CHAPTER 3

PRAZIQUENTEL:
Access to Medicines

With Alan Fenwick and Howard Thompson
This chapter examines the processes in expanding access to praziquantel, the drug of choice for treatment of schistosomiasis. This infectious disease is caused by parasitic worms (schistosomes) that live in the blood vessels of the human host. There are three major species that infect humans, two of which are found in Africa—*S. haematobium* and *S. mansoni*. Schistosomiasis is the second most prevalent parasitic disease after malaria, and according to the World Health Organization, an estimated 200 million people are infected, including 180 million in sub-Saharan Africa. Nearly 40 million people either have serious morbidity or will develop serious morbidity unless treated. About 1 million per year die from bleeding, bladder cancer, or liver and kidney infections. Schistosomiasis causes mild to serious health problems such as malnutrition, anemia, growth retardation, cognitive impairment, and chronic health problems and can contribute to increased susceptibility to other infections such as HIV/AIDS and tuberculosis. In short, schistosomiasis is a major cause of ill health in Africa.

The schistosome life cycle depends on both a human host and a snail host, with transmission occurring in fresh water lakes, rivers, and irrigation schemes. The adult male and female schistosomes, which are about one centimeter in length, live together in human blood vessels, and female worms can produce up to 300 eggs each per day. In heavy infections of *S. haematobium*, particularly in children, urine can be bright red with fresh blood. In the other species of schistosome (*S. mansoni*), the eggs and blood are found in the stool. The eggs that leave the human host in the urine or feces depend on reaching fresh water so that they can hatch. Emerging from the egg is a small larva that seeks out and infects a fresh water intermediate host snail. The larvae multiply in the snail, and four weeks later, thousands of the next stage larvae emerge from the snail into the water and swim around looking for a human host so that the cycle can continue.

Over time, schistosomiasis produces chronic health problems, as the bladder wall and the intestinal wall become thickened and fibrotic from the accumulation of eggs. Cancer of the bladder and colon can develop. In the liver, the build up of millions of eggs leads to fibrosis and blocking of the liver, blood pressure increases, the abdomen swells, and finally the pressure leads to a (usually fatal) episode of bleeding from burst blood vessels. People at risk for schistosomiasis are often the poorest of the poor, especially children and women in rural villages, as well as particular occupational groups (such as farmers, fishermen, and others with regular exposure to water). People in poor rural communities often depend on schistosoma-infested waters for household water, leisure activities, and crop irrigation, and become exposed to schistosomiasis through daily activities that require contact with
water. They often lack access to potable water and sanitation that would limit their exposure or re-exposure to infection.

This chapter focuses on access to a specific medicine (praziquantel) and the efforts of a particular organization (the Schistosomiasis Control Initiative) to expand access with important contributions from the World Health Organization. We are especially interested in ways to expand and sustain access to praziquantel through use of the market and other mechanisms. In only a few years, the Schistosomiasis Control Initiative (SCI) significantly increased access to praziquantel in Africa through a series of strategies that we examine: procurement, collaboration, information, registration, local formulation, and donation. We are particularly interested in the implications of these strategies for continued access to praziquantel (PZQ). Future access to praziquantel will depend on many factors, including the evolving market for the product, the actions of key players, the availability of international aid funding, and the perceptions of national ministries of health regarding both the disease and its treatment.

The case of praziquantel demonstrates that even very inexpensive medicines do not easily achieve their full potential effects in treatment and improving human welfare due to persistent obstacles to access. While affordability was a major problem in the past and remains an important obstacle to access, the current barriers are mostly related to adoption (low consumer demand and low government demand) and availability (lack of information about suppliers and price). The SCI greatly expanded access in a short time through massive funding from the Bill & Melinda Gates Foundation starting in 2002. But major challenges to sustained access remain in 2007 as SCI confronts a transition in its financing and activities.

**Product Development (Phase 1)**

Praziquantel was developed first for the veterinary market and then for the human market through interfirm collaboration between two German pharmaceutical companies, Bayer and E. Merck. The compound’s curative efficacy against various platyhelminths pathogenic to man was confirmed in testing during the 1970s.\(^1\) A single dose of PZQ (40 mg/kg body weight) was shown to effectively treat all schistosome species infecting humans (the three major ones being *S. haematobium*, *S. mansoni*, and *S. japonicum*).

PZQ was patented in Germany in December 1973 and in the United States in 1977.\(^2\) For the human market, Bayer approached the WHO in the late 1970s to request collaboration in multicenter clinical trials to demonstrate PZQ’s safety
and efficacy. The resulting collaboration in organizing the clinical trials achieved scientific success. From the time that PZQ was first patented in 1973 until one decade later, more than 400 articles were published on the preclinical and clinical aspects of the new product. By 1982, PZQ had been used for safe and effective treatment in 25,000 patients on three continents. The therapeutic validity of the initial trials of PZQ thus was confirmed through many experiments, broad clinical experience, and large-scale field control programs.

WHO’s assistance in helping to organize the clinical trials of PZQ was critical in this phase of drug development. The case thus represents an important instance of public-private collaboration in drug development for a tropical disease. By the mid-1990s, Bayer and E. Merck had registered the patent for PZQ in 38 countries. The public-private collaboration, however, did not effectively address issues of access to the product in poor countries:

_While the collaboration between Bayer and WHO was quite successful in conducting clinical trials for praziquantel, the relationship apparently did not include a written agreement on issues of pricing or distribution methods once the product was fully developed and registered. Some observers mentioned the existence of a ‘good faith agreement’ between individuals involved in the two organizations. Our research, however, was unable to identify any documents that would support the existence of an agreement between the two organizations or individuals on critical questions of how praziquantel would be made available._

This experience provides important lessons about public-private partnerships—that access issues need to be addressed as an integral part of product development efforts and that agreements on access need to be explicit, written, and transparent through an access plan.

**Introduction of Praziquantel (Phase 2)**

Praziquantel became available in Europe after 1978 and became generally available on the international market in the 1980s. It became recognized by experts and by the WHO as the drug of choice for all forms of schistosomiasis in humans because of its high efficacy, low toxicity, and ease of single oral administration. Oxamniquine, for example, was effective against _S. mansoni_ but not against other schistosomes, and its use consequently declined. The decline was hastened by development of resistance in Brazil, and the fact that oxamniquine was not as effective against _S. mansoni_ in Africa as against _S. mansoni_ in Brazil. By 1985, about 200 million people were estimated to be infected globally by schistosomiasis, while approximately...
1 million had been treated with PZQ. Studies of these experiences demonstrated that PZQ could effectively reduce the morbidity associated with schistosomiasis and reduce the excretion of schistosome eggs from infected individuals. The studies also showed, however, that even mass treatment of a community did not easily interrupt the transmission of schistosomiasis because of the high risk of reinfection in endemic areas and factors such as PZQ’s lack of efficacy against schistosomulae and immature schistosome worms in the human body. Regular treatment of school children and high-risk populations was thus needed to reduce the intensity of infection, reduce the risk of serious morbidity, and thereby produce major public health benefits.

But access to PZQ was limited during the 1980s and 1990s in most schistosomiasis-endemic countries. The key barrier was the drug’s affordability. When PZQ was originally marketed by Bayer in the 1980s, it was made available to developing countries at a discounted price of approximately $1 per 600 mg tablet (below the market price of $6.50 per tablet in Germany), equivalent to $4 to treat a 60 kg individual at the recommended dose of 40 mg/kg. Even at the discounted price, however, no African government could afford to embark on a schistosomiasis control program without external funding. External funding was provided by donors for some African countries (such as Mali, by the German aid agency GTZ) so that these countries could establish a national program using PZQ. But when this external funding ceased, so did the treatment programs; these early programs were totally unsustainable.

Subsequently several countries used international financing to establish successful national control programs for schistosomiasis. The best known examples are Egypt, China, and the Philippines, all using PZQ. Brazil also initiated a national program, but it relied on oxamniquine for many years (for treatment of S. mansoni) and only switched to PZQ in recent years. These countries depended on various sources of international financing. Egypt, for example, relied on loans from the World Bank and the African Development Bank to purchase PZQ, and a grant from the U.S. Agency for International Development (USAID) for research associated with the control program. China and the Philippines relied on World Bank loans to fund the programs.

The case of Egypt illustrates how PZQ treatment strategies (and consumption volumes) change as a control program evolves. In 1993, Egypt had total annual consumption of about 10 million tablets of PZQ, with sales of about 2 million tablets in the private market and 8 million purchased by the government. This figure increased from 1996 on, as mass chemotherapy replaced diagnosis and
treatment. Eventually PZQ use reached about 25 million tablets per year to treat 10 million people annually. As a result, by 2004 the reported national prevalence of schistosomiasis had declined to less than 5%. By 2005, the annual consumption of PZQ in Egypt had dropped back to approximately 5 million tablets as treatment focused on school children in the Nile Delta. This example illustrates that use of PZQ will generally be quite high in the first five years of a national control program using mass treatment and then will decline to a lower plateau of sustained treatment. This assumes that the high intensity infection areas are treated first and that the overall program is well managed. Later results from control programs in Burkina Faso, Mali, and Niger (initiated under SCI) suggest a similar pattern in these countries.\(^\text{14}\)

An assessment of the global market for PZQ in the early 1990s showed major gaps between supply, demand, and need for this product.\(^\text{15}\) The estimate of global supply in 1993 was 89 million tablets. This figure was based on a survey of active-ingredient production by the major firms then involved in PZQ production: Bayer and E. Merck in Germany and Shin Poong in South Korea. During the 1980s, the international market structure for PZQ production (raw material) had changed dramatically. Bayer and E. Merck started with 100% in 1981, but their market share dropped to 80% in 1985 with the emergence of Shin Poong’s manufacturing facility. Shin Poong’s production and market share continued to grow, reaching 55% in 1993, while the German firms declined to a combined 27% and Chinese companies rose to nearly 18%.

These trends in the production of PZQ’s active ingredient continued through the 1990s and beyond, with diminished production by Bayer and E. Merck and growing production by several Chinese companies. In 2004, five firms were identified as the major producers of active ingredient. Table 3.1 shows the estimated annual production by company for that year.

The global demand for PZQ, however, has historically been limited by a lack of national adoption by schistosomiasis-endemic countries and a low priority in global adoption for the disease by international agencies and non-governmental organizations (the “donors”). Donors make their decisions about funding priorities based on analysis, opportunities, and geopolitical factors, as well as trends and fads in international assistance. These decisions have great influence on the health policy strategic plans of countries that depend on foreign assistance to operate their health sectors. In some cases, donors have influenced national perceptions about the desirability of implementing a national schistosomiasis control program; in many cases, the availability of donor funding has been the critical factor
determining the feasibility of implementing a national schistosomiasis control program, which has then affected the demand for PZQ in the global market. In short, donor funding has frequently determined the level of demand and the level of access to PZQ in Africa.

The global need for PZQ presents a very different picture. In the 1980s, the WHO produced a global atlas of schistosomiasis and estimated national need for PZQ based on available data for schistosomiasis prevalence, population estimations, and assuming a strategy of selective treatment for all infected persons (at 40 mg/kg body weight). According to this calculation, there was a global need of 424 million tablets, compared to an estimated global supply of 89 million tablets in 1993. Supply at this time thus provided roughly 20% of the estimated global need. It is worth noting that the estimates of both supply and need were based on extrapolation from patchy and limited data, making the figures rather uncertain. Nonetheless, these calculations demonstrated an extremely low level of access to PZQ in the 1980s and 1990s—far below the quantity required to treat people infected with schistosomiasis.

Information is very limited on the actual availability of PZQ in African countries before 2002, when SCI began its operations. But it appears that several countries in sub-Saharan Africa purchased a small quantity of PZQ each year, probably

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>LOCATION</th>
<th>ANNUAL PRODUCTIONa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shanghai OSD Co., Ltd.</td>
<td>China</td>
<td>70 metric tons (112 million tablets)</td>
</tr>
<tr>
<td>Nanjing Pharmaceuticals Factory Co., Ltd.</td>
<td>China</td>
<td>50 metric tons (80 million tablets)</td>
</tr>
<tr>
<td>Shin Poong</td>
<td>Korea</td>
<td>50 metric tons (est.) (80 million tablets)</td>
</tr>
<tr>
<td>E. Merck</td>
<td>Germany</td>
<td>10 metric tons (16 million tablets)</td>
</tr>
<tr>
<td>Hang Zhou Minsheng Pharmaceutical, Ltd.</td>
<td>China</td>
<td>20 metric tons (32 million tablets)</td>
</tr>
<tr>
<td>Other manufacturers</td>
<td>China</td>
<td>Not available</td>
</tr>
<tr>
<td>TOTAL</td>
<td>Global</td>
<td>200 metric tons (320 million tablets)</td>
</tr>
</tbody>
</table>


a Estimated annual production, 2005; lack of data underestimates total production.
up to 200,000 tablets per country in the endemic countries in West Africa and around 300,000 tablets per endemic country in East Africa. These supplies were typically purchased through the government’s central medical stores and distributed to both private and government pharmacies. The drugs were used when patients came to a private clinician or government health center with symptoms (i.e., through a passive, patient-driven distribution system). If prescribed privately or at the health center, patients frequently ended up paying a relatively high price (between $2 and $10 per treatment, or two to ten times the initial procurement price of the pills). This practice continued through 2006. This higher price at the point of treatment reflected the costs of procurement, storage, and distribution, as well as the operating costs of the health center, plus the profits of the various distributors, middlemen, and prescribers involved in the delivery process.

Scaling Up through the Schistosomiasis Control Initiative (Phase 3)

In June 2002, the Schistosomiasis Control Initiative was established with $27.8 million funding from the Bill & Melinda Gates Foundation. The SCI marked a major turn-around in global attention to schistosomiasis control, which had been neglected in international development aid, global health policy, and national health policies since its last major surge in attention in the 1980s. As explained in the SCI’s final proposal to the Gates Foundation in March 2002, the goal of SCI was to “promote the development of sustainable schistosomiasis control programs in sub-Saharan Africa.” At about the same time, advocates for schistosomiasis control within the World Health Organization were pushing for greater global attention. They achieved two important milestones in global adoption with the passage of a resolution by the World Health Assembly in May 2001 and the establishment of a broad and inclusive new entity called the Partners for Parasite Control. SCI would assist selected countries in implementing the WHO’s May 2001 resolution with the target of providing regular treatment for “at least 75% of all school-aged children at risk of illness from schistosomiasis and soil transmitted helminths by 2010.” This would help increase demand for treatment throughout Africa. The new initiative would seek to demonstrate “proof of principle”—to the Gates Foundation and the broader international health community as well as national governments—to show that “schistosomiasis and concurrent worm infections can be controlled, at what cost, and with what impact on health.”

With its funding from the Gates Foundation, the SCI (based at Imperial College in London with Alan Fenwick as director) became a major product champion,
along with WHO’s parasite control experts, for PZQ and the treatment of schistosomiasis in Africa. These two product champions collaborated and supported each other in their efforts to promote greater financial resources and policy attention to PZQ access for the treatment of schistosomiasis. The idea for the SCI emerged from Fenwick’s personal experiences and his conviction that PZQ treatment could make a significant difference in the lives of millions of people affected by schistosomiasis. Fenwick had worked on research and control programs against schistosomiasis in Tanzania, Sudan, and Egypt, and had lived and worked in Africa for 35 years. He served on the WHO expert panel for schistosomiasis and had many publications on snail control, drug evaluation, chemotherapy, epidemiology, and zoonosis of schistosomiasis. He firmly believed that countries could be persuaded to initiate national control programs and that PZQ treatment could reach 40 to 80 million Africans in a four-year period, serving as an example for the rest of Africa. As stated in the proposal for a planning grant in 2000 (submitted by Fenwick and Reich), “Today there is no reason why anyone should suffer serious disease due to schistosomiasis.”

Due to funding limitations, SCI decided to focus on a relatively small number of countries and selected six (Burkina Faso, Mali, Niger, Tanzania, Uganda, and Zambia) from twelve that applied for support for national control programs. In 2004, SCI ran its first international tender for PZQ; the initiative purchased 32.7 million tablets in 2004, 30.2 million in 2005, and 12.5 million in 2006. SCI also received a donation of 13.7 million tablets in 2005, with additional donations in 2006 and 2007 (from MedPharm in Alexandria, Virginia). SCI thus became the single largest purchaser of PZQ ever on the global market, absorbing an estimated 90% of global trade of this drug in 2004 and 2005. SCI directed these supplies primarily to the six target countries. SCI planned to continue making purchases through the life of the project (initially five years from 2002 but then extended for several years more by the Gates Foundation) and expected that the donations through MedPharm would continue as well (Table 3.2).

In 2004, several African countries not receiving SCI support began to develop their own schistosomiasis control programs, and SCI donated small quantities of PZQ to non-governmental organizations (NGOs) and government agencies working in those countries. Recipients included the World Food Program and ICS (a Dutch-Kenyan NGO working in Kenya), along with government programs in Cameroon, Guinea, Kenya, Malawi, and Mozambique. The SCI hoped that its assistance to the six main country control programs would stimulate demand for PZQ in other African countries and that this demand would then be
funded (and sustained) by other donors, such as the World Bank, the African Development Bank, the EU, and USAID. SCI’s efforts have generated some additional funds, but whether the financing will be sustained remains to be seen.

A major factor that assisted in the Gates Foundation’s decision to support SCI was the falling price of PZQ. Starting in the late 1990s and through the early 2000s, the price of PZQ dropped sharply from its initial concessionary price of $1 per 600-mg tablet. The decline in prices resulted from a combination of factors: technical innovation in production processes, competition from new suppliers in South Korea and China, and the expiration of the original product patents held by Bayer and E. Merck and of the later process patents held by Shin Poong (which expired in 1994). Chinese companies had copied the production process for the active ingredient and were thus poised to respond to increased demand for PZQ due to the increased funding for control through SCI. In August 2004, SCI identified eight potential suppliers of PZQ, with prices ranging from $0.174 to $0.072 per tablet (Table 3.3). At this much lower price, the product became more affordable to both individuals and governments in Africa.

SCI found that the quality and price of PZQ tablets are determined in large part by the quality and price of the active ingredient, as well as by the size of the specific order and the scale of a purchaser’s commitment to future procurement over coming

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**Table 3.2** | PZQ delivered by SCI, 2003–2007 (Actual), purchases and donations

<table>
<thead>
<tr>
<th>MILLIONS OF PRAZIQUANTEL TABLETS DELIVERED/CALENDAR YEAR</th>
</tr>
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<tbody>
<tr>
<td>Country</td>
</tr>
<tr>
<td>Burkina Faso</td>
</tr>
<tr>
<td>Mali</td>
</tr>
<tr>
<td>Niger</td>
</tr>
<tr>
<td>Tanzania (incl. Zanzibar)</td>
</tr>
<tr>
<td>Uganda</td>
</tr>
<tr>
<td>Zambia</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Donated</strong></td>
</tr>
<tr>
<td><strong>Purchased</strong></td>
</tr>
</tbody>
</table>

*Note. Tablets were procured from the following companies: Shin Poong, MedPharm, Pharmchem, IDA, TPI, and Shelys. From Schistosomiasis Control Initiative, London, 2008. Used with permission.*

*The donated tablets came from MedPharm.*
years. Two companies, Shin Poong (Korea) and Shanghai OSD (China), met international quality standards for their products, so they could provide the active ingredient for PZQ to WHO, UN agencies, and various manufacturers.

SCI also sought to change perceptions of both the disease and the treatment by both global and national actors, and thereby promote adoption. In collaboration with WHO and supported by the advocacy efforts of the WHO-initiated Partners for Parasite Control, SCI actively approached ministries of health in Africa (through personal visits, publications, and training programs) to make them more aware of the low price of PZQ and the high morbidity due to schistosomiasis—and therefore the cost-effectiveness of treatment using PZQ. These outreach efforts (combined with the incentive of financial support) helped persuade a good number of African countries to become interested in schistosomiasis control and to compete for SCI support, and thereby adopt PZQ treatment as a national priority.

**SCI’s Strategies to Expand Access**

SCI developed and implemented six strategies to increase access to PZQ in Africa in their scaling-up efforts. These were the following:

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**Table 3.3 | Potential PZQ suppliers, August 2004**

<table>
<thead>
<tr>
<th>POTENTIAL PZQ SUPPLIER</th>
<th>PRICE (USD) AT AUGUST 2004 (CIF)</th>
<th>WHO-RECOGNIZED</th>
<th>SUPPLIER OF ACTIVE INGREDIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK</td>
<td>0.096</td>
<td>Yes</td>
<td>Yixing City Ying Yu Medicine Chemicals Co., Ltd</td>
</tr>
<tr>
<td>IDA</td>
<td>0.087</td>
<td>Yes</td>
<td>Shanghai OSD (and others)</td>
</tr>
<tr>
<td>MedPharm (CIPLA)</td>
<td>0.001^a</td>
<td>Yes</td>
<td>Hang Zhou Minsheng Pharmaceutical, Ltd.</td>
</tr>
<tr>
<td>Panacea Biotech</td>
<td>0.174</td>
<td>Yes</td>
<td>Shin Poong</td>
</tr>
<tr>
<td>Pharmchem</td>
<td>0.074</td>
<td>No</td>
<td>Nanjing Pharmaceuticals Factory Co., Ltd.</td>
</tr>
<tr>
<td>Shin Poong</td>
<td>0.072</td>
<td>Yes</td>
<td>Shin Poong</td>
</tr>
<tr>
<td>TPI (prices at Nov 04)</td>
<td>0.078</td>
<td>No</td>
<td>Shanghai OSD</td>
</tr>
<tr>
<td>Shelys (prices at Nov 04)</td>
<td>0.078</td>
<td>No</td>
<td>Shanghai OSD</td>
</tr>
</tbody>
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^a MedPharm’s very low price in this tender is because it agreed to donate 13.7 million tablets in 2004. It also bid on CIPLA’s behalf at the price of about US$0.075 per tablet.
• **Procurement**: Use external financing (from the Bill & Melinda Gates Foundation) to procure PZQ for six national schistosomiasis control programs and shape the market for PZQ in Africa

• **Collaboration**: Collaborate with international agencies to stimulate national demand for schistosomiasis control and for PZQ

• **Information**: Improve information flows about PZQ, its safety, efficacy, and low price

• **Registration**: Stimulate the registration of PZQ in endemic countries to create conditions for competitive tenders

• **Local formulation**: Stimulate the formulation of PZQ in Africa by manufacturers with Good Manufacturing Practice (GMP) approval

• **Donation**: Receive donations of PZQ and use them to support national control programs

These six strategies were designed to help correct market failures that adversely affected the PZQ market in Africa. The overall goal was to create a well functioning market, with multiple producers competing in a serious way for government tenders issued by national procurement agencies. This model would assure good quality, low prices, and continuing supply to government control programs. Below we review each strategy, its implementation, and limitations.

**Procurement**

SCI used procurement as a means to promote PZQ access for national control programs and also to stimulate competition for the product in Africa, thereby seeking to address some aspects of imperfect competition (a classic market failure). SCI used its purchasing power (from the Gates Foundation grant) to encourage several manufacturers and tablet formulators to develop their production capability and expand their presence in the African market. SCI continued making large purchases through 2006 and has funds to continue through 2008. SCI decided not to award its original tender in 2004 to a single supplier but to apportion it among the four bidders who prequalified with SCI for the tender (to encourage involvement by more manufacturers): Shin Poong, a for-profit private pharmaceutical company in South Korea; IDA, a nonprofit pharmaceutical procurement agency based in Holland; MedPharm, a pharmaceutical supplier and generic contract manufacturer with a donation program based in the United States; and Pharmchem/Flamingo, a pharmaceutical formulator in India. Two other companies in Tanzania, TPI and Shelys, were included in SCI’s procurement after the original tender in order to encourage African formulation of PZQ.
These two Tanzanian companies (discussed below) were found to meet U.S. Pharmacopoeia standards (after tablet sample analysis conducted by SCI on all batches purchased from all sources), and their price quotation was competitive with the other suppliers. SCI thus used its procurement opportunities to shape the market for PZQ in Africa and encourage competition among different kinds of companies as ways to reduce prices and create affordability.

Shin Poong entered the PZQ market in the 1980s, when it developed a new synthesis process that significantly reduced the production cost of the active ingredient. This technical innovation contributed to declines in the price of PZQ tablets by over 90% during the period 1990 to 2004. In the late 1990s, Shin Poong began to market its PZQ tablets in Africa through direct sales in countries and contacts with WHO, SCI, and the World Bank. Shin Poong's sales in Africa initially were small but have kept growing, making the company the leading supplier of PZQ to Uganda, Tanzania, and Zambia (through SCI) by 2006.

The International Dispensary Association, known as IDA, is a leading nonprofit procurement agency based in Holland. IDA developed a successful business of selling competitively priced generic pharmaceutical products for developing countries while guaranteeing international quality standards through extensive in-house quality control. IDA initially manufactured some drugs in wholly owned facilities but by 2006 had abandoned direct manufacture and instead purchased drugs from suppliers worldwide (especially from China and India), thereby providing lower priced but high quality products. IDA seeks the cheapest and best quality product at the time (therefore using a number of manufacturers), and then packs under the IDA label. Furthermore, IDA has worked closely with procurement agencies in developing countries to gain their confidence in IDA products and ensure that IDA products are registered in the destination countries. SCI purchased PZQ from IDA in 2003 and 2004, along with albendazole (for treatment of various common worm infections transmitted through soil) (see Table 3.3).

The third major supplier for SCI was MedPharm, a U.S.-based pharmaceutical company. In 2004, SCI and WHO were approached by MedPharm to consider whether SCI’s objectives and activities were suitable for the company’s drug donation program. While running a wholesale pharmaceutical business, MedPharm also promotes and supports deworming programs in the developing world through a drug donation initiative. In the donation program, MedPharm buys drugs from European and Indian formulators using donated funds from a Canadian NGO (called Escarpment Biosphere Foundation) through the Canadian Humanitarian Trust. In February 2004, MedPharm donated 680,000 PZQ and 1
million albendazole tablets to SCI for use in Zanzibar and Zambia. In June 2004, MedPharm pledged to donate a further 13.7 million PZQ tablets, which were delivered by the end of 2004, then added a further 12 million tablets in 2005. MedPharm suggested it could repeat the donation annually for the life of the original SCI project (through 2007). This pledge was met in 2004 and 2005. MedPharm then pledged to meet most of the needs of Tanzania in 2007 through its donated product.

**Collaboration**

To promote increased attention to schistosomiasis control in national health policies in African countries, SCI has collaborated with international agencies and other organizations. Three key international players are the World Health Organization, the World Food Program, and the World Bank. These activities have promoted both global and national adoption of PZQ use.

The World Health Organization has played a major role in setting global policy on schistosomiasis control and has been a central collaborator for SCI and global advocate for PZQ treatment. In May 2001, WHO set a global priority for the control of schistosomiasis and soil transmitted helminths (STH) by passing resolution 54.19 at the World Health Assembly. As noted above, this resolution states that all member states where these infections are endemic should provide regular treatment for schistosomiasis and intestinal helminths to 75% of all school-aged children by the year 2010. This statement of global adoption helped pave the way for SCI activities at the national level and helped stimulate national interest in control programs and PZQ. To create a positive collaboration, SCI included an ex-officio representative of WHO on its board of directors and a representative of the Special Programme for Research and Training in Tropical Diseases (TDR) on the expert advisory committee for the Schistosomiasis Research Program.

SCI also collaborated with the World Food Program (WFP) to stimulate demand for PZQ through its school feeding program. In the early 2000s, the WFP fed about 5 million children in countries in sub-Saharan Africa. With funding from the Canadian International Development Agency (CIDA), the WFP began efforts to deworm children widely and, where applicable, to treat children within the WFP school feeding program using albendazole against intestinal helminths and PZQ in schistosomiasis-endemic areas. The annual deworming was expected to increase the benefit of the food to the children rather than feed the worms that the children were harboring. The WFP also began looking for continued funding to support the deworming program since
it did not have guaranteed funds to purchase PZQ or albendazole. SCI provided small quantities of these medicines to the WFP for use in countries not selected for SCI-supported programs.

SCI also worked with the World Bank’s education program to stimulate schistosomiasis control programs in Africa. As part of its education reform efforts, the World Bank, with UNICEF and WHO, created the FRESH strategy (Focusing Resources on Effective School Health), which included deworming and other health interventions inside schools. The Bank offered to assist countries engaged in education reform with a school health component. As a result, the Bank committed over $1 billion to school health in 20 countries. Only a few countries, however, used the FRESH funds for school health (as of summer 2006). SCI and WHO have continued seeking ways to promote more effective use of this financing source for deworming through the education sector.

Information
A third major strategy adopted by SCI was to improve information flows about PZQ. For more than a decade prior to 2003, there was a serious lack of information about PZQ in Africa, which held back sales and consumption in many countries. First, PZQ manufacturers were not aware of sales opportunities in African countries because they did not have an established market presence there. Second, national governments in Africa were not aware of potential suppliers and the lower prices for PZQ then available.

Part of this information problem resulted from national drug procurement agencies in African countries that had cumbersome mechanisms for tendering, making it difficult to learn about new suppliers or their competitive prices and acceptable standards. In addition, national decision-makers about tenders were often committees that were content to accept monopoly prices from single prequalified sources rather than run a bona fide and open tendering process. By addressing these information gaps that affect both sellers and buyers, SCI has improved the market functioning for PZQ and improved the chances of effective competition in the tendering process.

Registration
A fourth strategy was to encourage the registration of PZQ products in different national markets in Africa. If a product is not registered, then it cannot be considered for government procurement or private sector purchase. Even the major supplier Shin Poong, for example, had not registered its PZQ products in many
possible national markets in Africa. SCI worked with Shin Poong (Korea), Med-Pharm (USA), and Flamingo (India) to help each company with the registration process for PZQ products in several African countries. Subsequently CIPLA (India) solicited SCI assistance in registering PZQ, and CIPLA in 2006 started a joint venture drug production facility in Uganda which may formulate PZQ. The result has been to increase competition for PZQ in national markets and thereby contribute to lower purchase prices for governments.

For example, in Burkina Faso, the national procurement agency (CAMEG) wanted to buy PZQ tablets for the national schistosomiasis control program. Historically, they had secured prices at approximately US$ 0.14 per tablet. By registering Shin Poong and Pharmchem/Flamingo in Burkina Faso, SCI increased the number of recognized suppliers from one, IDA (CIPLA), to three. (The Pharmchem/Flamingo partnership subsequently dissolved.) As a result, in 2004, CAMEG purchased PZQ at US$ 0.09 CIF (including the costs of insurance and freight) per tablet, substantially below the price originally offered by IDA when it was the sole seller in that country. It is expected that continuing market competition will maintain the lower prices for PZQ available in Burkina Faso after 2006. SCI also supported a direct order of PZQ by the Pharmacie Populaire du Mali, resulting in the purchase of 2 million tablets at US$.08 each (compared to a previous price paid of $0.12).

Local Formulation

SCI has also supported African companies that formulate praziquantel. Over the past decade, several African companies have formulated PZQ for sale (mostly to their own governments). Those companies include Cosmos (Kenya), EIPICO (Egypt), Shelys (Tanzania), and an ill-fated Shin Poong joint venture in Sudan. However, none of these companies has successfully marketed its product outside of its own country. EIPICO supplied almost 70 million tablets to the domestic Egyptian market (formulated with active ingredient from Shin Poong), but demand in Egypt has declined since 2002 after prevalence there dropped to below 5%. Several established manufacturers of PZQ’s active ingredient (including Shanghai OSD and Shin Poong) have indicated their willingness to supply active ingredient to a WHO-approved GMP African company to formulate tablets. Shanghai OSD has already supplied active ingredient for testing by the UK Government Chemist and to African manufacturers to validate their formulation process. These developments suggest that African pharmaceutical companies could produce PZQ at a quality and price acceptable to donors, international agencies, and national governments (depending in part on the size and duration of the orders).
Action Medeor, a leading German NGO, is also seeking to stimulate drug formulation in Africa. Action Medeor has developed a new business model (similar to the IDA model) in which drugs formulated in Africa can be purchased for international distribution. Like IDA, Action Medeor would quality-assure the drugs and test each batch. One of Action Medeor’s first suppliers would be based in Tanzania. Another group with similar objectives and working methods to IDA is La Centrale Humanitaire Médico-Pharmaceutique (France). This not-for-profit agency provides both drug and equipment procurement services and technical support through consultancies.

Recent changes in the Tanzanian market for PZQ illustrate the opportunities and challenges in seeking to promote local formulation in Africa. In 2001, the Tanzanian Food and Drug Authority declared that all companies wishing to sell medicines to the Tanzanian government must be approved by WHO for Good Manufacturing Practice (GMP). The deadline for compliance was June 2005. WHO GMP approval is an internationally recognized endorsement for the standard of manufacturing practices and the quality of drugs. This decision was taken to address problems of substandard quality, poorly formulated drugs in the Tanzanian market. These substandard medicines included both donated products and locally manufactured products.

Tanzania has seven domestic pharmaceutical companies that are largely dependent on government contracts, and several Tanzanian companies responded to the new government policy by investing considerable private funds in their plants to meet both Tanzanian GMP standards and international GMP standards. Over the two years from 2002 to 2004, $15 million was invested in the Tanzanian pharmaceutical industry. The majority of these funds came from private sources, including the CDC Capital Partners of the UK, a risk capital investor in emerging markets. At least three companies achieved GMP certification by January 2005. It is expected that these GMP-certified companies would explore opportunities to export their drugs to other markets in Africa. Two Tanzanian pharmaceutical firms supplied PZQ to SCI at competitive prices in 2005.

The Tanzanian Pharmaceutical Industries Limited (TPI) is a privatized pharmaceutical company whose management has worked to turn around a failing nationalized business and return it to profitability. The company’s management invested considerable private funds to achieve GMP standards by replacing obsolete facilities with a new plant and machinery. TPI was selected by Action Medeor as a potential supplier for its proposed procurement venture to internationally distribute drugs formulated in Africa. TPI is also the chosen supplier for the proposed...
venture of the Thai AIDS advocate, Krisana Kraisintu. Kraisintu expanded the availability of ARVs to Thailand and now works with TPI to formulate ARVs in Tanzania to the same international standards achieved in Thailand. She demonstrated that ARVs could be formulated in Thailand to international quality and price standards. Her success was confirmed when Médecins Sans Frontières International started purchasing and distributing TPI’s products. TPI previously formulated PZQ, but recently outsourced PZQ contracts to another Tanzanian pharmaceutical company, Shelys.

Shelys is the largest pharmaceutical company in East Africa. The company has ambitious expansion plans and by 2006 had completed a new facility close to Dar es Salaam. Prior to 2002, Shelys formulated PZQ for a small domestic market (100,000 tablets per year). Samples of tablets formulated by Shelys have been analyzed and found acceptable at U.S. Pharmacopoeia and European Pharmacopoeia standards. Shelys facilities were reported to be WHO GMP compliant by June 2005.

In 2006, both Shelys and TPI were formulating PZQ with active ingredient supplied by a Chinese firm, Shanghai OSD, and were confident that their tablets would meet international standards. The ultimate test for both companies will be their ability to satisfy the standards of other African governments in terms of both quality and price. SCI tested the product of both companies at the Laboratory of the UK Government Chemist, and they conformed to US Pharmacopoeia standards in 2005 and 2006. Both TPI and Shelys indicated that they will proceed to register their companies and products in Uganda and other African countries and hope to secure the export licenses needed for entry to foreign markets.

**Donation**

In contrast to other neglected diseases, schistosomiasis has not been the target of a significant corporate donation program. The originating company for PZQ, Bayer, refused for many years to provide substantial quantities of the drug for donation, although numerous approaches were made by WHO and others. Bayer’s response was to provide only relatively small quantities of PZQ for donation in Africa—in contrast to the major donation programs initiated by Merck for ivermectin, Pfizer for azithromycin, GlaxoSmithKline (GSK) for albendazole, and various companies for AIDS-related drugs. While Bayer did not take any major steps toward SCI, MedPharm (as noted above) approached the new organization and offered to donate substantial quantities of PZQ to the organization (providing nearly 14 million tablets in 2005, 10 million in 2006, and 6 million in 2007).
It is uncertain how the drug donations by MedPharm have affected the development of a market for PZQ in Africa or how this donation program could affect market development if donations were continued in the future. A drug donation program, for example, could have the unintended effect of suppressing the development of an African market for PZQ by making free product widely available. The extent of this impact, however, would depend on the size and duration of donations of praziquantel. Another risk is the program’s long-term sustainability (similar to questions raised about other single-product donation programs). As of 2006, however, the MedPharm donation was a relatively small proportion of SCI’s total delivery of PZQ, suggesting a relatively low risk of negatively affecting the African market for PZQ (although they could be concentrated and significant in particular countries or for specific companies).

Another possibility would be to use donated funds to purchase PZQ formulated in Africa by local companies. This approach would support local production and sales of good quality drugs at competitive prices in schistosomiasis-endemic countries. This approach could also stimulate the development of an African market for PZQ, which could help ensure continued availability of treatment at good quality and affordable prices. In 2008, however, MedPharm was unable to make a donation of praziquantel to SCI.

**Challenges of Sustaining Access (Phase 4)**

Through the combination of these six strategies, SCI dramatically expanded access to PZQ by growing the global supply of PZQ and increasing global demand for PZQ. As shown in Figure 3.1, SCI delivered a total of 40.29 million treatments in its six countries in Africa, to about 19.28 million individuals, from 2003 through June 2008. About half the treatments were first treatments with praziquantel, and about half second and third treatments. While this accomplishment represents a significant success for SCI, the effort has reached only about 10% of the population estimated to be infected with schistosomiasis and needing treatment with praziquantel. In addition, major challenges remain in providing the recommended repeat treatments with PZQ to assure adequate control of the symptoms and morbidity associated with the disease.

SCI’s ability to expand access to PZQ has depended in part on the low price of the active ingredient. Since 2002, the active ingredient price, which largely determined the factory gate price of the tablets, has ranged from a low of $76 per kilo to a high of $103 per kilo. The fluctuation resulted partly from the weakness of the U.S. dollar. At $76 per kilo, the active ingredient in each tablet cost about
Figure 3.1 | Annual treatments in the six SCI countries, 2003-2008

Note. This figure shows the number of praziquantel treatments delivered per year by SCI-supported national programs in Uganda, Burkina Faso, Niger, Mali, Tanzania, and Zambia. The data for 2008 are as of June 1 in that year. The data include new treatments plus second and third treatments for some individuals; approximately 40.29 million total treatments were delivered to about 19.28 million individuals—out of an estimated 180 million people in sub-Saharan Africa who need treatment for schistosomiasis. Data from SCI.

US$0.046, compared to US$0.062 at $103 per kilo. For the near future, the increased demand from SCI’s purchases could have two possible effects. First, increased demand could push up the price for PZQ if supplies are limited and companies try to profit from the rising demand. Second, the price could be pushed lower, as new companies initiate production and compete for a share of the growing market. So far, the impact of SCI’s increased demand has been the latter—driving down the price of PZQ tablets in the global market.

Future consumption of PZQ in Africa will depend on a number of factors. First is the treatment strategy adopted by the national control program. WHO recommends morbidity control as the overall goal, with new treatment programs first targeting high-infection populations. After these communities have been treated, a routine maintenance program aimed at school-aged children can be implemented. To reach this stage will take time—probably up to five years to reach all high-risk populations. However, once this coverage has been achieved, it should be possible for national governments to continue to provide treatment for
the newly exposed and at-risk populations. Consumption thus will depend on the treatment strategies adopted by national programs and the evolution of the national programs.

Most importantly, the development of national treatment programs for schistosomiasis in Africa will depend on additional external funding (unless national governments can be persuaded to use their own resources) and on the development of national capacity to implement the programs. SCI is trying to address both of these concerns. SCI has been seeking to secure long-term institutional funding from various external donors (outside the Bill & Melinda Gates Foundation) and also to support capacity-building in national ministries of health for schistosomiasis control programs. An important step in finding additional financing occurred in September 2006, when the U.S. Agency for International Development awarded a $100 million collaborative program to RTI International to implement integrated disease control for seven neglected tropical diseases, including schistosomiasis. SCI was named as one of five partner organizations collaborating with RTI, and Alan Fenwick was appointed project director, a post he held for four months before reverting to his position with SCI. The new program of integrated disease control was initially expected to operate in five African countries (Tanzania, Uganda, Burkina Faso, Mali, and Niger) with plans to expand to other countries and continents.

SCI estimated the consumption of PZQ in Africa during 2004 at approximately 40 million tablets. In 2005, this increased to about 70 million. With recent estimates of 180 million infected in sub-Saharan Africa, the amount of drug needed to treat all these people one time would be approximately 600 million tablets. If mass treatment were employed in high prevalence areas, the needed tablets could be half as much again. Based on these figures and the likelihood of some expansion to other countries with active programs, SCI estimated that around 260 million tablets might be required by 2007 and a similar amount per year for five successive years. This level of treatment would require approximately $20 million per year (at US$0.08 for a 600 mg tablet) for the drug costs alone. It is highly unlikely that African countries would be willing to provide these funds from their own domestic health budgets, which tend to be a patchwork of externally financed projects and donations. To achieve this level of treatment, therefore, donors will need to step forward to support national schistosomiasis control programs and the implementation of large-scale mass treatment. Between 2007 and 2010, treatment programs could continue to require 250 million tablets annually, assuming that SCI and WHO advocacy continues to be successful. After
this initial phase of mass treatment, consumption could settle at around 50 million tablets annually, assuming that most high-infection populations are treated first and that programs then shift to recurrent treatment of school children living close to lakes, rivers, and irrigation schemes. These estimates assume successful fundraising by SCI and WHO—and the newly formed Global Network for Neglected Tropical Disease Control (www.gnntdc.org). If sufficient funds are not secured, then consumption of PZQ could collapse—undermining any chance for sustained use of the technology.

All five suppliers of the active ingredient for PZQ have indicated that they would willingly expand production in response to serious orders. The supply of PZQ, therefore, could meet the demand—which depends largely on national government decisions on health priorities and international donor decisions on available funding.

The announcement of a new donation program in 2007 opened up another possible avenue for supporting access to PZQ into the future. WHO officials had spoken for years with Bayer (which sold PZQ for both human and veterinary use), with no progress on persuading the company to make significant product donations, and then met with representatives of E. Merck (the manufacturer of PZQ) twice in 2006. As Lorenzo Savioli, director of WHO’s Department of Control of Neglected Tropical Diseases, put it to the Financial Times, “Bayer tells us to talk to Merck, and Merck says to talk to Bayer.”23 In April 2007, finally, E. Merck agreed to donate some praziquantel through WHO for schistosomiasis control. The initial agreement was for 200 million tablets over 10 years, which will offer about 8 million additional treatments per year for school-aged children—out of an estimated 180 million people in need of treatment in sub-Saharan Africa. WHO officials applauded the new donation and hoped that it would be used to demonstrate further the highly positive health effects of treatment with praziquantel and perhaps lead to further donations.

**Conclusions**

SCI’s concerted efforts to increase access to praziquantel in Africa has shown that it is possible to increase the demand for PZQ and reduce the price of the drug in African countries (and thereby increase both adoption and affordability), that manufacturers can be induced to enter the PZQ market and expand their production of the active ingredient (and thereby expand availability), and that competition can be created among producers of the end product (and thereby expand
affordability for both governments and consumers) (see Table 3.4 for a summary of access barriers and strategies). SCI has also demonstrated that a single major buyer can expand access to an essential drug and can help push down prices as long as the buyer has adequate funds for purchases. (SCI thus has what economists call “oligopsony power,” in which a small number of purchasers can affect the market price for a product through the sheer volume they buy.)

The major issue now is how to ensure continued access to PZQ in Africa after SCI stops its funding of PZQ purchases as supported by the Gates Foundation grant. Sustaining access to PZQ over the long term will depend on heightened adoption—the development of both government and consumer demand for the product. Any decision by governments to use public financial resources to purchase PZQ will depend on their perception that the product is affordable and that the treatment is effective and important for the wellbeing of their populations at risk of schistosomiasis. In late 2006, SCI was examining its options after funding from the Gates Foundation stops; that time was postponed by an additional grant of $4.128 million that the foundation awarded in 2006 (largely to cover budget deficits due to the weak dollar). And in 2006, the Gates Foundation agreed to add a further $10 million to SCI to continue the program and integrate other diseases in selected countries. Some advisors to the SCI believe that other donors can be persuaded to take on the commitment for schistosomiasis treatment in Africa. Others suggest that integration with other infectious disease control programs could provide the answer (presumably still supported by international aid). But few believe that African countries will be willing to pay the costs of schistosomiasis treatment from their own government budgets in the short or the medium term; local funds are typically consumed largely by personnel costs. Sustaining access to PZQ thus will continue to depend on flows of external aid to African governments for some time.

The situation at mid 2008 provided some optimism for continued external support to supply praziquantel in Africa: In 2006 USAID launched a 5-year $100 million multi-country project to support integrated control of Neglected Tropical Diseases (NTDs). In September 2006, the U.S. consulting company RTI was awarded a contract to manage the funds. In FY 2007, $13 million were allocated for implementing integrated control of NTDs and another $13 million came through for FY 2008. It is hoped that for FY2009, up to $25 million will be allocated by the U.S. Congress, providing the first two years have shown adequate progress. SCI received a grant from RTI to implement the project in Burkina Faso and Niger, to assist with implementation in Uganda, and to procure praziquantel
for 2007–2008 (and probably through 2011). This USAID project, therefore, will help ensure that some praziquantel will continue to be delivered to Burkina Faso, Ghana, Mali, Niger, Uganda, Sierra Leone and South Sudan, until 2011. Then in February 2008, outgoing President George W. Bush unexpectedly announced that the U.S. will provide $350 million for the control of NTDs and urged other G8 countries and other donors to bring the amount to $1 billion as soon as possible. If this request is met, external funds for PZQ supplies could be maintained for some years to come. Advocacy efforts by the WHO and others have resulted in two additional partners coming forward. The first is Legatum, a private equity company, which has donated $8.9 million for the control of NTDs in Burundi and Rwanda. The second is the Bill & Melinda Gates Foundation, which has initiated meetings aimed at raising the $1 billion needed to control NTDs in Africa.

The development of a consumer-based market for PZQ will depend on adoption at the individual patient level, along with an ability to recognize and seek treatment for schistosomiasis. At present, there is a regular (though small) private-sector market for PZQ, available generally in private pharmacies in the cities and in some government health centers in rural areas throughout sub-Saharan Africa. The price in these outlets is often 10 to 30 times the price obtained by SCI in international tenders. This consumer price typically includes the procurement costs of the national procurement agency, the distribution costs, and the pharmacy’s profit. The middle class urban population can meet these costs with little difficulty. But this private pharmacy market is unlikely to be a major factor in national treatment of schistosomiasis because rural populations (where the disease is most prevalent) are believed to be unwilling and unable to pay these market prices. Whether rural residents would be willing to pay for treatment with PZQ (perhaps at a price close to cost) if they knew they were infected with schistosomiasis remains to be seen.

Changing perceptions—including global, national and end-user perceptions—about both the disease and its treatment have contributed to the expanding access to PZQ. In the six countries directly supported by SCI and in the five others partially supported, national and end-user knowledge of the symptoms of schistosomiasis and the appropriate treatment have significantly increased. With over 30 million people having received treatment, many of them at least twice, awareness and demand for further treatment are now significantly higher at both community and government levels. Nonetheless, there is still a long way to go before the target of the WHO resolution will be reached in non-SCI countries or can continue to be reached in the SCI countries.
# Need for a global champion to promote treatment of schistosomiasis

The Gates Foundation provided a major grant to establish the Schistosomiasis Control Initiative (SCI) and a grant to WHO to support and expand ongoing activities.

## Specific action

SCI collaborated with WHO and other international agencies to stimulate demand for schistosomiasis control and for PZQ.

## Specific action

SCI representatives visited African countries to negotiate agreements on schistosomiasis control and on providing PZQ with support from Gates Foundation and other sources.

## Specific action

SCI supported the production of videos and other materials on schistosomiasis control and treatment to raise awareness in both developed and developing countries.

### Table 3.4 Praziquantel access table

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Endnotes


4 Wegner.


10 World Health Organization.


13 Reich and Govindaraj.


15 Reich and Govindaraj.


17 Reich and Govindaraj.


20 Schistosomiasis Control Initiative, 3.


