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, MSD’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, MSD 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 substantially 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*

1Merck Co., Inc., Kenilworth, N.J., USA is known as MSD outside the United States and Canada
Availability

MSD 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)

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 countries 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, MSD 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, MSD 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)