



# PATH in China

From innovation to impact

Since 1979, PATH has collaborated with Chinese government agencies, nongovernmental organizations, research institutes, and manufacturers to improve health and save lives. In the 1980s, our work focused on helping Chinese manufacturers increase the quality and production of oral and injectable contraceptives, condoms, and intrauterine devices.

Since then, PATH has expanded our partnerships and work in China to cover a range of health areas, including maternal and child health, adolescent health, HIV/AIDS, tuberculosis, and vaccines and immunization. We have maintained an office in Beijing since 2003.

PATH's partnerships in China are having a remarkable impact, both inside China and beyond its borders. With technical assistance and support from PATH, China is becoming a leading supplier of lifesaving health technologies and products for use in low-resource settings.

## PROJECT AND OFFICE LOCATIONS IN CHINA



## OVERVIEW OF PATH'S STRATEGY AND WORK IN CHINA

PATH's strategy in China rests on three pillars:

- Developing a sustainable and competitive business model through our innovation and impact in the global health market and China health market.
- Improving local capacity, optimizing use of internal PATH resources, and increasing operational efficiency.
- Strengthening our storytelling about our work and exploring multiple local funding sources.

Our current programmatic areas of focus include tuberculosis, vaccines and immunization, neglected tropical diseases, child nutrition, malaria, diarrheal disease, and reproductive health.

*"In the next decade, China will play a unique and critical role in promoting health and development in sub-Saharan Africa and other low-resource settings, especially for women and children. PATH looks forward to collaborating with the Chinese government and companies to provide innovative and sustainable health solutions to vulnerable populations."*

—Steve Davis, PATH President and Chief Executive Officer

## IMPROVING TUBERCULOSIS CONTROL IN CHINA

China has a high burden of tuberculosis (TB) and multidrug-resistant TB. Since 2009, the Bill & Melinda Gates Foundation and the China National Health and Family Planning Commission have collaborated to develop and demonstrate effective, comprehensive TB control models using innovative tools and approaches. PATH assists Chinese partners of this program by:

- Building capacity and offering coaching in program management and operations.
- Providing technical assistance in comprehensive model demonstration and scale-up.
- Evaluating use of new tools and delivery approaches.
- Identifying unmet needs and coordinating experts' work to ensure timely technical assistance.

With PATH's assistance, the program has evaluated or demonstrated the operational performance of nine diagnostic tools, including five from domestic sources, and assessed the implementation of comprehensive TB control models in three cities across China, covering a population of 10 million. PATH is currently working with partners to evaluate medication monitoring in 24 counties to determine the long-term impact on treatment outcomes and helping to scale up comprehensive TB control models in Zhejiang Province, Jilin Province, and Ningxia Hui Autonomous Region, with a combined population of 88 million. The project is to provide a replicable reference model for nationwide implementation of the 13th Five-Year National Plan of TB Control (2016–2020).

## STRENGTHENING CAPACITY IN VACCINE DEVELOPMENT AND PRODUCTION

PATH has led a range of activities to help improve and expand vaccine development and production in China. Our support has covered many technical areas:

- Assay, process, and formulation development.
- Vaccine stability.
- Clinical trials (especially outside China).
- Compliance with Good Manufacturing Practices.
- Pharmacovigilance.
- International regulatory requirements.
- Decision-making tools for countries.

Since 2006, PATH has worked with the Chengdu Institute of Biological Products Co., Ltd.—a subsidiary of the China National Biotec Group Co., Ltd. (CNBG)—to bring an



#### Countries that have rolled out the Japanese encephalitis vaccine:

- Cambodia
- India
- Laos
- Nepal
- North Korea
- South Korea
- Sri Lanka
- Thailand
- Vietnam

effective, affordable vaccine against Japanese encephalitis to people in Asia and the Western Pacific. In 2013, this vaccine became the first vaccine from a Chinese manufacturer to achieve prequalification by the World Health Organization (WHO), marking China's entrance into the global vaccine marketplace. With favorable public-sector pricing, the vaccine has been used in immunization campaigns and programs in a number of Asian countries (see map). By the close of 2016, more than 232 million people had received the vaccine.

At the same time, as the world strives to eradicate polio, PATH is helping to boost production of an affordable bivalent oral polio vaccine (bOPV) through a partnership with the Beijing Bio-Institute Biological Products Co., Ltd (BIBP). PATH is assisting with a clinical study in Kenya to assess the immunogenicity and safety of the bOPV in comparison with a previously approved vaccine. Once the vaccine is prequalified by WHO, BIBP will be ready to supply up to 240 million doses each year.

In addition, PATH and the Wuhan Institute of Biological Products Co., Ltd. (a subsidiary of CNBG) have collaborated to develop a hexavalent oral rotavirus vaccine to protect children against diarrheal disease. And we have supported two Chinese manufacturers to accelerate WHO prequalification of vaccines to prevent infection with human papillomavirus, the primary cause of cervical cancer. Since 2011, PATH has provided assistance to Chinese companies to increase the number of WHO-

prequalified vaccines as part of the Advancing Vaccine Manufacturers Project.

*"As a nonprofit organization, PATH has been helping people in need in China and other countries. As a partner, we appreciate the behind-the-scenes support that PATH has been providing throughout a decade, especially their science-based advice."*

-Dr. Xiaoming Yang, Chief Executive Officer and President, China National Biotech Group Co., Ltd.

#### DEVELOPING DIAGNOSTICS AND DRUGS

PATH has been at the forefront in developing new diagnostic tests for use in low-resource settings. For example, PATH partnered with QIAGEN, a German company, to develop the *careHPV™* test, a robust, affordable, and accurate DNA test to detect human papillomavirus. The test is manufactured in Shenzhen, China, and is approved for use by the China Food and Drug Administration.

PATH has also helped to control neglected tropical diseases through innovation in diagnostics and drugs. For instance, we are leading an international consortium to advance global use of tribendimidine to treat infections with soil-transmitted helminths. Innovative financing for this work has come from a life sciences investment firm and a global health impact fund. Our partners in China include the National Institute of Parasitic Diseases at the Chinese Center for Disease Control and



Prevention, which developed the drug, and the Shandong Xinhua Pharmaceutical Co., Ltd.

## CREATING NEW DEVICES FOR REPRODUCTIVE AND CHILD HEALTH

To help protect women against both unintended pregnancy and sexually transmitted infections, PATH and our partners developed the Woman's Condom, a next-generation female condom that is more acceptable to users than earlier products. The Shanghai Dahua Medical Apparatus Co., Ltd., manufactures the product, marketed under the brand name O'Lavie®. PATH has helped to increase product awareness in China, verify acceptability with users, and develop a sustainable market. Many partners across China have supported PATH's work in market research, testing, and advocacy to build awareness and strengthen the environment for female condoms. The Woman's Condom has been approved by the Shanghai Food and Drug Administration, received CE mark approval, and been registered in several countries. It has also been prequalified by WHO.

For preterm infants who have difficulty breastfeeding, experts recommend hand expression of breast milk and use of a small cup for feeding. PATH and our partners developed the Nifty Feeding Cup for these infants. The simple-to-use cup incorporates special design features such as a unique reservoir and flow channels that allow infants to sip breast milk at their own pace. The cup is manufactured in Suzhou, Jiangsu Province.

To prevent diarrheal disease among children from drinking contaminated water, PATH has worked to make household water treatment products more accessible. In China, we have collaborated with three firms to produce, distribute, and sell products based on a design initially developed by PATH.

## LOOKING TO THE FUTURE

China's role in the global health marketplace is expanding. PATH will continue to engage with the Chinese government to advance the country's role in global health. We will further partner with Chinese companies across technology platforms—including vaccines, drugs, diagnostics, and devices—to help them meet international quality standards, develop markets, and become

large-scale suppliers of affordable products for improving health and saving lives in low-resource settings.

*"We have really enjoyed partnering with the PATH China TB project team for the past several years. Their professional attitude, technical knowledge, project management skills, and dedication to the ongoing China Ministry of Health–Bill & Melinda Gates Foundation TB Control and Prevention Project deserve our sincere acknowledgment."*

—Dr. Yanlin Zhao, Director, China National Tuberculosis Reference Laboratory

## Funders

Many organizations have supported PATH's work in China. Major funders have included the Bill & Melinda Gates Foundation, Netherlands Ministry of Foreign Affairs, and US Department of Health and Human Services.



PATH is a leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

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