



Access to Health: Statement of Guiding Principles

Millions of people worldwide are living longer, more productive lives today thanks, in part, to breakthroughs in science, better health care and access to innovative medicines and vaccines. However, targeted and coordinated action from all stakeholders is needed to ensure greater access to health around the world, both today and for future generations.

As a research-intensive biopharmaceutical company, Merck's role is first and foremost to discover and develop, in a responsible and economically sustainable manner, innovative medicines and vaccines that address unmet medical needs. We also recognize that, in collaboration with key stakeholders, we have a role to play in helping to ensure our science advances health care, and our products are accessible and affordable to those in need.

Therefore, we use this Statement of Guiding Principles to guide our global approach to access to health. As demonstrated through our key performance indicators, we are committed to taking measurable action to advance these principles and report our progress.



Discovery and Invention

Pursuing the most promising science, Merck discovers and invents medicines and vaccines that address vital global health needs where we can have the greatest impact, now and in the future.

We will evaluate and reflect global unmet medical need in the research and development of our products.

Key Performance Indicator: Percentage of top 20 global burdens of disease addressed by our products and pipeline

We will invest in research and development to address infectious diseases that have a significant global public health burden, including in low-income and middle-income countries, and where emerging science suggests opportunities to substantively reduce this burden through medicines or vaccines.

Key Performance Indicator: Narrative of our R&D investments in infectious diseases

We will collaborate with diverse partners to expand our research and development capacity to address unmet global health needs and pursue opportunities to provide access to compound libraries and molecules to spur discovery and development of new products.

Key Performance Indicator: Number of established significant external licenses and collaborations

We will conduct our clinical trials, including trials in low-income and middle-income countries, in accordance with the global standards of Good Clinical Practices, applicable local regulatory requirements and following the ethical principles that have their origin in the [Declaration of Helsinki](#).

Key Performance Indicator: Good Clinical Practice/ Pharmacovigilance (GCP/PV) inspections by regulatory agencies of the company or clinical trial investigators, that led to significant fines, penalties, warning letters or product seizures



Availability

Merck makes available a reliable, safe global supply of quality medicines and vaccines, and invests in solutions to enable timely access to our products, in a responsible and sustainable manner.

We will maintain strict quality standards and effective supply chain management to ensure the safety and security of our products, no matter where they are manufactured.

Key Performance Indicator: Percentage of sold units recalled during a given year (recall rate globally)

Key Performance Indicator: Percentage of logistics partners with a security risk assessment completed annually (Target: 100%)

We will sustain an interdependent, flexible supply chain that takes into account global and local market supply needs, including through digital transformation and innovation.

Key Performance Indicator: Percentage of countries² around the world reached annually with our products (Target: 75%)

Key Performance Indicator: Percentage of orders shipped on time and in full (Target: 95%)

We will work to register our products where there is a need and the infrastructure to support their safe delivery to patients. When appropriate, we will work to have our products prequalified through the World Health Organization (WHO) prequalification process.

Key Performance Indicator: New product and device registrations (annual)

Key Performance Indicator: Products that have achieved WHO prequalification (cumulative)



Affordability

Grounded in a deliberate systematic approach, Merck develops, tests and implements innovative solutions that address barriers to access and affordability of our medicines and vaccines. This enables us to serve the greatest number of patients today, while meeting the needs of patients in the future. Where appropriate, we pursue these solutions in partnership with private, governmental, multi-lateral or non-profit organizations.

We will expand access to our products through dedicated, market-based affordability solutions that allow flexibility to reach at-need populations and patients — including those in low-income and middle-income countries — taking into consideration public health need, economic conditions and health care infrastructure.

Key Performance Indicator: Number of countries where dedicated affordability solutions have been initiated

In low-income countries, we will continue our long-standing policy of not filing for product patents.

Key Performance Indicator: Number of patents filed in low-income countries, as defined by The World Bank in its country and lending groups classifications (annual)

When market-based solutions are inadequate or unavailable, we will pursue programs to provide direct access to our medicines and vaccines, including product donations and patient assistance programs.

Key Performance Indicator: People reached globally through product donation and patient assistance programs and partnerships (in millions)



Strengthening Systems and Addressing Inequity

Through partnerships, investment and innovation, Merck applies its expertise and invests its human and financial resources, to address systemic barriers to access to health where we believe we can make the strongest contributions to health systems, communities and our patients around the world.

In partnership with local communities and other stakeholders, we will support capacity building for health systems and care delivery where our support can make a meaningful difference. We will address underlying barriers to access, including social determinants of health, that lead to health inequities. We will measure the impact of our investments.

Key Performance Indicator: Annual investment in partnerships, programs and impact investments that support health care capacity-building and address underlying barriers to access to health (in millions)

Key Performance Indicator: People reached through investment in partnerships, programs and impact investment that support health care capacity-building and address underlying barriers to access to health (in millions)

Key Performance Indicator: Percentage of investment in partnerships and programs to strengthen health care capacity and address barriers to access, that is allocated to impact evaluation

We will evaluate and address public health needs by working with local healthcare providers globally, to increase knowledge of product need and use. We will invest in activities to improve patient awareness and education.

Key Performance Indicator: Investment in patient- and provider-education programs (in millions)

This statement of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the recent global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2020 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).