



# Guiding Principles

## on Access to Healthcare

*A Project of the BSR Healthcare Working Group*

### **Cover Letter**

Improving access to healthcare globally is a pressing societal challenge. Progress has been made but we are faced with new challenges such as the increasing threat from Non-Communicable Diseases (NCDs) to the health of the world's population. There is a need for continued innovation to address current and future unmet medical and healthcare needs. This requires new thinking and a comprehensive approach: all stakeholders of a healthcare system have to work together in seeking sustainable solutions that promote universal access to care.

These Guiding Principles on Access to Healthcare are a call to action to expand access to quality healthcare. They build on the experience and lessons learned by the industry from working with many stakeholders to help improve access to medicines and vaccines for areas as diverse as HIV/AIDS, neglected tropical diseases and childhood immunization. New collaborative and system-wide approaches are needed. While government is primarily responsible for the well-being of its citizens, we—signatories (below) of the Guiding Principles—believe that by endorsing and delivering on the Guiding Principles the industry can meaningfully contribute to expanding access to healthcare globally.

As signatories of these Guiding Principles, we aspire to:

- Explore and develop appropriate ways to increase our contributions in the areas set forth in the Guiding Principles.
- Collaborate with key stakeholders—including governments, multi-lateral organizations, global health organizations, NGOs, and other industries—to address our shared responsibility for expanding access to healthcare.
- Share progress with stakeholders on activities in support of expanding access to healthcare.

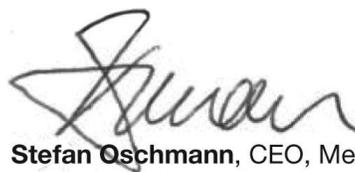
The Principles are aspirational guidelines to frame our response which may be adapted to meet individual and evolving circumstances. And as we reflect on our experiences in working towards the 2015 Millennium Development Goals, we hope that these principles will help contribute to thinking around the post-2015 Development Agenda.

We encourage others to join us in supporting these principles to expand access to healthcare.

## Signatories



**Yoshihiko Hatanaka**, President and CEO, Astellas



**Stefan Oschmann**, CEO, Merck Serono



**Lamberto Andreotti**, CEO, Bristol-Myers Squibb (1)



**Joseph Jimenez**, CEO, Novartis (1)



**Haruo Naito**, President and CEO, Eisai



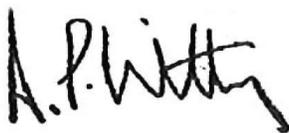
**Lars Rebien Sørensen**, President and CEO, Novo Nordisk (1)



**John C. Lechleiter, Ph.D.**, Chairman, President, and CEO, Eli Lilly



**Dr. Severin Schwan**, CEO, Roche (1)



**Sir Andrew Witty**, CEO, GlaxoSmithKline (1)



**Christopher A. Viehbacher**, CEO, Sanofi (1)



**Alex Gorsky**, Chairman and CEO, Johnson & Johnson (1)



**Yasuchika Hasegawa**, President and CEO, Takeda (1)



**Kenneth C. Frazier**, Chairman, President, and CEO, Merck (1)

- (1) Founding signatories are members of Business for Social Responsibility's (BSR) Healthcare Working Group who initiated and developed these Guiding Principles. Organizations may become signatories of these principles whether or not they were involved in the initiation and development of these Guiding Principles. Inquiries may be sent to BSR at [gpah@bsr.org](mailto:gpah@bsr.org).

## Preamble

Maintaining and expanding access to quality healthcare is a shared responsibility that requires bringing together complementary capabilities to drive system-wide changes. We—the signatories of these Guiding Principles—acknowledge the important role of the healthcare industry in striving to address global health challenges. Solving these challenges is a human necessity, and a business priority.

While governments are primarily responsible for the well-being of their citizens, we can support government efforts to expand access to healthcare by harnessing our unique competencies. In addition to government, we will collaborate with other key stakeholders—including multi-lateral organizations, NGOs, and other industries—to identify common agendas wherein we collaboratively address barriers that prevent people from receiving quality healthcare.

The following Guiding Principles frame our efforts—both as independent companies, and as a collective body of signatories—to reduce the global burden of disease by helping to ensure that medicines, vaccines, diagnostics and other medical technology and assistance are effectively developed and deployed. In all activities: we place paramount importance in the quality and safety of our products; we seek compliance with applicable laws and regulations; we promote strong ethical business practices (such as those that are embodied in our industry codes and standards); and strive to deliver commercial returns required for industry to sustain innovation.

Our Guiding Principles recognize the importance of each of the following five core areas:

- Collaboration
- Research and development
- Expanding availability of healthcare services
- Developing health systems resources
- Respecting human rights

## Collaboration

*Expanding access to healthcare is complex and requires the participation and cooperation of numerous diverse stakeholders, with complementary responsibilities and capabilities, to solve systemic challenges.*

- *Collaborators:* Positively impacting access to healthcare requires industry to work together with other stakeholders—including, governments, patient groups, healthcare providers, NGOs, multilateral organizations, payers, regulators and other organizations. We recognize that each stakeholder brings its own commitment, expertise and resources, to improve development, deployment and availability of medicines, vaccines, diagnostics and other medical technology while respecting areas of expertise and legitimacy.

## Research & Development

*R&D is the primary mechanism through which we seek to meet unmet health needs.*

- *Developing and Adapting Products:* We invest in R&D across a broad range of disease areas to address prevention, detection, diagnosis, and treatment of diseases (communicable, non-communicable and neglected) and work to expand the applicability of medicines and medical products.
- *Promoting Innovation & Intellectual Property Rights:* We depend on R&D to promote innovation and we support a variety of approaches such as clear patent policies and, when appropriate, voluntary licensing and collaborative models to increase access to our products. We believe that appropriate intellectual property protection enables innovation and creates the necessary conditions to make our R&D sustainable and enhance innovations over time.
- *Clinical Trials:* We are dedicated to increased transparency of our clinical trial results, while respecting a company's proprietary information and a patient's personally identifiable information, as well as ensuring the safety, dignity, well-being, and legal rights of those taking part in trials. We only perform clinical studies in countries that are in compliance with international guidelines, and in countries where we intend to make the product available.
- *Building Local R&D Capacity:* We support the development of R&D capabilities, for example, through technology transfers, clinical trials and skills building.

## Availability

*The results of our innovations are only of value to patients if they are available and accessible. Approaches need to be market appropriate and reflect adherence to globally recognized compliance guidelines.*

- *Pricing:* Individually, we seek appropriate pricing strategies that recognize the value of innovation while addressing barriers to access. Strategies may include value-based pricing and differential pricing where price is a barrier and there is a strong commitment to expanding access to healthcare in a sustainable manner.
- *Registration:* We support the broad, timely and efficient registration of high quality medicines through appropriate regulatory frameworks.
- *Commercialization:* We support exploring new business models, which may include innovative financing and distribution mechanisms, to expand access in a manner that remains supportive of long-term commercial viability.
- *Policy:* We contribute to shaping policy that expands sustainable access to healthcare, and supporting the development, registration, distribution and monitoring of health innovations.

## Health System Resources

*Quality healthcare rests on the strength and capacity of local health systems.*

- *Capacity Building:* We collaborate with key stakeholders to strengthen health systems through a variety of means such as training health practitioners, advancing patient education, investing in health infrastructure and improving supply chain efficiency and integrity.
- *Detection, Prevention and Awareness:* We support improvements in detection, prevention and health literacy to build awareness and educate the public on ways to prevent and treat disease.
- *Investing in our employees and suppliers:* We invest in our employees and suppliers through training programs and capacity building, which contributes to community development.

## Respecting Human Rights

*A respect for human rights is at the foundation of our activities.*

- *Respecting Human Rights Norms:* We support principles that have their origin in the UN's "Guiding Principles on Business and Human Rights," the Universal Declaration on Human Rights, and the Declaration of Helsinki.
- *Non-discrimination:* We respect global human rights standards and support access to our products within communities, irrespective of differences.

## Disclaimer

The signatories view these Guiding Principles as an industry framework for developing individual, internal policies, procedures and practices on access to healthcare. These Guiding Principles do not create any rights in, or liability to, any person or organization, public or private.

All discussions within the BSR Healthcare Working Group forum—with regards to the Guiding Principles on Access to Healthcare and other items as well—will be conducted on an over-arching industry wide level in accordance with a pre-agreed agenda for each meeting and with strict adherence to any applicable competition laws. In particular no strategic or forward looking information, that enables a participant to plan ahead accordingly or to coordinate commercial activities, will be discussed or shared.