### **IMPACT & INNOVATION SERIES**



# **Preparing for the Global Market:** China's Expanding Role as a Vaccine Manufacturer

Reflections from a Gathering of Unlike Minds

At the 2011 Pacific Health Summit in Seattle, a workshop on China's global role in vaccines and immunization convened a lively, interactive panel of Chinese government and industry leaders. Key topics included the state of vaccine manufacturing in China today, domestic manufacturing and research and development (R&D) capacity, the evolution of regulatory systems as international standards become primary priorities, and areas for partnerships and collaborations with international partners. Workshop participants hailed from across many sectors and geographies. This report is a summary of the rich and thoughtful discussion that took place.

#### Inside

- 2 ... China's Vaccine Manufacturing Landscape
- 5 ... Updating China's Vaccine Regulatory System
- 11 ... Key Areas of Opportunity

### Contributors

**Sally Davies**, Chief Medical Officer, UK National Health Service

Kewen Jin, General Manager, Aura Partners

Meng Li, Deputy Director of International Cooperation, China National Biotec Group (CNBG)

**Rob Lin**, Deputy Director of Financial Planning and Analysis, Global Health Program, Bill & Melinda Gates Foundation

**Jilan Liu**, Special Advisor, The National Bureau of Asian Research

**Qi Shen**, Director, Biological Products Testing at the National Institutes for Food and Drug Control, State Food and Drug Administration (SFDA) **Shi Li**, CEO, Shanghai Zerun Biotechnology Co., Ltd

Yu Wang, Director General, China's Center for Disease Control and Prevention (CDC)

**Yonglin Wu**, Vice President, China National Biotec Group (CNBG)

Xiaoming Yang, President, China National Biotec Group (CNBG)

**Jiankang (Jack) Zhang**, Director, China Program, PATH



PACIFIC HEALTH SUMMIT SEATTLE-LONDON

A 2011 Pacific Health Summit workshop report

### The Current Vaccine Manufacturing Landscape in China

n March 2011 the World Health Organization (WHO) approved China's State Food and Drug Administration (SFDA) as a functional regulatory authority for vaccines. This approval means that the SFDA fulfills the WHO's criteria for international standards in vaccine regulation, and thus Chinese-made vaccines approved by the SFDA should ultimately meet internationally recognized standards and can apply for WHO prequalification status.<sup>1</sup>

The WHO's major announcement comes at a time when China's vaccine manufacturing industry is arguably at its most robust. Today, China's 40 domestic vaccine manufacturers produce 49 types of vaccines that protect against 27 diseases. The industry's massive annual output totals nearly 1 billion doses, the world's highest yield in terms of a single national economy's vaccine output.

What are the forces behind China's recent enormous growth in this area? The answer: intense competition among domestic manufacturers, a surge of investment capital both from within the country and abroad, tremendous government support, the return of motivated and educated emigrants with experience in multinational pharmaceutical and biotechnology companies, and an eagerness to expand product sales to the international market. Placed against the backdrop of SARS and avian flu outbreaks in recent years as well as a constantly advancing, cutting-edge domestic disease surveillance system run by the China CDC that reaches every township in China in real time, the boom in vaccine innovation and manufacturing is even more understandable.

"The concentration of players in China's vaccine industry is very low, so the competition is intense," remarked **Yonglin Wu**, Vice President, China National Biotec Group (CNBG). CNBG is China's largest biological products manufacturer and part of the state-owned Sinopharm Group, China's largest pharmaceutical company. China's vaccine industry as a whole comprises a mix of public, semi-private, and private firms of various sizes.

An additional factor that has contributed to the recent growth of China's pharmaceutical industry is a growing number of multinational pharmaceutical companies that have built a presence there in recent years, as well as the growing trend of collaborations between Chinese vaccine manufacturers and these multinational players.

"The concentration of players in China's vaccine industry is very low, so the competition is intense."

> Yonglin Wu, Vice President, China National Biotec Group (CNBG)

**Xiaoming Yang**, President, CNBG, noted a positive experience of collaborating with Merck concerning hepatitis B vaccine: "We've had very good experiences with them," said Yang. "About twenty years ago, they

<sup>1</sup> WHO prequalification ensures that vaccines used in national immunization services in different countries are safe and effective for target populations at the recommended schedules, and that they meet particular operational specifications. Every year, billions of U.S. dollars-worth of medicines and vaccines are purchased by international procurement agencies for distribution in resource-limited countries. Prequalification is intended to give these agencies the choice of a wide range of quality medicines for bulk purchase. For more information, see the WHO webpage, "A system for the prequalification of vaccines for UN supply," http://www.who.int/immunization\_standards/vaccine\_quality/pq\_system/en/index.html.



transferred the technology for hepatitis B vaccine. Then we manufactured the vaccine domestically and provided it to the whole country. This is a great example of a successful partnership between multinationals and local pharma."

More recently, in July 2010 Merck and Sinopharm signed a cooperation agreement on HPV vaccine and several others, with a focus on marketing Merck products in China.

In addition to garnering the interest of multinationals, China's domestic vaccine industry has also attracted Chinese expatriates. **Kewen Jin**, General Manager, Aura Partners, mentioned the arrival of returning Chinese professionals and the energy they bring to the industry. "Almost like an Internet start-up, these firms are often started by people who were born in China, went to the West for graduate school, worked there and learned the trade, and have now come back to China to take advantage of the healthy business climate," he said. Global health leaders have taken note of the recent boom of the vaccine industry in China. "I am terrifically impressed by how things have changed since I visited Shanghai four years ago," said **Sally Davies,** Chief Medical Officer, UK National Health Service. "Back then, the vaccine manufacturers and the SFDA were clearly just beginning the ramp-up, and now industrial and regulatory efforts are progressing with the WHO prequalification. Progress is dramatic, and will have a big impact on global health."

### Making Products for Different Domestic Markets: Public and Private

In China the government is the primary purchaser of domestically produced vaccines, and purchases all of the vaccines covered under its Expanded Program on Immunization (EPI). This market is known as the

### **China's Domestic Immunization Success**

China's Expanded Program on Immunization (EPI) is extraordinarily successful, with an immunization rate that regularly exceeds 90% at the township level, a hepatitis B infection rate of less than 1%, and the eradication of polio.<sup>†</sup> These figures are even more impressive when factoring in China's diverse landscape as well as its population, the world's largest, of 1.3 billion people.

What are the keys to the success of China's national vaccine program, and is it possible to replicate in other countries? Participants discussed a myriad of interconnected factors, among them:

- Comprehensive immunization as a national priority in practice as well as in policy;
- Providing EPI vaccines free of charge;
- Recognition that there is more to achieving immunization than just the vaccine itself; and
- Cross-discipline, collaborative efforts covering all aspects of the program.

China's comprehensive national immunization program has continually been a top priority for the government since its inception in 1978, steered by the recognition that a healthy population equals a healthy economy. Leaders actively organized and built the necessary infrastructure and personnel, and the EPI has since expanded from its original four vaccines to covering nearly all of the vaccinepreventable diseases found in China. EPI vaccines are mandatory for children to attend school and are given free of charge.

Active cooperation among stakeholders and a universal adherence to vaccination requirements are key factors to achieving high immunization rates, said **Yu Wang**, Director, China's Center for Disease Control and Prevention (CDC). "A collaborative approach among those who share a stake in immunization is essential." As such, China's EPI workforce comprises 400,000 workers, including not only clinicians, but also CDC employees and other public health personnel whose roles are to inform, direct, and encourage immunization.

Yu Wang emphasized, "The development of safe, highquality vaccines is a fundamental building block, but the delivery and service systems are also essential components of a successful immunization program."

<sup>&</sup>lt;sup>7</sup> Reports indicate that non-indigenous polio has been recently found within Chinese borders. In September 2011 ten cases of wild poliovirus type 1 (WPV1) were reported in China's western Xinjiang Autonomous Uyghur Region. The viruses were found to be genetically related to the polio viruses currently spreading in Pakistan. Per the WHO, the last WPV case in China was reported in 1999, due to an importation from India. However, the last *indigenous* polio case occurred in China in 1994. For more information, see "Ongoing outbreak of wild poliovirus type 1 in China: WHO/ Europe's recommendations and response," http://www.euro.who.int/en/what-we-do/health-topics/ disease-prevention/vaccines-and-immunization/news/news/2011/09/ongoing-outbreak-of-wildpoliovirus-type-1-in-china-whoeuropes-recommendations-and-response.



"public market." Notably, the government not only purchases EPI vaccines, but also sets their prices, which are usually set very low. With the government as the sole purchaser in the public market, participants noted, those manufacturers concentrating on EPI vaccines are not subject to the same set of free market variables that often determine vaccine prices.

"Chinese innovation will go in the direction of the private market, toward new vaccines that are not covered in China's EPI, toward vaccines aimed at the international market."

> Yonglin Wu, Vice President, China National Biotec Group (CNBG)

On the flip side of the public EPI market, the domestic private market comprises optional vaccines, those that are suggested but not required by the EPI. Chinese consumers pay for these vaccines, which cover diseases such as rabies and typhoid for example, out-of-pocket, and receive them of their own accord.

Since prices in the private market are not set by the government, manufacturers can charge far more for the vaccines that they sell there. Due to the higher profit margins, "Chinese innovation will go in the direction of the private market, toward new vaccines that are not covered in China's EPI, toward vaccines aimed at the international market," said Yonglin Wu.

Participants tied these public-private pricing complexities to the challenges that manufacturers face around upgrading technology and investing in R&D. As there is little to no profit potential in the public market, manufacturers continue to produce EPI vaccines using the old methods and equipment.

# The Path to WHO Prequalification: Updating China's Vaccine Regulatory System

The March 2011 announcement by the WHO adds a new dynamic to the traditional Chinese marketplace. For Chinese manufacturers, the WHO's stamp of international approval on the SFDA means that they will be able to submit their vaccines for WHO prequalification for entry into the global public market—a market that includes international vaccine procurement bodies such as UNICEF and GAVI.

Coinciding with the March announcement, the Chinese government simultaneously rolled out new criteria for its Good Manufacturing Practices (GMP)<sup>2</sup> designed to align SFDA's regulations with the WHO's international standards for quality assurance in pharmaceutical manufacturing. Vaccines that meet these updated standards will be much better positioned to apply for and receive WHO prequalification.

Describing many of the goals and processes in the new GMP system, **Qi Shen**, Director, Biological Products Testing at the National Institutes for Food and Drug Control, SFDA, pointed to the SFDA's, significant regulation and monitoring of every level of vaccine production, noting its judicious restrictions on the use of antibiotics and preservatives in vaccine manufacturing.

**Meng Li**, Deputy Director of International Cooperation, CNBG, reminded participants that regulation and

standards are certainly not new for China: "China's SFDA has very strict regulatory standards. They may even exceed international standards in some cases," she said.

The challenge, however, is matching practices with policies, and bringing China's vaccine industry fully up to speed with both new and international regulations. Participants acknowledged that considerable time and resources will be required for industry to comply with the Chinese government's latest GMP criteria and gear up for the WHO prequalification process. "There is a broad-based incentive in China to create new regulations and rules in order to harmonize with the international criteria," said Kewen Jin.

Emblematic of how significant a priority it is to the government that Chinese vaccine manufacturers meet international standards of quality and enter the global market, the SFDA's strict criteria stipulates the compliance of Chinese pharmaceutical companies to the updated GMP by the end of 2013. Manufacturers who are actively working toward meeting WHO prequalification receive government funding for the endeavor. If compliance is not reached by the end of 2013, manufacturers will lose their license to manufacture. Thus, participants noted, there is a huge sense of urgency within the industry to implement the necessary reforms to meet these most recent standards.

<sup>2</sup> Specific to pharmaceutical production, GMP (Good Manufacturing Practice) is the facet of quality assurance that ensures consistency and quality among drug products, including vaccines. For more information, see: http://www.who.int/medicines/areas/quality\_safety/quality\_assurance/production/en/.



# The Industry Perspective

mplementing new vaccine regulatory criteria, agreed participants, is much easier said than done. Discussion explored the different factors that contribute to the unclear path between policy and implementation, with a focus on the view from industry.

"One key challenge in this process," explained **Jilan Liu**, Special Advisor, The National Bureau of Asian Research, "is that sound policy is not always soundly implemented at the ground level." In other words, this doesn't mean that strict policies aren't in place; on the contrary, they absolutely exist, but they can be exhibited and manifested in different ways than in, for example, many Western contexts.

Addressing regulatory complexities within such different contexts can create barriers to immediate cohesion with the new GMP and WHO prequalification standards.

Participants noted that many in China's vaccine industry have never worked in an environment that is officially regulated by an outside overseeing body—that is, not the company itself but the SFDA and the WHO. It was acknowledged that preparing for the WHO prequalification will require a new mindset in many companies.

Pointing to her own experiences with hospital accreditation as a consultant for the Joint Commission International on Hospital Accreditation, however, Jilan Liu painted an optimistic picture of how large Chinese entities evolve to meet international criteria. "In the very beginning, it can be very hard to get an organization accredited," she explained. "Going through the mindset change, process reengineering, and reorganization, and then having to incorporate policies and procedures into daily practice by everybody within the organization, is no small matter. But after one organization actually becomes accredited, many others quickly follow. The Chinese excel at learning from good examples—that's the beauty of the Chinese model."

Many companies have already taken significant, tangible steps to meet the WHO certification criteria. According to Xiaoming Yang, CNBG plans to invest about \$10 billion in the next five years to upgrade its manufacturing facilities to meet both the standards of the WHO and the Chinese government's new GMP. The company applied for GMP inspection of its facility in June 2011. Under the new standards, CNBG intends to establish Japanese encephalitis (JE) as its first vaccine certified by the SFDA.



### CNBG and PATH: Joining Forces against JE

While international markets have been relying on a three-dose Japanese encephalitis (JE) vaccine, China has been effectively immunizing its children with a single-dose JE vaccine for over twenty years. Compared to the internationally better-known JE vaccine, China's JE vaccine is more practical and better-suited to the realities of lower-resource settings, where tracking and follow-up are among the many challenges.

Why isn't China's JE vaccine already more widely available outside of China? The safe, effective, and inexpensive vaccine has been virtually unknown to the rest of the world due to regulatory, language, and cultural barriers.

In close collaboration with PATH, CNBG began undertaking the important task of establishing JE as China's first WHO-prequalified vaccine, a project that is slated for completion within the next two to three years. While CNBG provides the manufacturing capacity, capability, and knowledge, PATH provides the corresponding "soft infrastructure" support necessary to usher use of the Chinese JE vaccine into the parts of the world that would benefit most, via such means as funding, technical assistance, and international outreach and communication.

With SFDA approval already obtained, CNBG's single-dose JE vaccine is on track to become the first Chinese-made vaccine to be prequalified by the WHO. The international availability of CNBG's JE vaccine will create wider protection against a destructive disease that often afflicts the poorest and most marginalized. The CNBG-PATH partnership may serve as a model for how Chinese vaccine manufacturers can collaborate with international organizations and expand their markets while making a powerful contribution to global health. Panelists discussed several areas where China's vaccine industry needs assistance to prepare for obtaining WHO prequalification and entering global public markets. Soft infrastructure, R&D, quality assurance, and new technologies were identified as key areas in which international collaboration would be most useful and invited.

### Soft Infrastructure

While China's vaccine industry already possesses cutting-edge "hardware," or traditional infrastructural elements in terms of buildings and machinery, companies' "soft infrastructure" needs are growing rapidly—particularly regarding management policies and procedures.

Participants defined "soft infrastructure" or "software" in this context as institutional policies, procedures, processes, and management systems and philosophies (pertaining to both personnel and products). While all agreed that the appropriate facilities and technical knowledge are present, opportunities to implement and strengthen the aforementioned areas are great, especially when preparing to compete in global markets, which operate very differently from the Chinese domestic market. Manufacturers acknowledged that in many cases they need to adapt existing institutional structures in order to become significant players in those new and more diverse markets they hope to reach.

Often it is simply a question of practical experience. "In China's vaccine industry, there is a need for international market perspective," noted **Jiankang** (Jack) Zhang, Director, China Program, PATH.

"Chinese companies are open to guidance from external partners to help realign manufacturing and marketing philosophies to meet international "The Chinese excel at learning from good examples—that's the beauty of the Chinese model."

> Jilan Liu, Special Advisor, The National Bureau of Asian Research

expectations, as well as navigate worldwide marketing and export standards, such as language and cultural norms, trade law, insurance, and distribution logistics," Jack Zhang continued.

Another "soft infrastructure" need concerns internal company procedures and systems. One example, said Yonglin Wu, is to "upgrade existing QMS [Quality Management Systems] to fall in line with WHO prequalification standards." Participants also discussed the need for training in developing or revamping SOPs [Standard Operating Procedure] to meet the SFDA's new GMP criteria.

"Lots of Chinese labs, buildings, hardware, and equipment are as good as those of multinationals, if not better, but it's the SOP that warrants improvement right now," emphasized Kewen Jin. "The SOP is what is needed for things to go right every day, every single day, even when your boss is not around. The culture of not running a red light in the middle of the night when there are no police around—I think that kind of culture needs time to be drilled down and made to stick."

**Shi Li,** CEO, Shanghai Zerun Biotechnology Co., Ltd., who spent nearly 25 years in the United States working for major multinational pharma companies, concurred. "In regard to hardware facility," he said. "I think that China is now much more advanced. ... The policies and guidance have in essence almost reached international





standards already. The missing parts are the team; the software, i.e. the management and practice; the people training; and the effective communication."

"Now the challenge in communication between potential Chinese and foreign partners is not the language," Shi Li continued. "The communication needs have to do with the understanding of social and business culture. Foreign partners need to understand Chinese communication and business culture, and people within China need more understanding of the business culture and operations in a multinational company. Bridging this kind of communication gap helps both sides understand each other's business, expectations, and partnership potential."

The workshop discussion overwhelmingly illustrated how Chinese manufacturers welcome and invite collaboration with external partners around evolving soft infrastructure, particularly in terms of aligning specific industry niches like production line organization and international quality assurance. Participants pinpointed several key areas where international collaboration could enhance and support soft infrastructure improvements:

- Improve English and other foreign language competency to better communicate and conduct business with overseas markets, multinational firms, and international organizations
- Provide guidance around information technology tools to optimize the modern production process
- Advise on international trade laws and mechanisms to build domestic literacy around these issues
- Share technical knowledge of global distribution processes, insurance, and supply chain logistics
- Share intercultural communication knowledge to facilitate smooth partnerships with foreign firms and organizations
- Advise on guiding management structures and philosophies to account for the industry's continuing brisk growth, and the influence and influx of returning migrants

"In the past, the major barrier hindering Chinese vaccines from going abroad was communication with the world," said Yonglin Wu. "Working with the WHO, the Gates Foundation, PATH, and similar organizations are a great help to us—these types of partnerships are very important."

In addition, the WHO is working closely with various manufacturers to provide training for inspectors and auditors. "I think that Chinese-made vaccines will become more widely available to the global market within five years," said Jack Zhang.

"The missing parts are the team; the software, i.e. the management and practice; the people training; and the effective communication."

### Reflections on Pricing: Effects on Public Confidence and Innovation in R&D

ne major discussion thread explored how existing low vaccine price points in China impact quality perception of Chinese vaccines abroad, and influence manufacturers' investment capacity in innovation and R&D at home.

# Low Prices and Perceptions of Quality

Participants acknowledged that the traditionally low price points of Chinese-made products have contributed to perceptions of poorer product quality. Participants also acknowledged that public confidence, both at home and abroad, regarding Chinese products has wavered in the wake of recent food, toy, and drug scares.

"Fair or unfair, perceived or real, there is certainly a perception about the quality of Chinese-made vaccines," said Kewen Jin. "I think it's up to us—the Chinese manufacturers—to show that our products are credible."

How can Chinese manufacturers ably demonstrate the quality and efficacy of their vaccines given the complexity of vaccine pricing? Participants posited that the SFDA's attainment of vaccine regulatory approval by the WHO is one major step toward proving that China's regulatory standards for vaccines match international quality standards.

Yet the WHO prequalification does not address the pricing component of quality perception. As China is universally known for its low-priced products, many think that Chinese-made vaccines for the global public market will remain low in cost, thus offering the potential to bring more vaccines to more countries and more people.



"I think it's up to us—the Chinese manufacturers—to show that our products are credible."

Kewen Jin, General Manager, Aura Partners

However, as China's vaccine industry evolves, as the international market opens, and as domestic manufacturers build their soft infrastructure to promote vaccine innovation and meet international standards, participants acknowledged that rock-bottom prices will no longer be a safe assumption. They concurred that as Chinese-made vaccines become WHO-prequalified and enter the global market, their prices are likely to rise, given market dynamics. Acknowledging this tension, Jilan Liu asked the participants to consider not pushing too hard on prices, especially on current China prices.

"Even if manufacturers are willing to lower the prices in exchange for a contract, prices below a certain threshold would inevitably suppress innovation, and short-change safety and quality, which would eventually undermine public confidence," she said. "There have been plenty of such examples in food and other sectors that we should try not to repeat."

Thus, a key discussion conclusion was that the line of reasoning that China's entry to the international market will result in the incursion of cheap vaccines for the world is not necessarily accurate. It was acknowledged that higher quality vaccines will probably mean higher priced vaccines, despite the overall average price drop that may result from the entry of Chinese-made vaccines.

Participants emphasized that high-quality products, the utilization of the best technology and systems, and international credibility all surpass the maintenance of low pricing as their primary priorities in getting their vaccines out to the world. To bolster the vaccine industry's global competitiveness and reputation in innovation and production, industry leaders shared that China's manufacturers are reframing their price-based model, which emphasizes low prices, to a technology-based one, which prioritizes quality assurance.



### Low Prices and Incentives for Greater Innovation and R&D

Low prices also affect manufacturers' ability to invest in innovation and R&D, an issue which participants noted has become even more critical with the WHO prequalification now within reach, as well as for companies to remain competitive in an ever-globalizing world. However, all agreed that one common obstacle to deeper engagement by Chinese manufacturers in innovation and R&D has been the traditionally low price point of Chinese products as noted above. present price point expectations may impede the industry's advances. With WHO prequalification in sight, however, there is much more motivation to invest in R&D due to the promise of global public markets. "In the past, our R&D strategy has been focused on the Chinese market," said Yonglin Wu. "Now we must focus on a much broader target market." He noted that many vaccines produced in China are replicas of ones that have existed for many years, with the initial innovation having originated in other countries. Marking a 21st century shift, many Chinese vaccine manufacturers now want to create brand new vaccines and carve out a respected international reputation as vaccine innovators.

"Modernizing our methods of vaccine research and assessment in order to give the public new vaccines that are safer and more convenient to deliver—this is more important than very low prices."

> Yu Wang, Director General, China's Center for Disease Control and Prevention (CDC)

Since the Chinese government sets prices for the vaccines purchased for its EPI program, the prices for those vaccines are set very low. While the advantages to manufacturers are guaranteed customers and orders, the low prices reap comparatively little in profits, and thus less capital and drive to invest in R&D.

"I think we can all agree that vaccine manufacturers need to make money," said **Rob Lin**, Deputy Director of Financial Planning and Analysis, Global Health Program, Bill & Melinda Gates Foundation. "That creates incentives for them to produce quality products; it also puts in place incentives for them to create innovative products for future demand."

Both the aspiration and the drive to make strides in vaccine innovation are clear among China's vaccine manufacturers, but as discussed above, the world's Participants noted that Chinese manufacturers are experiencing a different kind of pressure than other big pharma, which do not have the same history of rock-bottom pricing. Chinese manufacturers have traditionally offered low prices, but maintaining those prices becomes difficult, if not unworkable, as they invest more in meeting new

sets of regulatory standards, upgrading hard and soft infrastructure, and innovating around new vaccines—all extremely costly ventures.

"With very low prices, we worry about how the industry will be able to adapt newer techniques to change old vaccines," explained Yu Wang. "So we view a low price as one consideration rather than the main consideration, because modernizing our methods of vaccine research and assessment in order to give the public new vaccines that are safer and more convenient to deliver—this is more important than very low prices."

Thus, they recognize the necessity of devoting more funding to R&D. Xiaoming Yang noted that CNBG is working to increase the percentage of its annual revenue invested back into R&D, from the current figure of 7%, to 15%.

### International Partnerships to Advance Innovation and Reach Underserved Communities

nternational partnerships for R&D—with donors, foreign governments, multinational pharma, and other stakeholders—are one way that Chinese manufacturers are overcoming the obstacle of reconciling high R&D costs with the low profit margins of the global public market.

These collaborations have taken on various forms, including technology transfers, partnerships that share risk and costs, and product development partnerships. For example, CNBG, in partnership with PATH, is progressing on a promising new vaccine for multivalent rotavirus. "The Chinese vaccine industry is actively seeking opportunities in production line expansion and technological transfer," said Yonglin Wu. "Our partnership with PATH is part of a larger effort we're making to extend our reach to other countries."

The joint CNBG-PATH project on rotavirus vaccine is one example of the Chinese vaccine industry's interest in formulating vaccines for diseases that most often afflict impoverished countries and communities, where the promise of profit from vaccine sales is lacking. Xiaoming Yang mentioned that CNBG was also exploring the possibility of developing a cholera vaccine that may potentially benefit poor countries like Haiti.

Participants agreed that these kinds of international partnerships will be increasingly critical in the future.

### **Key Areas of Opportunity**

Now that the path to obtaining WHO prequalification status and the promise of global markets is at hand, China's vaccine manufacturers are more interested than ever in communicating and collaborating with international partners and organizations. Participants identified the following areas as key challenges to address and compelling opportunities for engagement and partnership.

#### R&D

Some manufacturers are already actively working to expand and reform their R&D operations. Technology transfer and co-ownership of projects in vaccine innovation are two areas ripe for new partnerships.

#### Soft Infrastructure

Chinese manufacturers are interested in "soft infrastructure"—international training and expert input in the areas of institutional processes, philosophies, and procedures, as well as in particular subjects and areas of competency that help them understand, and remain competitive in, foreign markets and to international vaccine procrement bodies.

#### Cross-Cultural, Cross-Border Cooperation and Partnerships

Workshop participants agreed that there is an ongoing need for Chinese vaccine firms to enhance communication and cooperation efforts with other countries, companies, and organizations, both multinational and foreign.

Doctors administer diphtheria and tetanus vaccinations provided by the WHO to displaced children in Port-au-Prince, Haiti, following the 2010 earthquake.



### Looking to the Future: China's Broader Role in Global Health

Participants discussed the tremendous potential impact that China's vaccine manufacturing capacity will have on the world once it is unleashed to global markets, following WHO prequalification of JE and other Chinese-made vaccines.

### "China recognizes that it has a responsibility in global health and is willing to meet the challenge."

Jiankang (Jack) Zhang, Director, China Program, PATH

China has already demonstrated

sound commitments to global health, as evidenced by the government's numerous financial pledges and aid projects for social and economic development in Africa, along with its efforts there to fight malaria. Building on this commitment, Xiaoming Yang noted, "CNBG is very interested in diseases specific to developing countries."

WHO prequalification for the country's vaccine industry will open the door for China to become even more of an important contributor to global health. Markets guaranteed to be impacted include GAVI-eligible countries, as GAVI is likely to be a high-volume purchaser of prequalified Chinesemade vaccines. Specifically, China's entry into the world vaccine market could result in two particularly game-changing turning points: lowering global procurement prices and reducing supply shortages. Even though the "China price" may eventually be a thing of the past, the combination of China's high-volume manufacturing levels, long experience producing EPI vaccines, and the flattening of vaccine prices for international vaccine procurement bodies like GAVI and UNICEF could make an enormous difference in helping the globe meet the Millennium Development Goal to reduce child mortality.

Flagging this potential, Jack Zhang stressed: "China recognizes that it has a responsibility in global health and is willing to meet the challenge."



Published in the United States of America by The National Bureau of Asian Research (NBR) www.nbr.org

© 2011 by The National Bureau of Asian Research

Compiled by Rebecca Kennedy. Designed by Joyce Baltazar.

For information about Pacific Health Summit discussions and participants, as well as information on resulting initiatives and collaborations, visit <u>www.pacifichealthsummit.org</u>.

*Summit participant photos by Mark Weeks. Photos property of the Pacific Health Summit unless otherwise noted.* 

12