

ARNOLD & PORTER
KAYE SCHOLER

New Compliance Challenges: Asia Pac Public Private Pharmaceutical Partnerships

Keith M. Korenchuk
Partner

Shanghai
September 15, 2017

apks.com

Arnold & Porter Kaye Scholer LLP
All Rights Reserved.

Changing Business Models, Changing Compliance Risks

- **Public Private Partnerships (PPP) in Asia**
- **What are they?**
- **What do they cover?**
- **How do they work?**
- **What is the role of compliance?**

Public Private Partnerships (PPP): A Case Study



PATH mobilizes cross-sector partnerships, starting with a country's needs, partnering with government and civil-society institutions to develop and introduce health solutions that address the country's highest priorities

Partnerships created with corporations, foundations, social entrepreneurs, individuals, as well as governments and multilateral institutions provide complementary strengths and capabilities



Celebrating 40
years of innovation
to save lives

PATH Projects: China

- PATH's relationships in China began in 1979, and it has collaborated with government agencies, nongovernmental organizations, research institutes, and manufacturers
- **Projects in China**
 - **Tuberculosis:** PATH is part of a collaborative effort to address China's high burden of TB and multi-drug resistant TB by developing and demonstrating effective, comprehensive TB control models using innovative tools and approaches
 - **Vaccines:** PATH partners with Chinese vaccine developers and manufacturers. For example, PATH supported the Chengdu Institute of Biological Products to produce a vaccine against Japanese encephalitis. It was the first vaccine from a Chinese manufacturer to achieve prequalification by the World Health Organization (WHO)
 - **Diagnostics and drugs:** PATH is collaborating with Chinese and global partners to develop, advance, and manufacture a new DNA-based diagnostic for HPV. It also leads an international consortium to advance the use of a new drug called tribendimidine, to treat infection from parasitic worms known as soil-transmitted helminths.
 - **Devices for reproductive and child health:** PATH's work to make health devices and tools available and affordable worldwide has long been supported by collaboration with Chinese manufacturers. Innovations produced with Chinese partners include household water treatment products, the woman's condom and the Nifty Feeding Cup, a simple, handheld cup that allows infants who cannot breastfeed to lap breast milk.

PATH Projects: India

- PATH has worked in India since 1978
- **Projects in India**
 - **Vaccines:** For nearly 10 years PATH supported the introduction and scale-up of a vaccine against Japanese encephalitis. Currently, PATH is supporting encephalitis treatment centers to build the skills of health personnel, create community awareness, and strengthen data management to identify and treat encephalitis from other causes
 - **Innovative technology:** PATH also partnered with Serum Institute of India Private Ltd. to develop an affordable vaccine for epidemic meningitis A in sub-Saharan Africa. Known as MenAfriVac®, it is a prime example of how PATH engages Indian companies and experts to improve health
 - **Tuberculosis:** In Mumbai, PATH supports a unique public-private partnership that is increasing the private sector's contribution to universal access to high-quality TB services—a model that could be adapted to other diseases. PATH has also provided technical assistance to strengthen TB laboratory networks
 - **Nutrition:** PATH helped the government develop national guidelines for breast-milk banking and set up milk banking systems using cost-saving technologies, such as a pasteurization monitoring process guided by mobile phones. PATH also worked closely with Indian partners on rice fortification, establishing a low-cost, high-quality production facility that now reaches hundreds of thousands of children every day, and developing a market and distribution system through India's public- and private-sector channels.

Scoping Compliance Risks: Practical Considerations

- Evolving business models and the challenges they present for compliance
- The nature of PPPs cuts across traditional functions
- The risks inherent in a siloed approach to PPPs
- Engaging the project team to identify compliance risks
- Is compliance at the table?
- Input of compliance in designing controls to manage risks

Managing Compliance Risks: PPP Governance

- **Key compliance governance considerations**
 - Decision-making
 - Oversight and auditing
 - The roles of commercial and medical from the company perspective
 - Transition and exits

Managing Compliance Risks: Areas of Focus

- Key compliance risk areas (not including IP, business and transactional)
 - Third party risks
 - Anticorruption
 - Privacy and Data Protection
 - Counterfeiting
 - PV and safety
 - Charitable

Managing New Compliance Risks

- Key takeaways and lessons learned