Strengthening national regulatory capacity

PATH supports countries to ensure health products are safe, effective, and swiftly delivered

Before a new medical product can be evaluated in a clinical trial or made available to the public, it must be assessed and approved by a country's national regulatory agency. In the United States, for example, the US Food and Drug Administration reviews products intended for Americans. These regulatory processes protect the public's health by ensuring the safety and efficacy of products before they are widely distributed.

Many low-income countries, however, lack the resources, expertise, or capacity to adequately regulate the development and use of health technologies in line with international standards. At the same time, everyone agrees on the importance of rigorous oversight to ensure that clinical trials are monitored for safety and that unsafe or ineffective technologies do not enter the marketplace.

Investments to strengthen local capacity for regulating the development, manufacture, and use of health technologies around the world will help countries improve their ability to independently regulate health products.

STREAMLINING INTRODUCTION OF NEW TECHNOLOGIES

Introducing a new medical product in a country requires a clear regulatory pathway that identifies which agencies must review and approve the product, what data must be submitted, and a timeline of the steps to receive approval. One challenge is that the regulatory requirements and standards vary across countries, making it difficult for product developers to swiftly and efficiently test and deliver new health tools to multiple populations.

Many organizations are working to help countries align their regulatory processes and meet globally recognized standards, and to ensure that countries are equipped to lead these processes independently in the future. To help achieve this, the World Health Organization's (WHO) African Vaccine Regulatory Forum and PATH brought the first vaccine designed specifically for Africa to market.

PATH/Gabe Bienczycki

Health workers in Burkina Faso prepare to deliver the first doses of MenAfriVac™—a vaccine developed to protect specifically against the most common type of meningitis in Africa.

PATH and WHO launched the Meningitis Vaccine Project in 2001 to develop a low-cost vaccine to significantly curb deadly meningitis A epidemics in sub-Saharan Africa.

The WHO's African Vaccine Regulatory Forum, in collaboration with PATH, engaged scientists and regulators from the 25 countries comprising Africa's "meningitis belt" to streamline the entire regulatory process. Together, these groups conducted reviews of the clinical trial plan and rules of conduct, as well as inspections of clinical trial sites to ensure that the studies complied with international and national standards. Additionally, the African Vaccine Regulatory Forum convened the national regulatory authorities to conduct reviews of the final trial data in support of vaccine registration in the countries.

By engaging national regulatory authorities throughout all stages of the vaccine development and licensure process, countries were prepared and able to implement rapid, large-scale introduction as soon as the vaccine was approved.

In 2010, the MenAfriVac™ vaccine, produced by Serum Institute of India Ltd., was prequalified by the WHO for purchase by United Nations agencies. By December 2010, the first doses of MenAfriVac™ were delivered to sub-Saharan Africa as part of large-scale immunization

campaigns. As of July 2012, more than 56 million people received the vaccine with no cases of meningitis A reported among those vaccinated.

PATH/Gena Morgan

A health worker tests an infant for malaria in Lusaka, Zambia. The world's most clinically advanced malaria vaccine, RTS,S, could soon protect infants and children from this common cause of child death.

ENSURING THE SAFETY OF CLINICAL TRIALS

Before a new medicine, vaccine, or diagnostic is tested with people, regulatory authorities in countries where the clinical trial will take place must review and approve the study's plan and rules of conduct. This process is critical to ensure the study is safe and meets national ethical standards.

To strengthen regulatory capacity in developing countries—which often host clinical trials because they are hardest hit by many diseases—it is imperative that private and public research institutions conducting studies collaborate with national regulatory authorities to review the clinical trials.

For example, PATH and our partners worked closely with the WHO's African Vaccine Regulatory Forum and regulators from seven African countries to conduct a joint review of a clinical trial evaluating the effectiveness of the most advanced malaria vaccine candidate: RTS,S.

This monumental research effort helped African scientists and regulatory officials increase their capacity to oversee clinical trials, align national regulatory requirements, and expedite the study review process.

Today, the large-scale efficacy trial evaluating the vaccine has enrolled more than 15,000 children and infants at 11 sites in seven African countries.

EXPANDING ACCESS TO PROVEN HEALTH TECHNOLOGIES

For 20 years, a vaccine was used in China to protect more than 200 million children from Japanese encephalitis—a neglected disease that disproportionately impacts people living in poor rural communities in Asia—while millions of other children remained at risk because the vaccine was not approved or available in all endemic countries.

To facilitate access to this vaccine, PATH established cross-sector partnerships at local and international levels in 2003 to enhance disease surveillance, negotiate affordable vaccine pricing, and assist with the planning and implementation of immunization programs.

PATH initiated negotiations with the vaccine's manufacturer, the Chengdu Institute of Biological Products in China, to increase access to the Japanese encephalitis vaccine. PATH supported the construction of a new factory and is helping the manufacturer prepare data and submit an application for prequalification from the WHO. The WHO prequalification is a prerequisite for a product's eligibility for procurement by UN agencies—one mechanism for helping ensure affordability. Additionally, prequalification from the WHO is often used as a proxy for approval from under-resourced national regulatory authorities, and is an indication that a product is safe for global markets.

As a result, the Japanese encephalitis vaccine has been introduced in five new countries, including India, where about 81 million children have been vaccinated since 2006.

BUILDING CAPACITY FOR A HEALTHIER FUTURE

We have learned that investments that strengthen national regulatory capacity in other countries is a cost-effective way to improve product development for global health technologies—and ultimately save lives.

Regulatory processes are designed to ensure that products are safe and effective before they are widely distributed. As global commerce expands to developing countries, the strength of regulatory authorities impacts people around the world. The United States should continue working with national authorities to strengthen regulatory processes so that desperately needed health products are delivered, improving health and equipping countries with the expertise and infrastructure to make important health decisions for years to come.

PATH
A catalyst for global health

PATH is an international nonprofit organization that transforms global health through innovation. We take an entrepreneurial approach to developing and delivering high-impact, low-cost solutions, from lifesaving vaccines and devices to collaborative programs with communities. Through our work in more than 70 countries, PATH and our partners empower people to achieve their full potential.

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July 2012