to address resistant pathogens with high burdens in LMICs. In addition, it can enhance access planning for its late-stage pipeline candidate, SP0202 (21-valent pneumococcal vaccine conjugate), which is currently in Phase III, outlining concrete measures for access and clarifying in which LMICs its access plan applies.

Expand access to its newest on-patent vaccine, MenQuadfi®. Sanofi already registers its on-patent vaccines in an average of 38 LMICs, more than any of its peers. However, its newer vaccine MenQuadfi® – indicated for the prevention of invasive meningococcal disease from six weeks of age – is currently only registered in 14 countries. Sanofi can expand access to MenQuadfi® using strategies utilised for its other vaccines, such as expanding registration, implementing appropriate access strategies and supranational supply, prioritising countries with highest unmet need.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Sanofi publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites, implementing mass balance estimations. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products and require supplier compliance through contractual provisions – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

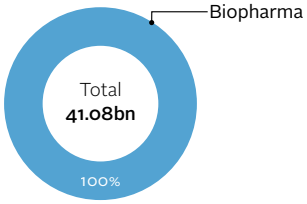
- In December 2024, Sanofi expanded its collaboration with SK Bioscience to work on developing, licensing and commercialising next-generation pneumococcal conjugate vaccines (PCVs) for both paediatric and adult populations.
- In June 2025, Sanofi received a US Food and Drug Administration (FDA) indication extension approval for its Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (MenQuadfi®) to include children aged 6 weeks to 23 months.
- During the 2026 AMR Benchmark period of analysis, Sanofi engaged in technology transfer initiatives. In March 2025, Sanofi signed a collaboration agreement with Vietnam Vaccine Joint Stock Company (VNVC) to transfer vaccine manufacturing technology and expertise. In June 2025, Sanofi entered a strategic alliance with the Institute Pasteur and Brazil's Fiocruz.

Sanofi

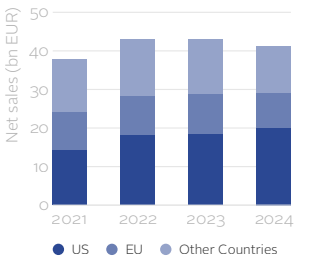
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, diabetes, immunology & inflammation, neurology, oncology, rare diseases
Product categories: Innovative medicines and vaccines
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Net sales by business segment (2024) – EUR



Net sales by geographic region – EUR



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine			o	o	o	o	o	
Antifungal medicine			o	o	o	o	o	
Antibacterial vaccine			o	o	1	o	o	
Antifungal vaccine			o	o	o	o	o	
Total projects	1	1	o	o	1	o	o	3
Access plans			o	1	o	o		1

Specific product categories in discovery and pre-clinical phases cannot be disclosed.

PORTFOLIO *for diseases in scope*
Sanofi has multiple products in its anti-infectives portfolio. However, it did not disclose the total number of products. The figure below shows a selection of products selected for analysis.

9 products selected for analysis

On Patent	Off Patent	Vaccines
None	• amoxicillin (*Access antibiotic*) • amoxicillin/clavulanic acid (*Access antibiotic*) • azithromycin (*Watch antibiotic*) • levofloxacin (*Antituberculosis medicine*) • rifampicin (*Antituberculosis medicine*) • clotrimazole (*Antifungal medicine*)	• Hexaxim® • Menactra® • MenQuadfi®

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PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Low-performing. Sanofi has a small pipeline, with one vaccine in clinical development, and no projects addressing 'critical' or 'high' priority pathogens. It does not engage in R&D for innovative antimicrobial medicines. Although it has an access plan in place for its sole late-stage candidate, the plan lacks concrete details, and the intended geographic reach is unclear.

Small pipeline focused on pneumococcal vaccine development. Sanofi's small pipeline includes 3 projects targeting pathogens in scope; one of these is a vaccine targeting *Streptococcus pneumoniae* which is currently in Phase III of clinical development. The company does not have any candidate in the pipeline that addresses 'critical' or 'high' priority pathogens as defined by WHO, neither does it have any innovative medicine in its pipeline; its sole clinical project (a vaccine) fell outside the scope of WHO's innovation assessment of medicines. Sanofi reports having an in-house discovery programme for pathogen(s) in scope.

Below-average performance, with access plan in place but unclear geographic reach. Sanofi has an access plan for its late-stage candidate, PCV21, a Pneumo Conjugate Vaccine for paediatric populations, developed in partnership with SK bioscience. Clinical trials have taken place, or are still underway, in 4 countries in scope of the Benchmark. The access plan features a registration strategy for some countries in scope (although exact countries are not specified) and an equitable pricing approach.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It does not report the number of products manufactured at its own or suppliers' sites that meet discharge limits, or whether it incorporates AMR provisions into supplier contracts. Sanofi publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Basic environmental risk management to mitigate AMR at both its own sites and suppliers'; tracks compliance of antibacterials with discharge limits at its own sites. Sanofi's environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It estimates antibacterial discharges at its own sites using mass balance, but underlying quantification details (e.g., dilution factors and quantification timeframe) are unclear. It is also unclear whether Sanofi implements CAPAs when PNECs are exceeded. Additionally, Sanofi does not report the number of its antibacterial products that comply with PNECs. The company requires antibacterial suppliers to follow the Industry Standard, including mass balance estimation, which is verified by chemical analysis when applicable. Audits are conducted at a risk-based frequency using PSCI principles, including PNEC-based limits. It's unclear whether AMR provisions are in contracts or how many supplier products meet discharge limits. No information could be identified on whether Sanofi works with external waste treatment plants to minimise AMR risk from manufacturing.

Publicly discloses basic details of its AMR mitigation strategy but is not publicly transparent about compliance with discharge limits. Sanofi publicly reports implementing the Industry Standard across its supply chain. For its own sites, it publicly reports quantifying discharge levels using mass balance estimation. However, it does not publicly disclose the audit results with measured discharge levels, the number of products complying with PNECs or the names and locations of manufacturing sites per antibacterial products for either its own sites or its suppliers' sites.

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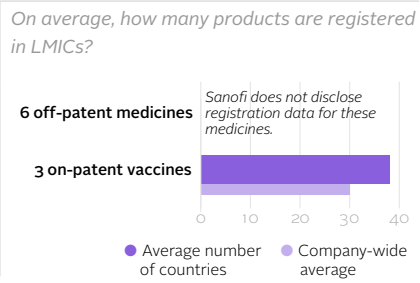
APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Performs well in registering its 3 on-patent vaccines in more countries than peers, implementing comprehensive access strategies and supplying them through multiple channels. Sanofi addresses appropriate use by not deploying sales agents for any antibacterial or antifungal medicines within its portfolio. However, the company did not disclose registration data or access strategies for the off-patent medicines assessed; as such, its efforts to expand access to these products remain unclear. Sanofi lacks efforts on surveillance, with no involvement in AMR surveillance during the period of analysis.

Sanofi registers its on-patent vaccines more widely than its peers, though its performance for off-patent medicines is inconclusive.



Sanofi does not disclose any registration data for its off-patent antibacterial and antifungal medicines to the Benchmark. Its on-patent vaccines are registered in 38 countries,* including 3 countries where the corresponding disease burden is high. For some of its vaccines, Sanofi engages in WHO's Prequalification process to facilitate registrations.

Below-average performance, with no evidence of access and stewardship strategies for any of the 6 off-patent/generic products assessed. While Sanofi does not disclose any access or stewardship strategies for the 6 products analysed, the company does apply a general access-to-medicine strategy across its entire portfolio. In addition, 2 of the 6 products – levofloxacin and rifampicin – are part of Sanofi's Global Health Unit (GHU), through which the company offers its medicines at affordable prices across 40 LMICs. While the company tracks and reports quarterly on the number of patients receiving medicines through its GHU, it has not provided evidence of how many patients have specifically been reached with levofloxacin and rifampicin. For the other 4 assessed products, Sanofi does not provide any evidence of monitoring its access strategies, nor does it report the number of patients reached.

Above-average performance, providing access to all 3 on-patent vaccines assessed through multiple channels, including supranational procurement mechanisms. Sanofi discloses access strategies for its hexavalent vaccine Hexaxim® and both its meningococcal vaccines, Menactra® and MenQuadif®. Sanofi supplies Hexaxim® through the PAHO Revolving Fund at the lowest available price for all participating countries. In addition, Sanofi also provides Hexaxim® directly to self-procuring countries, such as Mexico and South Africa, where the company is working on a technology transfer to its local partner BIOVAC. Menactra® has been supplied through UNICEF, with Sanofi committing to a rapid response in case of confirmed outbreaks. As part of this, in 2024 Sanofi supplied 227,000 doses to Cameroon. The company plans to continue participating in the UNICEF tenders, while replacing the vaccine with the newer MenQuadfi®. During the period of analysis, MenQuadfi® was launched in Egypt and 192,000 doses were supplied in 2025.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Sanofi implements demand planning and data sharing through its internal Integrated Business Planning process, which involves collaboration across key departments (marketing, sales, supply chain, finance), and uses sales forecasts (up to 36 months) to inform planning. However, it does not report sharing forecasts with external stakeholders. Sanofi maintains buffer stocks and follows an inventory policy to set target levels for APIs and products, which is reviewed biennially to manage long-term risks and maintain optimal stock. It also implements dual sourcing for antibacterial and antifungal medicines. However, it is unclear whether it uses automated inventory systems. It mitigates substandard and falsified products by verifying suppliers through GMP audits and reports cases to relevant stakeholders. It also implements security measures, such as serialisation and AI-driven threat detection. However, it does not disclose the total number of sites that are GMP compliant or implement any additional quality measures implemented in countries with evolving regulatory systems.

Clearly addresses appropriate use across its business practices. Sanofi does not deploy sales agents to sell and/or promote its antibacterial and antifungal medicines to HCPs. Through its global public policy, Sanofi ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also ensures that transfers of value (ToVs) are made at fair market value. While Sanofi abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated by law or other codes of practice. Sanofi's public policy also applies to third parties working on its behalf.

No involvement in AMR surveillance. Sanofi was not involved in any AMR surveillance programmes during the period of analysis.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.