

# 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, improved health care and access to innovative medicines and vaccines. Nevertheless, there remains an urgency for targeted and coordinated action to further extend access to solutions that address critical global health needs.

As a research-intensive biopharmaceutical company, our purpose is to ***use the power of leading-edge science to save and improve lives.*** First and foremost, we discover, develop and deliver innovative medicines and vaccines in a responsible and sustainable manner.



Our Company actively works in partnership with various stakeholders, including private enterprises, government agencies, multilateral and non-governmental organizations, to help ensure our science advances health care. These collaborations are a key part of our work to enable access to health care that is affordable, efficient, equitable and sustainable on a global scale.



**This Statement of Guiding Principles was developed to steer our global approach to *improving access to health.***

Our commitment to improving access is embedded in our business strategies and across functions and geographies. On an annual basis, we track and report the number of people reached by our products around the world through commercial channels, clinical trials, voluntary licensing, and product donations.<sup>1</sup>

In collaboration with key stakeholders, we work to help ensure our products are accessible and affordable worldwide. ***Our company-wide access to health goals and key performance indicators demonstrate our commitment to taking measurable action to advance these principles.*** We report on our progress in our annual Impact Report.

<sup>1</sup> This people reached metric estimates the number of people who have received a Merck & Co., Inc. product through commercial channels, clinical trials, voluntary licensing and product donations. Product donations include people reached through the MECTIZAN Donation Program, U.S. Patient Assistance Programs, and the Merck Medical Outreach Program. Sources of data are Merck & Co., Inc. and third-party data sets that are tracked within an enterprise-wide internal database. The people reached metric for all sources is calculated as doses sold divided by the average dose schedule for a given market in a given year. People taking multiple products may be counted as multiple people toward the total estimate.

# Discovery and Invention

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

## Principle:

We evaluate and reflect global health needs in the research and development (R&D) of our products.

We invest in R&D to develop medicines and vaccines that address diseases with a significant global health burden, including in low-and middle-income countries (LMICs).

We collaborate with a diverse range of partners to expand our R&D reach to address global health needs. We pursue opportunities to provide access to compound libraries and molecules to spur the discovery and development of new products.

We conduct our clinical trials, including studies in LMICs, in accordance with the global standards of Good Clinical Practices (GCP), applicable local regulatory requirements and ethical principles derived from the Declaration of Helsinki.



## Key Performance Indicator:

Percentage of the top 20 global burdens of disease addressed by our products and pipeline<sup>2</sup>

Narrative of our R&D investments in infectious diseases and diseases that disproportionately impact populations in LMICs

Number of significant R&D collaborations established<sup>3</sup>

Number of GCP/Pharmacovigilance inspections by regulatory agencies of the company or clinical trial investigators, that led to significant fines, penalties, warning letters or product seizures

<sup>2</sup> As defined by the Global Burden of Disease study conducted by the Institute for Health Metrics and Evaluation.

<sup>3</sup> These collaborations are deemed 'significant' because they involve an asset or technology with the potential to make an important enhancement to our R&D capabilities.

# Availability

Our Company makes available a reliable, global supply of medicines and vaccines, and invests in solutions to enable timely access to them *in a responsible and sustainable manner*.

As an integral part of our access strategy, our manufacturing and supply chain teams actively participate in the early stages of product development and commercialization. This proactive engagement helps us to anticipate and plan for future manufacturing and supply chain requirements, as well as market-specific demands.

Our Company operates a streamlined and efficient supply chain network, producing medicines and vaccines that adhere to the highest standards of quality, safety and environmental responsibility. We rigorously comply with regulations, adhere to Good Manufacturing Practices and implement industry best practices.

**Access to Health Goal:**  
**Percentage of countries around the world reached annually with our products (goal: 75% of countries)<sup>4</sup>**



**We are committed to global product availability, quality manufacturing and operational excellence in our supply distribution.**

## Principle:

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

We sustain an interdependent, flexible supply chain that leverages innovation and technology to meet global, regional and local market supply needs.

We work to register our products where there is a need and the infrastructure to support safe delivery to patients.

## Key Performance Indicator:

- Global number of product recalls
- Number of product recalls exclusively outside of the U.S.
- Global number of units subject to recall
- Percentage of orders shipped on time and in full
- New product registrations
- Number of countries with products prequalified by the World Health Organization

<sup>4</sup>Countries are defined by the World Bank Country and Lending Groups. Includes only human health products.



# Affordability and Sustainable Access

Our Company develops, tests and implements access solutions that **address barriers to access and affordability** of our medicines and vaccines. This allows us to serve the greatest number of people today and expand our ability to meet the future needs of more people around the world. Where appropriate, we pursue these solutions in partnership with private enterprises, government agencies, multilateral and non-governmental organizations.

**We enable access to our innovative medicines and vaccines through dedicated, market-based access solutions for people who can benefit, taking into consideration **public health need, economic conditions and health care infrastructure.****



**Access to Health Goal:**  
**Enable 350 million more people to access our innovative medicines and vaccines through access solutions by 2025<sup>5</sup>**

Access planning starts in the early development phase, recognizing that this is the critical stage where we have the greatest opportunity to create long-term, sustainable access solutions, particularly for LMICs. Our strategic approach focuses on both expanding access to our innovations and maintaining and growing a sustainable business.

## Principle:

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

## Key Performance Indicator:

Number of people reached globally through product donations and patient assistance programs and partnerships<sup>6</sup>

<sup>5</sup> Metrics contributing to this goal are displayed on an annual basis and provide information on the number of people we estimate now have the option to access medicines and vaccines as a result of our sustainable access strategies, solutions and partnerships. These solutions include our commitment to Gavi and UNICEF (rather than doses shipped), collaborations to optimize resources in health systems, expanded financial coverage through insurance, and new community-based channel partnerships. "Innovative medicines and vaccines" refers to our Company's on-patent products. Enable "more people" is defined as populations supported by initiatives implemented and launched in market and will be in comparison to the baseline (2020) as of 2025. Evidence for metrics is sourced from publicly available data and proxy sources by market. While proxies differ by market, all methodologies are evaluated and represent our best estimate of people enabled to access innovative medicines and vaccines. People who were enabled to access innovative medicines and vaccines did not necessarily receive such innovative medicines and vaccines.

<sup>6</sup> Product donations include people reached through the MECTIZAN Donation program, as well as our Company's U.S. Patient Assistance Program and Medical Outreach Program. The number of people reached with product donations is also counted in our Company's "people reached" estimate.

# Strengthening Health Systems and Addressing Inequity

Through partnerships and collaboration, our Company applies its expertise and invests its human and financial resources to **address systemic barriers to care** where we believe we can make the strongest contributions to health systems, communities and people around the world.



## Access to Health Goal:

Further advance health equity by reaching more than 50 million people in LMICs and in populations underserved by health care in high-income countries<sup>7</sup> by 2025.



## Principle:

In partnership with local communities and other stakeholders, we support capacity building for health systems and care delivery. We address underlying barriers to access, including social determinants of health, that lead to health inequities.

We collaborate with partners to strengthen capacity of health workers, with a focus on those providing care in low-resource settings

## 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)

Number of health workers trained through major partnerships, programs and impact investments

<sup>7</sup>Social investments include our Company's philanthropic partnerships, programs and impact investments. "People underserved by health care" are defined as those that face health disparities due to disadvantages related to insurance status, social determinants of health, race, ethnicity, gender identity/sexual orientation, age and/or language preference.