

# PATH's Guiding Principles for Private-Sector Collaboration

PATH creates sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. Our mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.

Collaboration—including collaboration with the private sector—is a key element in PATH's approach. Our goal for private-sector collaboration is to achieve maximum sustainable benefit for public health through engaging private-sector collaborators to apply their development, manufacturing, and distribution strengths toward innovative technologies that, in the absence of PATH involvement, would not be a private-sector priority.

## Purpose and Scope

PATH developed these Guiding Principles for Private-Sector Collaboration to:

- Articulate key institutional policies and positions regarding PATH collaborations with private-sector companies.
- Provide PATH staff with guidance in managing private-sector collaborations.
- Provide current and potential private-sector collaborators with an overview of PATH's perspectives and expectations for collaboration.

PATH's board of directors and president fully endorse these principles. The principles convey both the broad direction and the specific actions that they expect of all PATH teams that form collaborations with private-sector companies.

These principles primarily address the following types of collaborations:

**Transfer of a technology developed or owned by PATH.** PATH develops a technology in-house and transfers the intellectual property to a private-sector collaborator for further development, manufacturing, and distribution.

**Support by PATH for development of a collaborator's product.** PATH provides significant resources or expertise (such as funding, management, codevelopment, and assistance with clinical studies) to a private-sector collaborator to support the collaborator's development of a product.

**Support by PATH for introduction of a collaborator's product.** PATH supports and/or undertakes significant programmatic activities (such as field trials, epidemiological studies, and advocacy programs) that demonstrate and communicate the public health value of a product produced by a private-sector collaborator.

# Principles for Private-Sector Collaboration

To achieve our mission while preserving PATH's integrity and status as a publicly funded, nonprofit, nongovernmental organization, collaborations with private-sector companies must be consistent with the following principles.

## Clear Link to Mission

PATH's collaborations with private-sector companies must lead to positive impact on the availability, accessibility, and affordability of important health products for public health programs in developing countries.

When assessing whether a proposed private-sector collaboration will have sufficient mission linkage and impact, PATH considers the following key issues:

**Availability:** Have PATH and the collaborators created a product-development program that is sufficiently rigorous, funded, and prioritized to provide a reasonable opportunity for success?

**Accessibility:** Have PATH and the collaborators envisioned a manufacturing and distribution plan that can lead to sufficient quantities of the product through appropriate channels to meet clearly defined public-sector demand in developing countries?

**Affordability:** Have PATH and the collaborators openly discussed and agreed upon a product pricing approach that can result in widespread adoption in public-sector programs of developing countries over a reasonable time through purchase by local governments or support of international donor agencies?

Because PATH is a nonprofit organization working under US tax law, it is important to document the mission-oriented contributions and commitments of the private-sector collaborator. PATH achieves this by developing appropriate commitments by the private-sector collaborator to increase the availability, accessibility, and affordability of the technology in developing-country public health programs. Each collaboration will require that PATH and the private-sector company explore a variety of approaches, incentives, and mechanisms to reach a balanced relationship aimed at serving both public good and commercial objectives.

## Recognition of Private-Sector Needs

In collaborating with a private-sector company, PATH must recognize the company's need for commercial benefit in order to ensure a sustainable commitment to the collaboration.

PATH's goals for availability, accessibility, and affordability of products for developing-country public health programs will likely be met if PATH's expectations of the private-sector collaborator are realistic and structured to take into account many factors, for example:

- The legitimate need of the private-sector company to pursue a profit in order to ensure a sustainable supply of the product.
- Recognition of the full range of costs necessary from product development to commercialization.

## Clear Definition of Roles, Responsibilities, and Expectations

In all collaborations, the relationship between PATH and the private-sector company must be clearly defined through an appropriate written document or agreement.

These agreements must cover, at minimum, the following information:

- The objectives of the collaboration, the roles and responsibilities of each partner, and the expected outcomes.
- The accountability and performance milestones that will be used to ensure that the goals of the collaboration are met.
- A clearly defined management and decision-making structure of the collaboration.
- A clearly stated process for monitoring, evaluating, and terminating the collaboration.

## Transparent Collaboration

As a publicly funded organization, PATH must maintain a level of transparency in its collaborations with the private sector.

At the same time, PATH understands the commercial needs of its private-sector collaborators and will meet requirements to maintain confidentiality of proprietary business, project, and product information. For all collaborations with private-sector companies, PATH needs, at minimum, to be able to disclose:

- The existence of the collaboration and identity of company.
- The broad purpose of the collaboration.

PATH will work with the collaborator to agree upon the appropriate level of disclosure.

## Appropriate Selection of Collaborators

Because the success of any collaboration depends on the selection of a good partner, PATH must conduct a thorough assessment before entering into a formal collaboration with a company.

PATH will:

- Assess the reputation of the company, its corporate behavior, and its economic viability to ensure compatibility with PATH's mission and reputation.
- Review the scientific and technical capabilities of the collaborator to make sure they are appropriate for the collaboration.
- Ensure that the public health outcomes and return on public-sector investment will be commensurate with the effort involved in establishing and maintaining the collaboration.

## Appropriate Management of Risk

PATH must carefully assess and manage both the broad institutional risks as well as the specific project risks when collaborating with a private-sector company.

Examples of risks that PATH may face include product liability, financial loss, and damage to its reputation. Risks can be appropriately managed by following the principles outlined in this document and ensuring that proper indemnification and enforcement mechanisms are in place in contractual agreements between PATH and private-sector collaborators.

## Dissemination of Results

As a publicly funded organization, PATH has a fundamental obligation to ensure dissemination of the results of its private-sector collaborations.

PATH also recognizes the importance of linking dissemination of results with appropriate protection of intellectual property and will work with private-sector collaborators to achieve this objective.

## Awareness of Potential Conflicts of Interest

In all collaborations with private-sector companies, PATH must carefully assess the potential for both perceived and real conflicts of interest at both the institutional and individual staff member level.

Proactive disclosure of PATH's relationships with private-sector companies is fundamental to the proper management of conflict of interest issues.

## Ensuring High Standards of Quality and Ethics

PATH must ensure that all collaborative research, product development, and introduction activities meet the highest standards of safety, quality, and integrity.

In particular, PATH places the utmost importance on ensuring the ethical and respectful treatment of human participants in research endeavors. PATH also believes in humane treatment of animals involved in research and production.

PATH expects its private-sector collaborators to:

- Meet international standards for good manufacturing, clinical, and laboratory practices.
- Maintain scientific integrity in all collaborative work.
- Ensure that proper reviews and approvals are obtained by institutional review boards.
- Adhere to mutually agreed-upon standards of humane treatment of animals.