

BMZ



Federal Ministry
for Economic Cooperation
and Development

Bringing Medicines to Low-income Markets

A guide to creating inclusive business models
for pharmaceutical companies



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Bringing Medicines to Low-income Markets

A GUIDE

to creating inclusive business models for pharmaceutical companies

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for Economic Cooperation
and Development

Dear Entrepreneurs:

For the German Federal Ministry for Economic Cooperation and Development (BMZ), there can be no sustainable development without sustainable economic development. And there can be no economic development without a strong private sector. We need your investments, your know-how and your capacity for innovation, in particular when it comes to providing products and services in low-income markets.

We consider inclusive business to be a key concept for generating more private sector solutions, more innovative solutions to development issues. For us, improving health is one very important issue in development. We are working worldwide to enhance health systems as a whole, to improve the prevention and treatment of HIV and AIDS and other infectious diseases, and to strengthen women's rights and choices in contraception, pregnancy and birth. Ensuring that those in need have access to high-quality and low-cost medicines is only one part of the solution to the manifold health-related issues that millions of people must deal with on a daily basis, but one of

great importance. Inclusive business models can contribute substantially and sustainably to increasing the availability, accessibility, acceptability and quality of essential medicines for the poor. At the same time, inclusive business models provide new and challenging opportunities for entrepreneurs to enter into low-income markets.

This guide focuses on the role of pharmaceutical companies in enhancing access to medicines for poor people in developing countries and emerging economies. It showcases several excellent examples of innovative entrepreneurship in the health sector. We hope that these examples will support and inspire you in your efforts to create inclusive business models that benefit your business and the health of low-income customers.

Hans-Jürgen Beerfeltz
State Secretary
German Federal Ministry for Economic Cooperation
and Development (BMZ)



SANOFI 

The lack of access to health care and medicines among most of the world's population is an unacceptable state of affairs. As one of the world's leading health care companies, Sanofi is aware of global health care challenges and committed to playing an active role in serving the needs of patients. We consider it our duty to improve access to medicines and vaccines.

Sanofi's Access to Medicines programme aims to meet the needs of all patients – especially the poorest – in disease areas in which the Group has developed specific expertise. Through our various activities, we are helping developing and emerging countries break free of the vicious circle of disease and poverty.

We focus our know-how in improving access to medicine in the following areas:

- Providing disease management, communication and educational support at every point in the health care chain;
- Developing differentiated pricing policies that facilitate access to medicines;
- Tailoring R&D to meet current and future needs.

Since no single institution, private or public, can tackle this complex issue on its own, Sanofi is dedicated to working in partnership with scholars, authorities and non-governmental organisations to develop targeted and locally adapted projects for underprivileged populations in developing and emerging countries.

Reaching customers and patients living in poverty is often poorly understood and helps explain why medicines frequently do not reach the people who need them. Developing greater awareness of business models tailored to the lives of low-income populations is a must. Pharmaceutical companies aiming to better serve people who live in poverty will therefore find this timely study very useful.

Although much in recent years has been achieved to improve access to medicines, there are still many challenges ahead that we actively target with our partners. The insights and best practices presented in this study will go far in helping us fill information gaps along the way.

Dr. Robert Sebbag
Vice President Access to Medicines Sanofi

An estimated 4 billion people live on incomes less than \$3,000 per year in local purchasing power parity (PPP)¹ terms. Their spending on health constitutes an estimated market of \$158.4 billion PPP per year.² More than one-third of this health spending goes to pharmaceutical products.³ Nevertheless, this market has barely been tapped by pharmaceutical companies, which means that billions of patients are not adequately served. Indeed, even though low-income people already spend a significant amount of money on health, they get little value for it. As seeing a doctor is often complicated and expensive, patients in many cases just buy a drug – often the wrong one – at the local shop. In addition, drugs at local outlets are frequently outdated, and are often counterfeit. Despite the poor quality, these drugs often cost much more than their counterparts in high-income markets. People pay a poverty penalty!

If pharmaceutical companies were able to sell their products in low-income markets, they could contribute to improving health outcomes among these populations. But reaching into these markets is not business as usual. Health systems are typically not functional. Key structures and actors these companies usually rely on are missing. Qualified doctors and pharmacists, proper regulation, logistics systems, insurance and other financial services – all these market enablers are frequently lacking or of poor quality. As a result, traditional business models just don't work.

Despite these challenges, some companies are successfully venturing into low-income markets. They understand that future growth will largely take place in these markets, and are experimenting with new business models to overcome these hurdles. The present report builds on their experience, analysing over 100 documented examples from pharmaceutical companies as well as other organisations such as NGOs, and is enriched with insight from 30 expert interviews. By extracting and presenting lessons derived from this analysis, the study aims to encourage and enable more successful approaches to bringing medicines to low-income markets. It builds on the insight that business models that include low-income people – so called inclusive business models – can create opportunities for both sides: business and patients.⁴

The study focuses on how pharmaceutical companies can reach out to low-income patients as customers. While considerable attention has previously been paid to the production side^{**} of business models serving low-income markets – addressing issues relating to R&D, patenting and licensing, registration and manufacturing, the customer-side has drawn comparatively little analysis. Our study therefore looks at the typical marketing functions within the pharmaceutical value chain: market research and product development, marketing, communication, sales and pricing. In all four domains, pharmaceutical companies must rethink their traditional approaches in order to address this target market.

**SEE "APPROACH" ON PAGE 66*

***SEE PAGES 26/27,
SPOTLIGHT "BEYOND OUR SCOPE"*

A guiding framework based on the four As – acceptance, awareness, availability, and affordability⁵ – is used to help companies think about new approaches in creating a compelling value proposition for low-income patients. Companies must create products patients find acceptable and are aware of (and that hold easily understandable benefits), and which are both available and affordable. In addition, a fifth A – other actors – is also of vital importance. In fact, business models in low-income environments often benefit from close collaboration with other, sometimes unusual partners. These partners enhance the viability of a business model considerably as they form the ecosystem in which the business model is embedded. Considered together, these five As comprise what we call the 4As+1 tool.

The study consists of six chapters, which can be divided into four main sections:

- **The first chapter** makes the case for pharmaceutical companies to venture into the low-income market. It provides market data and describes challenges.
- **The following five chapters** form the heart of the report. Chapter two introduces the 4As+1 tool. The subsequent four chapters examine each of the first 4As in turn, highlighting challenges and promising approaches. These chapters also underscore the importance of the fifth A, namely relevant actors with whom companies can partner. Case studies illustrate the arguments at each point.
- **The final chapter** provides practical guidance to pharmaceutical companies on how to get started with inclusive business, including tips for strategy, internal organisation and partnerships.
- **An extensive support directory** in the appendix provides a list of relevant organisational contacts and pointers to further reading.

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Business case

Many rural Indians are considered low-income and have a great need for health services and medicines. Arogya Parivar was created to specifically address this market segment's unique needs.



Photo: Arogya Parivar

Around the world, 1.7 billion people lack access to essential medicines, in many cases drugs that could save their lives. Many more face immense difficulties when in need of treatment. For example, specialists may be long distances away, while health care providers (HCPs) in close proximity are poorly skilled.

Sometimes patients are cheated by informal vendors selling counterfeit drugs. Most of these patients live in the slums and villages of the developing world. They value their health just as much as anyone else. And they spend significant amounts on it, often 5% of their income or more.

If pharmaceutical companies could cater to this population, they would not only contribute to the improvement of health outcomes, a significant humanitarian goal, but also win access to a big and growing market. However, few pharmaceutical

companies have to date ventured into low-income markets. Conditions in these areas are too different to enable existing business models to be simply expanded. Nevertheless, an increasing number of enterprises are exploring these markets, starting with small pilots. They know that future growth in the sector will come from the 4 billion people who live at the bottom of the economic pyramid (BoP). Some companies, like Novartis*, have already cracked this market successfully. We can learn from them ...

* SEE CASE STUDY

CASE STUDY 1

Arogya Parivar, India

Establishing a sustainable business model for India's rural population

When Novartis created its social business in India it had a clear mission: "To improve healthcare access for the under-served poor located at the 'bottom-of-the-pyramid' using a social-business approach". India was selected as a pilot location. The country's fast-rising population of nearly 1.2 billion, roughly 70% of which is rural, as well as its increasing purchasing power, offered clear potential for future market growth.⁶ Health needs today often go unmet, especially in rural areas, where 65% of the population lacks access to essential medication.⁷

As a first step, Novartis invested considerable time in developing a better understanding of local needs. Market research indicated that the target population, people with an income between \$1 and \$5 a day, needed basic primary care products such as antibiotics, painkillers and antacids. To appeal to this target group, Novartis created a separate brand for the low-income market, called Arogya Parivar. It sells over-the-counter products, generic medicines from its subsidiary, Sandoz, as well as products from its Pharmaceuticals and Vaccines divisions addressing 12 prevalent disease areas. Products use local language and smaller packet sizes for acute therapy in order to keep out-of-pocket costs low.

However, adapting products was not enough. Limited health infrastructure and a lack of awareness of health issues proved to be the largest challenges in reaching consumers. The company thus looked for a scalable solution that would allow it to tackle these challenges

on a small, manageable scale. It came up with a decentralised model based on "cells", which offer integrated solutions to health problems rather than just products.

In this context, a cell is an operational unit that addresses a population of about 180,000 to 220,000 people. In each cell, a supervisor manages operations. He or she visits doctors and pharmacists to explain products and deliver health information, books sales and, if necessary, refers them to micro-finance institutions to obtain loans enabling them to stock essential medicines, thus ensuring availability. A health educator organises community health camps and meetings to address late disease diagnosis and help prevent the loss of livelihoods. The health educator as well as the supervisor are recruited from the community. They speak the local language and understand local needs, enabling them to gain trust more easily.

Starting on a small scale, Novartis developed three single-cell pilots in 2006 and 2007. Drawing on the experience gained in the field as well as feedback from the project's stakeholders, Arogya Parivar became financially sustainable within 3-4 years. Ultimately, the model was expanded to 257 cells serving 42 million people in 31,000 villages across 10 states in India. Currently, the company is planning to roll out the model in additional countries in sub-Saharan Africa and Asia.

Source: Interviews with Anuj Pasrija and Dorje Mundle, Novartis.

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Need: 1.7 billion lack access to essential medicines

The WHO estimates that approximately 1.7 billion people lack access to essential medicines.⁸ It defines essential medicines as “those that satisfy the priority health care needs of the population”.⁹ For example, in India and Africa, 50% or more of the population does not have regular access to essential medicines. In Uganda, only about 55% of the medicines deemed essential, such as drugs to treat HIV/AIDS, malaria, tuberculosis, cancer and diabetes, can be found in free health facilities.¹⁰

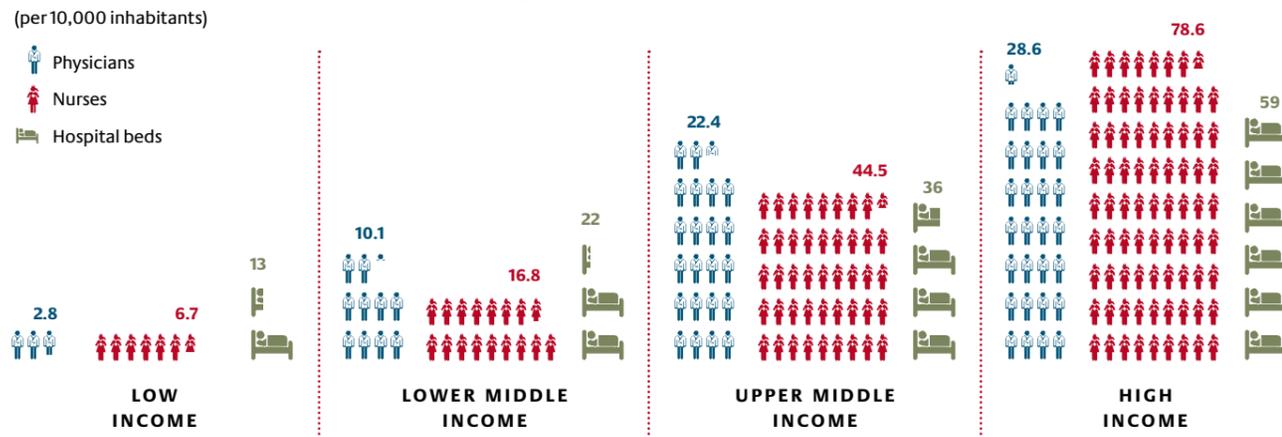
Where they do have access, low-income people often pay more for drugs than do their wealthier counterparts. Although the increase in the production of generic drugs has led to dramatic declines in medicine prices in recent decades, especially in developing countries, this has not translated directly into reduced prices for low-income people. Indeed, drugs in low-income markets tend to be more expensive than elsewhere in the world, a phenomenon referred to as the “poverty penalty”. Comparing international reference prices, median prices for drugs in developing countries are 2.7 times higher in the public sector and 6.3 times higher in the private sector than in developed countries.¹¹ These high add-on costs often occur in the supply chain, due to high taxes and tariffs, substantial mark-ups by wholesalers and retailers, expensive local purchases to compensate for short-term supply shortages, and the prevalence of informal intermediaries or even imposter pharmacists that charge high fees.¹²

In addition, the broader health systems serving people living in poverty often perform extremely badly. In many cases, low-income countries lack the infrastructure and health care workforce necessary to ensure adequate access to medicines and treatment in slums and rural areas. On average, only 2.8 physicians are available per 10,000 inhabitants, compared to 28.6 physicians in high-income countries.^{*} To get access to professional health care, low-income patients often have to travel long distances under difficult road and transportation conditions, which costs time and money. Travel to a specialist or a hospital can be more expensive than treatment itself. If doctors or health care centres are within reach, they are often ill-equipped or poorly skilled.

* SEE FIGURE 1

Poverty and health thus combine to form a vicious circle. The living conditions in the slums and villages of developing countries are a direct cause of ill health. Sanitation and hygiene are substandard and cause germs to spread, houses are not properly protected from insects that can transmit diseases, and food may be insufficient in quantity or lack the necessary nutrients, especially for children and pregnant women. Moreover, becoming sick is itself costly. People must make significant expenditures for drugs and health care, mostly out of pocket. While they are sick, they and those caring for them cannot work, losing income-earning opportunities. On average, a health crisis occurs more than once a year in every household in India¹³ – and health expenses are a major contributor to pushing households into poverty.¹⁴

FIGURE 1 Medical personnel and hospital beds, by income groups (per 10,000 inhabitants)



Source: WHO 2011, World Health Statistics.¹⁵

Demand: A double burden of disease

Low-income countries¹⁶ today face a double burden of disease. On the one hand, communicable diseases such as HIV/AIDS and malaria are still a major challenge, and are a focus of public health initiatives. On the other hand, these countries also face a considerable burden due to non-communicable diseases (NCDs) such as diabetes or cancer, especially in urbanised areas. In 2008, NCDs accounted for even more deaths than communicable diseases in this group of countries. Consequently, the top seven causes of death in low-income countries, which together account for nearly half (48%) of all deaths, include both communicable and non-communicable diseases.

SEE FIGURE 3 BELOW

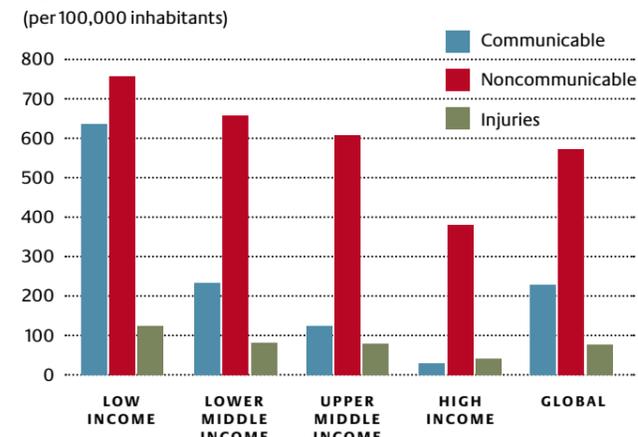
A number of communicable diseases can be treated with inexpensive prevention measures or existing medicines. Pneumonia is a common acute respiratory infection, and the leading cause of death in children, killing an estimated 1.6 million every year. The provision of immunisation or antibiotics could prevent many of these deaths. Unfortunately, only around 20% of children suffering from pneumonia are actually treated with the medicines they need.¹⁷

By contrast, in lower-middle-income countries, NCDs constitute the most pressing challenge. In this country group, the top three causes of death were heart disease, other cerebrovascular diseases and chronic obstructive pulmonary disease, all non-communicable diseases. Together, they accounted for 34% of all deaths in 2008.¹⁸ Additionally, NCDs such as diabetes or cancer are becoming an increasing challenge.

The importance of NCDs is expected to rise further in both low-income and lower-middle-income countries during the next years. As populations are lifted out of poverty, behavioural and disease patterns change accordingly. Increasing income levels, rapid urbanisation and population aging contribute to the common risk factors for NCDs, such as physical inactivity or increased alcohol and tobacco use.¹⁹ According to WHO estimates, the number of deaths in low-income countries caused by communicable diseases will approximately halve between 2004 and 2030, while deaths attributed to NCDs will nearly double in the same period of time.²⁰

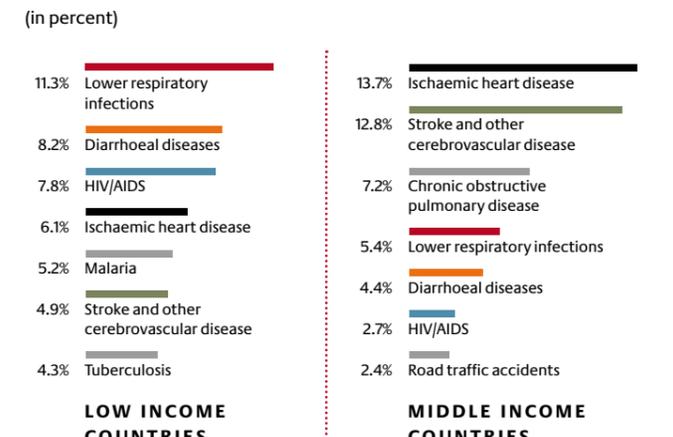
Preventive measures, such as education on the importance of healthy diets or the consequences of tobacco and alcohol use, play an important role in dealing with NCDs.²¹ Once they occur, they should always be accompanied by a complete disease management programme that includes behavioural change and, in most cases, medication. However, the supply of drugs to treat conditions such as cardiovascular disease or diabetes in developing countries is even more limited than that of medicine for communicable diseases. A United Nations task force responsible for monitoring the Millennium Development Goals stated in 2010 that: “In low-income and lower-middle-income countries, the availability rate of medicines for treatment of acute illnesses was four times that of medicines for chronic diseases”.²²

FIGURE 2 Age-standardised mortality rates, by cause in 2008 (per 100,000 inhabitants)



Source: WHO 2011, World Health Statistics

FIGURE 3 Top seven causes of death (in percent)



Source: WHO 2011, Top Causes of Death²³

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Target group: 4 billion underserved customers

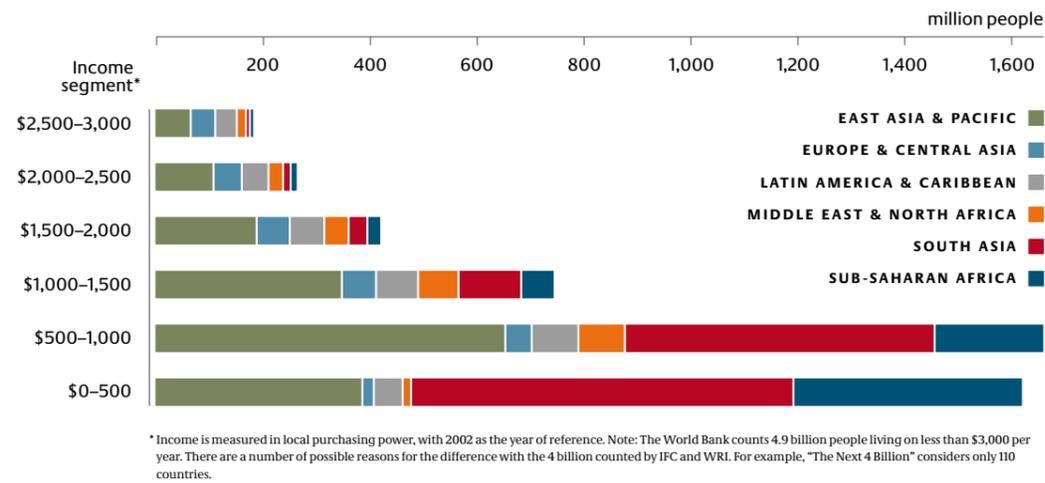
Globally, an estimated 4 billion people live on incomes of less than \$3,000 per year in purchasing-power parity (PPP) terms.²⁴ They constitute the so-called base of the economic pyramid (BoP) (Figure 4).²⁵ Although often referred to as a whole, this group is diverse – the economic structures of the low-income population vary between countries and regions.

Around 1 billion people earn less than \$1 per day in local purchasing power. They are regarded as extremely poor by any standard.²⁶ They lack not only capital but also the opportunity to meet their most basic needs, such as adequate food supply, uncontaminated drinking water, safe shelter and sanitation. Basic health care is very often missing as well. To address these gaps, pharmaceutical companies can cooperate with donors and international organisations through their philanthropy programmes.

However, low income is not no income. People who live in the slums and villages of developing countries – particularly those who earn more than \$2 PPP per day – do in fact have resources, but are typically unable to employ them efficiently due to inadequate access to formal markets. For example, due to a lack of education or a lack of health infrastructure, they opt for self-medication, often purchasing the wrong drugs or even worse, counterfeits. Products they have access to may not work in their living environment, as they require proper storage or even cooling, both of which are difficult to ensure in regions where power outages are frequent. Transportation to a hospital or to an adequate specialist is often more expensive than the treatment itself. With minimal or no public safety nets and only very limited insurance coverage, already traumatic health events can have devastating effects on household finances as costs – particularly for medicine – are covered out-of-pocket.

Inclusive business models that aim to identify and unlock these market inefficiencies can create opportunities on both sides of the market transactions, for business and patients alike.

FIGURE 4
Number of people living on less than \$ 3,000 (PPP)
(per year, by income segments, in millions)



Source: PovcalNet / World Bank

Market: \$56.7 billion and growing

Even with very limited disposable income, people spend a considerable proportion of their resources on health care and medicines. For example, the average poor household in rural India allocates up to 2.9% of its annual expenditure to health. For other countries such as Bolivia or Sierra Leone, this figure can range as high as 7.5%.

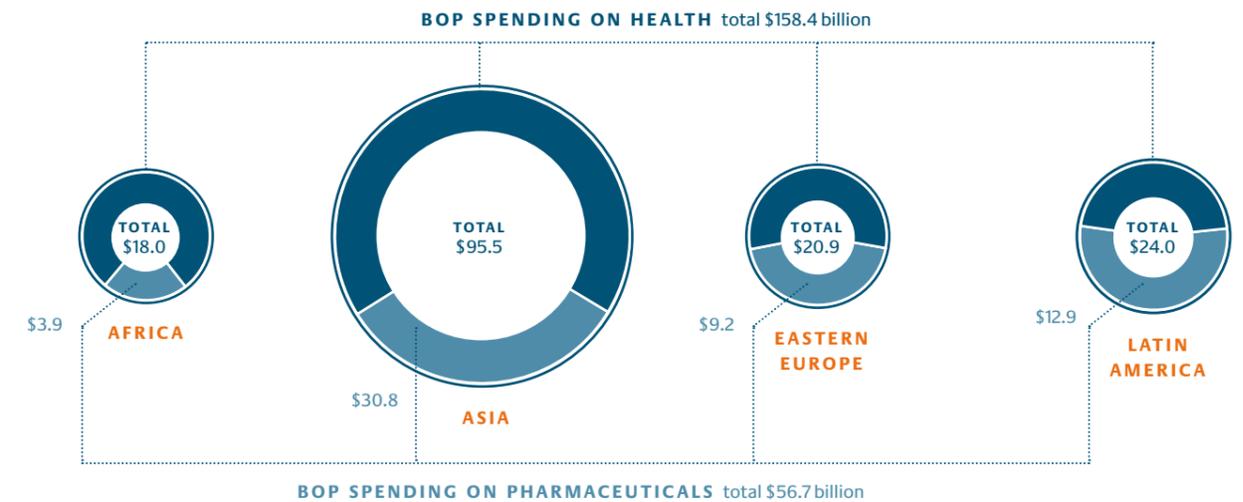
The World Resources Institute (WRI) and the International Finance Cooperation (IFC) estimate the aggregate annual household spending on health for those living on less than \$3,000 per year to be \$158.4 billion (PPP).²⁷ Asia alone accounts for \$95.5 billion (PPP) in annual health expenditures, reflecting a large BoP population.²⁸ Average health spending by BoP households is generally higher in urban than in rural areas.²⁹ Pharmaceuticals account for more than one-third of overall health spending.³⁰ In Africa, for example, households that live at the BoP spend between 51% (Uganda) and 87% (Sierra Leone) of their health budget on pharmaceuticals. In Latin America, this figure ranges from 50% (Colombia) to 74% (Brazil).

SEE FIGURE 5

A variety of factors, including the availability and quality of health services and medicines, influences households' overall health expenditures. The high share devoted to pharmaceuticals is derived from the fact that self-medication tends to be the first response to illness.³¹ This pattern seems particularly prevalent in lower income segments, and diminishes as income rises. However, there is a clear link between financial resources and spending on health. The more disposable income a household has, the more it spends on health. It seems that with higher incomes, people tend to spend their health budget not only on pharmaceuticals, but to have more funds available for – or more access to – additional health-related services such as counselling by a doctor or even hospitalisation.

The World Bank estimates that real GDP growth rates in developing countries will stabilise at 6% – 7% between 2011 and 2013.³² In addition, the population in less developed countries is expected to grow by more than 2 billion in the next 30 years, up to 9 billion in 2050.³³ Driven by rising incomes and a growing population, demand for medicines and health can be expected to increase strongly in coming years.

FIGURE 5
BoP spending on health and pharmaceuticals
(in billion \$)



Source: WRI/IFC 2007, The next 4 billion

Constraints: Difficult market conditions

The ongoing need for medicines and medical care within this population is immense. There appears to be a dormant, as-yet-untapped demand with large growth potential in low- and middle-income countries. But if so, why have pharmaceutical manufacturers not run to take advantage of this significant opportunity?

The answer lies in the difficult conditions of market access. In the slums and villages where low-income consumers live, numerous market constraints create an environment in which private companies, including pharmaceuticals manufacturers, find it difficult to operate. In a study of 50 cases, the UNDP has identified five main areas of constraints.³⁴ These constraints also apply to the case studies that form the basis of this report:

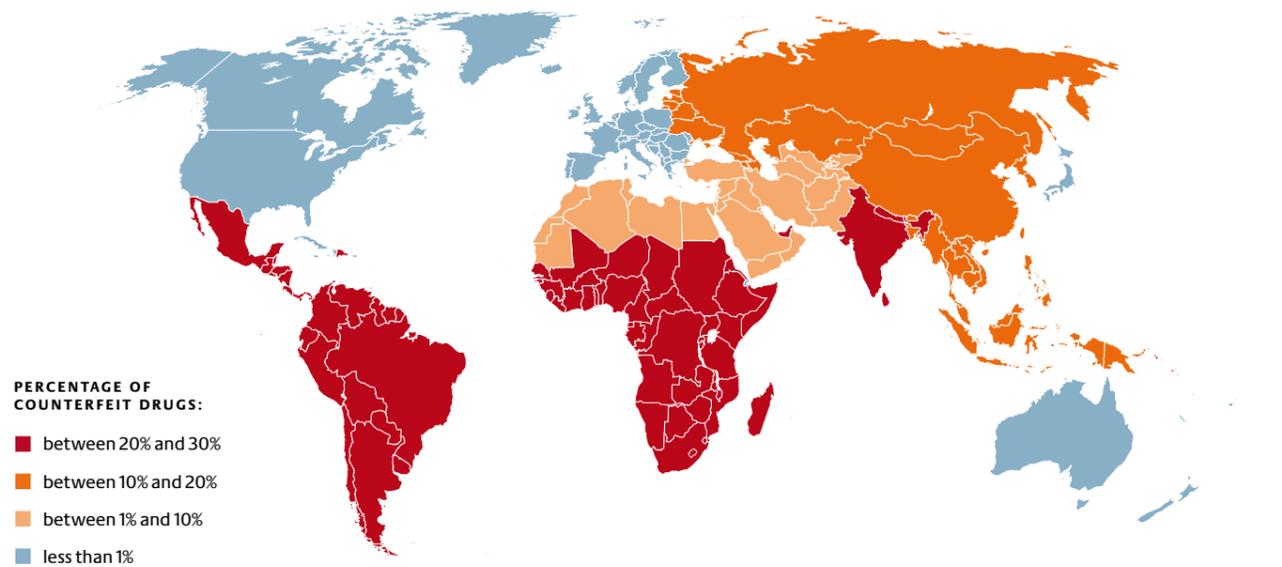
- **Market information:** Pharmaceutical companies addressing low-income patients for the first time typically lack an understanding of the low-income market. This often includes a lack of data on local health systems, such as how many doctors or health centres are available, patterns of local health-seeking behaviour, and disease prevalence, as well as information on needs, demand and specific local market conditions. For example, when aiming to adapt a product to suit local needs, they may lack information about local distribution and storage conditions for medicines requiring special stability and packaging, or on which package size and design would resonate best with people's habits, taste and level of literacy.
- **Regulatory environment:** The pharmaceutical market is heavily regulated. However, in low-income markets, adequate regulations – or effective enforcement of existing regulations – are often lacking. Actors operate in informal markets that lack transparency. This has significant consequences. For example, drug prices are inflated due to uncontrollable mark-ups charged by middlemen. Counterfeit drugs are commonly encountered. It is estimated that up to 30% of products sold in Africa and Asia are fake.³⁵

- **Physical infrastructure:** Companies find it difficult to reach low-income patients, especially in rural villages. Road conditions are often poor, and some villages are not reached by road at all, or are accessible for only part of the year. Logistics providers are often unavailable. Health centres and medical equipment are non-existent or very rudimentary. Energy needed to keep vaccines cool is in short supply. Power outages are frequent. And although more and more people have access to mobile phones, it is still hard to reach some people, and points of Internet access are still miles away for most.
- **Knowledge and skills:** When marketing new products to low-income patients, low education levels are a challenge. Patients lack familiarity with basic medical concepts, and thus often do not believe in the effectiveness of certain treatment options. Even more challenging is the lack of knowledge and skills among individual HCPs. For example, only 34% of “doctors” in the slums of Delhi have a formal medical degree.³⁶

- **Access to financial services:** Patients, health care providers, pharmacists, wholesalers and other actors in the business ecosystem often lack access to credit and insurance products. About 70% of low-income patient drug spending is paid for out of pocket.³⁷ * This is inefficient, as it may encourage them to defer preventative measures or treatment of weak symptoms until their condition worsens to the point where nothing can help. In case of serious health events, they spend their savings and sell their assets to pay for medicine, doctor visits and hospital fees. Wholesalers, pharmacists and doctors – who often also sell medicine – face difficulties keeping medicine in stock. Health care providers and clinics in these areas can rarely afford new equipment or training for their personnel.

These constraints appear again and again in low-income markets, and the same patterns will be repeated in the detailed chapters on each of the 4As. Working under these conditions, pharmaceutical companies need new approaches to reach their prospective customers.

FIGURE 6
Estimated global distribution of counterfeit medicine



Source: Compiled from different sources³⁸

FIGURE 7
Public and private expenditure on health
(by income group)



Source: WHO 2011, Health Statistics.

* SEE FIGURE 7

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The 4As+1 tool



The 4As+1 tool helps companies develop business models that are adapted to the conditions of low-income markets. Sanofi's well-designed business model ensures that treatment is available, affordable and interlinked with preventive measures for those who need it most, such as this mother and her child.

Photo: Sanofi

To create value in low-income markets, pharmaceutical companies require innovative business models. These business models can overcome widespread constraints in the market environment of low-income patients. They manage to create value along four dimensions: acceptance, awareness, availability and affordability. In many cases, pharmaceutical companies work closely with other actors to create this value proposition. We therefore refer to this guiding framework as the 4As+1 tool.

CASE STUDY 2

Sanofi and DNDi, Africa

The 4As+1 tool at work: Sanofi and DNDi co-develop ASAQ to fight malaria

Sanofi, a leading global pharmaceutical company and manufacturer of malaria medication, and the Drugs for Neglected Diseases Initiative (DNDi), a non-profit organisation that aims to address unmet patient needs in the context of neglected diseases, entered into a public-private partnership in December 2004. The partners sought to jointly develop a safe, rapidly acting fixed-dose combination (FDC) to treat malaria in Africa. The result, called ASAQ, proved to exemplify the criteria for each A:

Acceptance: FDCs, colour-coded tablets and pictograms were developed to improve patient compliance. Large package sizes (25 blisters) were provided for institutional public health use. Both product adaptations were developed with input from NGOs such as the Medicines for Malaria Ventures (MMV) and local researchers.

Awareness: Information and education tools for patients and health care providers give guidance on using the drug safely and effectively along with other services provided by Sanofi's Impact Malaria Program.

Availability: The partnership was set up to produce ASAQ mainly for institutional buyers such as the Global Fund, which typically work through national governments or NGOs to make it available to patients.

Affordability: From the partnership's inception, acceptable price levels were set at \$1 for three-day adult treatment and \$0.50 for children. No patent would be issued. To reduce the risk of product

diversion, ASAQ has a different trade name, branding and distribution channels than Coasucam, a regular pharmacy retail product that has the same active ingredient combination and strength, but higher prices.

Actors: The collaboration between Sanofi and DNDi reduced the financial burden for each partner and enabled them to combine expertise. Sanofi's annual financial contribution ranged from €6 to €10 million between 2002 and 2009. DNDi supported the project with €8 million collected from various donors. Each partner provided considerable expertise within its own domain: DNDi did much of the pre-clinical and clinical work with various academic institutions around the world, including in target countries, and subsequently convened an independent panel of experts to provide independent advice on ASAQ distribution and appropriate patient drug use. Sanofi developed the process required to enable production on an industrial scale, conducted pre-clinical pharmacotoxicology studies, put together the registration files in countries where malaria was endemic, prepared the launch in these countries, and conducted follow-up clinical studies to strengthen local pharmacovigilance capacities.

The results speak for themselves. ASAQ was launched in 2007, one year earlier than Sanofi could have managed independently. The product is WHO pre-qualified, and the business model is sustainable, with 45 million patients treated in 2010.

Source: Interview with Dr. Robert Sebbag, Sanofi; DNDi website. www.actwithasaq.org

The 4As+1: A guiding framework

A business model describes the rationale of how an organisation creates, delivers and captures value. At the heart of every successful business model is a compelling value proposition. Customers must understand how they would benefit from the product, and the benefits must be greater than the costs. To create this value proposition, Marketing 101 advises a consideration of the “4Ps”: product, promotion, place and price. For the low-income market, a parallel set of guiding principles can be derived, addressing instead the dimensions of acceptance, awareness, availability and affordability. BoP scholars have termed this framework the “4As”.³⁹

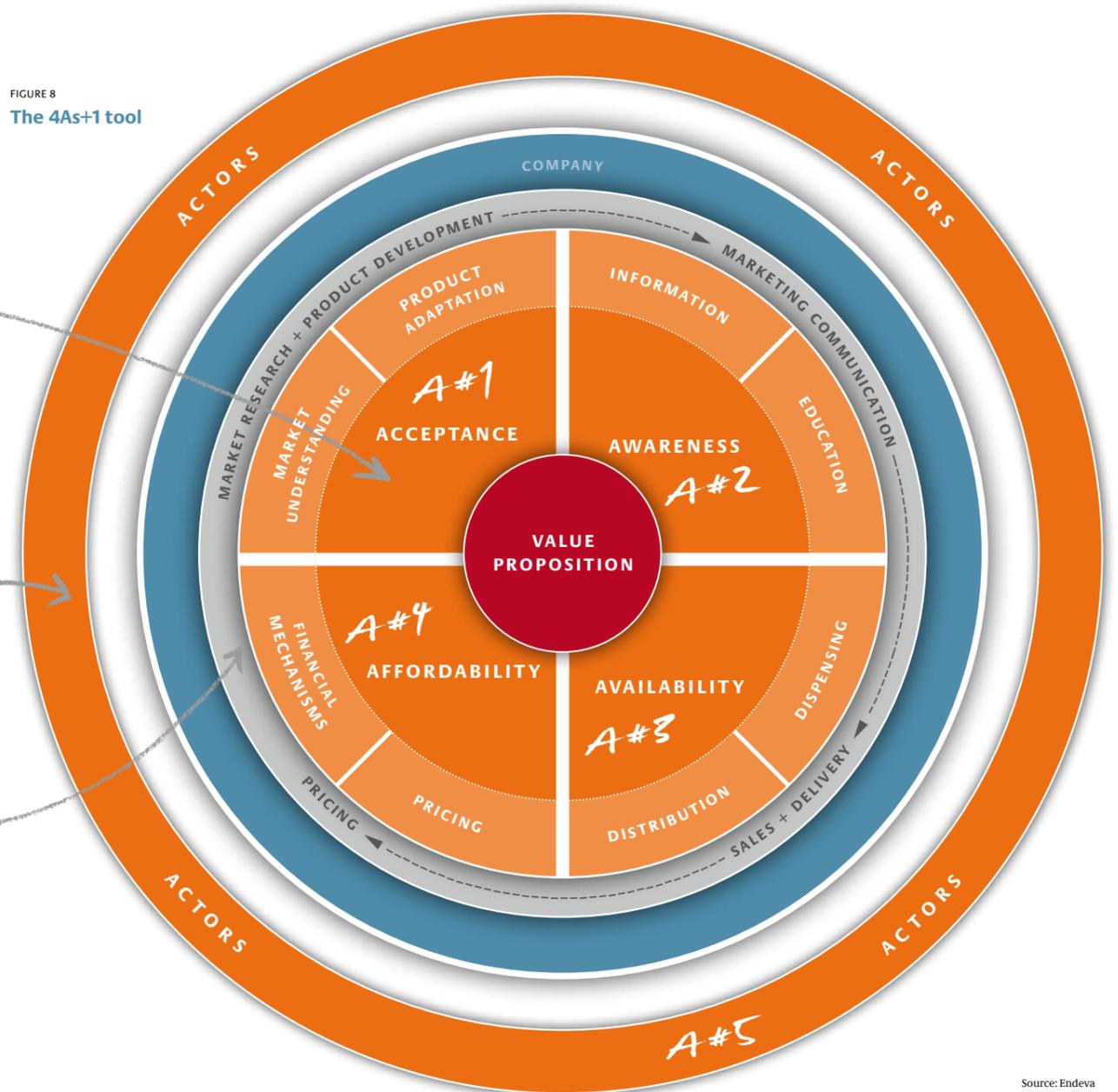
The 4As have proven an effective framework to capture insights from our case study analysis. Companies need to offer products and services that patients find acceptable. Facilitating acceptance means developing an understanding for the target market – and adapting products according to patients’ needs. Awareness can be enhanced by providing information and education – ideally in conjunction with neutral partners. When aiming to make products available, proper dispensing and distribution need to be ensured. Innovative financing mechanisms and pricing methods contribute to making products affordable for patients. The 4As are also closely linked to the marketing-related elements of the pharmaceutical value chain, including market research and product development, marketing communication, sales, delivery and pricing.

The 4As serve as a guiding framework for the following chapters, which present in detail the challenges and solutions to creating value both for patients and the company. In short, they address the following questions:

- **Acceptance:** To what extent do patients accept medicines, treatment regimens and health care providers?
- **Awareness:** How aware is the population of health-related issues (i.e., symptoms, quality of medicines and health care providers)?
- **Availability:** How readily available are medicines, health infrastructures and health care providers to local populations?
- **Affordability:** Can patients, health care providers, pharmacists and institutional payers afford and finance medicines and health services?

To realise the full potential of these 4As, a **fifth A** is vital: other actors, such as health-related NGOs, MFIs, governments or international organisations.

FIGURE 8
The 4As+1 tool



The fifth A: Key actors in the health ecosystem

To create value, companies rely on a fifth A: a variety of actors that form the ecosystem of the business. Pharmaceutical companies in particular depend on the “health ecosystem” around them to ensure that the correct high-quality product reaches those in need in an appropriate way. For example, they rely on a network of wholesalers to distribute their products; on pharmacists, clinics and doctors to provide counselling and properly dispense medicine; and on the government for proper regulations that ensure transparency in the supply chain and prevent counterfeiting, among other tasks.

When targeting people that reside in rural areas and urban slums, pharmaceutical companies face a different ecosystem than that encountered in mature markets. Many of the actors they usually rely on are absent, or don’t fulfil their roles properly. However, new actors such as NGOs, international organisations, donors or local communities can step in to fill these gaps. Understanding the different potential configurations of actors and roles, as well as the vast potential for partnerships and innovation, is crucial for pharmaceutical companies aiming to tackle the low-income market.

Public sector/government

Health is considered a public good. A healthy population should be in the interest of every government, since it is a prerequisite for economic and human development. Therefore, the state plays a very important role in health care and the delivery of medicines. Yet its depth of involvement, as well as the reservoir of resources and capabilities available to execute the required activities, varies strongly by country. Particularly in least developed countries (LDCs), the public sector’s ability to live up to expectations can be quite limited.

Market access: The domestic government determines the degree to which the private sector is allowed to participate in the health sector. While health care is in public hands in some countries, in others the private sector is welcome. Governments can decide to protect their domestic market through high tariffs, or can alternately seek to attract foreign direct investment.

SEE PAGES 26/27,
SPOTLIGHT “BEYOND OUR SCOPE”

Regulatory role: The government strongly regulates the market to protect its population. Regulations encompass topics such as new product registration, patent enforcement, standards for manufacturing, distribution and storage, and the monitoring, promotion and dispensing of medicine.

Financing: Domestic governments provide medicines as well as health care infrastructure and services. Depending on the country, the government finances health care fully or partially through insurance systems for the whole population or selected groups. However, governments in low- and middle-income countries often at least partially lack the capacity and resources to do so.

Delivery: Governments provide critical elements of the health system, including hospitals, health centres, medical equipment and health personnel. Again, the extent to which the infrastructure is in public or in private hands depends on the individual country.

Education: Secondary and tertiary educational institutions that train high-quality health care providers for all levels of care, from nurses, pharmacists and lab technicians to specialist doctors, need to be put in place by the public sector and can be supplemented by private training institutions. In addition, the state has a responsibility to provide a certain level of health education to the broader population through public health campaigns and within school curricula.

International organisations

International organisations serve mostly as donors and technical advisers. Among this group are the Global Fund, the IFC and regional institutions such as the Asian and African Development Banks (ADB and AfDB). International organisations such as the World Bank, the World Health Organization (WHO) and the World Trade Organization (WTO) also play an important stewardship role, facilitating discussions between different types of actors and countries, and contributing to the development of health policies such as the Essential Medicine List, the WHO’s treatment guidelines, and the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) patent regulations. These organisations mostly interact with governments and private-sector associations, not individual companies, except in selected cases.

Bilateral donors

Bilateral donors such as the German Federal Ministry for Economic Cooperation and Development (BMZ), the U.S. Agency for International Development (USAID) in the United States and the Department for International Development (DFID) in the United Kingdom provide financial and technical assistance to developing and emerging countries. They assist local governments in these countries in strengthening health systems, improving health education and addressing other health-related issues. In addition, bilateral donors generally have programmes in which they partner with companies in the form of public-private partnerships.

Private foundations

Private foundations serve mainly as donors, with very few providing technical advice. The largest foundation in the global health sector is the Bill & Melinda Gates Foundation, which makes annual contributions to health programmes of \$800 million. It is involved in many aspects of health, from product development partnerships to health infrastructure improvements. Many smaller foundations also provide funding for health-related topics such as health awareness campaigns.

Micro-finance institutions (MFI) and micro-insurers

MFIs offer loans from \$10 to \$10,000, often without requiring traditional collateral. Loans are supposed to be provided for productive uses only. Thus, a pharmacist could use a loan to stock new medicine. De facto, more than half of all micro-loans are used to smooth consumption.⁴⁰ Patients often rely on loans to pay for serious health events. This is a consequence of the lack of an effective health financing system such as health insurance.

Many MFIs have been working to add micro health insurance products to their portfolio, filling an important gap. However, micro health insurance products today remain in a pilot stage. Their main challenge is reaching a sustainable scale due to the frequent lack of functioning health infrastructures, a lack of trust on the part of patients, and the complexity of processing and validating large volumes of claims.

Non-governmental organisations

Non-governmental organisations (NGOs) are mission-driven organisations. They often conduct advocacy campaigns to put the health needs of low-income people on the political agenda. In addition, many NGOs provide products and services to low-income patients. They step in where other actors are not present or do not meet the needs of populations living in slums and rural areas. The NGO landscape is very broad, ranging from groups operating internationally to local grassroots organisations. Micro health franchises and non-profit social marketing companies selling and promoting health products such as malaria bed nets or family planning methods have become influential actors.

Private sector

Private enterprises play a crucial role in the development, distribution and dispensing of medicines. This applies not only to pharmaceutical manufacturers, but to the entire health sector, including diagnostic companies, health service providers, private health insurance providers, distributors and pharmacies. The size of the private health sector, ranging from health care services to pharmaceuticals, is mostly driven by the investment climate and the role allowed to private companies by the government. Private companies from different sectors can work together to offer health solutions, either as collaborators in partnerships, as in the example of Novartis, IBM and Google in the SMS for Life project,^{*} or in business-to-business relationships, as in the example of Sproxil^{**} working with pharmaceutical manufacturers to validate originator medicines.

The private sector is the focus of this report. However, all other actors mentioned are important partners without whom business models could not work. The following chapters will give further insights into the potential for cooperation between actors in such a way as to raise awareness of health-related issues and make medicines acceptable, available and affordable to low-income patients through effective business models.

* SEE PAGE 43,
CASE STUDY
“NOVARTIS SMS FOR LIFE”

** SEE PAGE 39, CASE STUDY
“SPROXIL”

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SPOTLIGHT

develoPPP.de – development partnerships with the private sector

The develoPPP.de programme supports cooperation between the private sector and institutions of development cooperation. Hence the three Ps in develoPPP, which refer to public-private partnerships, or development partnerships with the private sector.

Development partnerships bring together the innovative energy of the private sector with the resources, knowledge and experience of institutions of development cooperation. Their goal is to sustainably improve people's living conditions in partner countries of the German Federal Ministry for Economic Cooperation and Development (BMZ), while at the same time enhancing the economic, ecological and social framework for economic activity. In these joint projects and programmes, partners share the responsibility, costs and risks.

A partnership between your business and the BMZ can help lower the costs involved in pioneering inclusive business models for sustainable development. It can also help reduce risks and facilitate the transfer of know-how needed to upscale successful pilots. Companies can harness the long-standing and wide-ranging expertise of BMZ and its implementing organisations in developing and emerging countries to realistically assess the obstacles and opportunities inherent in BoP markets. The BMZ and its implementing organisations contribute financial and human resources to assist in the design and implementation of inclusive business models for sustainable development and have access to an extensive network of civil society, private sector and state organisations in the partner countries of German development cooperation. develoPPP.de is implemented by the Deutsche Investitions- und Entwicklungsgesellschaft (DEG), the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and sequa gGmbH, and commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ). Since the programme began in 1999, around 1,400 projects in over 70 countries have been conducted, with nearly 10% of the funds going to health-related projects.

Several times a year, DEG, GIZ and sequa hold idea competitions for interested German and European companies. The best approaches can win project co-financing of up to €193,000. Three competition categories offer different opportunities for cooperation:

develoPPP.topic

Calls for proposals under this heading have a sector-specific focus on areas that exhibit a major development policy need. The topics are regularly redefined and assigned to one of the three implementing organisations, DEG, GIZ or sequa. The most recent topics are available online at: www.develoPPP.de

develoPPP.innovation

In this category, businesses are encouraged to take the initiative in idea competitions that are not restricted to specific topics. Companies can submit especially innovative proposals built around their specific field of know-how. Inclusive business models for sustainable development are particularly welcome.

develoPPP.alliance

In addition to the calls for proposals, develoPPP.de also offers the chance to engage in high-impact projects that have proven to be successful and replicable. The resulting strategic alliances encompass several partners and countries, and entail significant development-oriented investments that frequently bring about change throughout entire sectors.

develoPPP.de



FOR FURTHER INFORMATION VISIT:
WWW.DEVELOPPP.DE

CASE STUDY 3

GIZ and Bayer HealthCare, Bosnia and Herzegovina

GIZ and Bayer HealthCare partner to raise awareness on sexual health

Sexually transmitted diseases and unwanted pregnancies are a major problem in Bosnia and Herzegovina (BiH) among young people between 14 and 26 years old, largely due to lack of information on sexuality and family planning methods. Reasons for this deficiency in information is due to outdated education material in schools, insufficient training of local health providers and the lack of cooperation between schools, youth and health centres on the respective topic. Bayer HealthCare Pharmaceuticals is a market leader in hormonal contraception, and is seeking to develop a market in the region. In 2011, GIZ and Bayer HealthCare Pharmaceuticals joined forces to form a Development Partnership with the Private Sector (DPP) slated to run for two years. The project aims to raise awareness of sexual rights among young people aged 14 to 26 in 14 selected municipalities across BiH, and to increase the use of modern family planning methods.

Source:
Interview with Rubeena Esmail-Arndt, GIZ and
Klaus Brill, Annette Wiedenbach, Bayer HealthCare

In order to achieve this goal, the two partners agreed on four major components:

- A standardised training package for health care providers meeting international standards and adapted to the local environment in collaboration with the Ministry of Health and Education in BiH.
- Capacity development and training for health centre staff, enabling them to deliver youth-friendly lectures in school for youth aged 14 to 19, and provide peer-to-peer education.
- Media campaigns (TV, radio, press) and on-line web counselling.
- Provision of oral contraception with users counselled and monitored by medical staff.

The partnership's success is grounded in the partners' complementary capabilities: GIZ is well versed in pedagogical issues, training and marketing. It is able to provide connections between schools, health centres and administrative bodies, and is perceived as a credible international and semi-governmental promoter of health. Bayer HealthCare Pharmaceuticals, in turn, provides the technical expertise in the areas of family planning methods and media campaigns, as well as providing the product. The two partners split the project's costs roughly equally.



Teens are trained to engage in peer-to-peer education. This is effective, particularly in areas like sexual health.



Breakdance and birth control? Young people use fresh approaches to raise sexual health awareness in urban areas in Bosnia and Herzegovina.

Beyond our scope – a glance at the entire value chain

The way in which pharmaceutical companies can develop and produce medicines for low-income populations, a process that includes R&D, patenting and licensing, registration and manufacturing, has been the focus of much research and activity.* The current state of the field is described briefly below.

R&D: Originator versus generic products

In most industrialised countries, innovative new compounds are provided with 20 years of patent protection to reward developers for their investment and entrepreneurial risk, and to create incentives for the creation of new products.

However, this results in two negative consequences for low-income patients. First, the premium price*** that the originator is able to charge often excludes people living in poverty from access, and second, due to a lack of purchasing power, little research and innovation is being applied towards diseases prevalent primarily in low-income markets – the so-called neglected diseases.

A number of promising initiatives have been launched in recent years in response to these shortcomings. The most advanced are product development partnerships (PDP), especially focused on HIV, tuberculosis, malaria and other neglected tropical diseases, which have collectively launched 13 products to date. In these partnerships, NGOs have worked with pharmaceutical companies, academic institutions, governments, donors and patients in low-income countries to share knowledge and resources, with the goal of developing affordable products for underserved patients. Examples include the TB Alliance and the Medicines for Malaria Venture (MMV).⁴¹ Another such initiative is the One World Health Institute, the first not-for-profit pharmaceutical company supported by grants and donations, with the aim of developing and delivering medicines for children for specific diseases such as malaria, hookworm and diarrhoea. Most recently, Medicines 360° was launched as a non-profit pharmaceutical

company to target Millennium Development Goal 5, the improvement of maternal health. The third promising example, still in its infancy, is the Health Impact Fund, initiated and promoted by an academic group led by German philosopher and researcher Thomas Pogge. Its underlying idea is to compensate originator companies for their investments and development risk not through exclusive patents, but through a fund supported by governments and other donors. The size of the “reward” will depend on how much the developed product reduces the global burden of disease, based on a combination of the number of quality-adjusted life years (QALY)⁴² gained and the quantity of products dispensed. A pilot using Johnson & Johnson’s TMC-207 anti-tuberculosis compound is planned to launch by the end of 2011.⁴³

In addition, selected originator companies such as Sanofi,*** GlaxoSmithKline, Merck & Co Inc., and Novartis have established special R&D units focused on global health needs that are tasked with developing new pipeline compounds or adjusting existing ones to serve low-income market needs.

Products for which patents have expired are referred to as off-patent medicines. They can be produced and marketed as generic products by any company without a licence from the originator company, or as branded generics by the originator company.⁴⁴

Generics, branded and non-branded, have been the driving force behind improving access to and lowering the costs of medicines in the last decade. Many generic manufacturers originate from emerging markets such as India where these medicines are badly needed, generating not only access, but also employment and economic growth. Nowadays, most large originator companies have a generic product unit and/or have formed alliances with generic manufacturers to market branded generics.

Furthermore, some larger generic manufacturers have invested in R&D units enabling them to develop expertise in product adaptations such as paediatric or fixed-dose combinations.****

Patenting and licensing

In 1995, members of the World Trade Organisation (WTO) signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which has since that time formed the basis for international medicine patent regulations. It includes a provision allowing a country to issue compulsory licences for a medicine, which means a government has the authority to allow a non-patent holder to manufacture and market a medicine in its domestic market. However, the non-patent holder must first have tried to attain a voluntary licence from the patent owner, and the patent holder must receive adequate remuneration. Governments are allowed to waive the requirement to first seek a voluntary licence in cases of “national emergency”.

In November 2001, following the onset of the HIV/AIDS pandemic and the lack of access for patients to treatment, the WTO added two provisions to the agreement through the Doha Ministerial Declaration on TRIPS and Public Health, both related to LDCs and countries that lack their own manufacturing capacity. First, LDCs are not required to enforce patents until 2016, and second, countries that do not have local manufacturing capacities are now allowed to import generic products that are manufactured under a compulsory licence (WTO 2011).⁴⁵ The latter provision allowed many sub-Saharan countries to import HIV/AIDS medication from India or China.

In recent years, originator companies providing medication for HIV/AIDS and related diseases, including Novartis, Gilead, ViiV, Boehringer Ingelheim, Bristol Myers Squibb, Roche and others, have started to grant voluntary licences to generic manufacturers under specific conditions. These may include a requirement that producers meet good manufacturing practices (GMP) as defined by the U.S. Food and Drug Administration (FDA)⁴⁶ or the World Health Organization (WHO),⁴⁷ thus ensuring a high standard of quality, or that products be distributed only in LDCs. Most originator pharmaceutical companies engage in direct technology transfer to ensure that the licenced product meets the same standards as the original. The originator companies either provide these licences royalty free, or charge licencees a royalty fee, depending on the company, the product and the country. The licencee is then responsible for manufacturing, registering, marketing and distributing the product. This is especially interesting for smaller companies such as Gilead, which does not have the capacity for global operations. Licencees pay Gilead a 5% royalty fee on finished products, but are free to establish their own prices for these medications. Through Gilead’s licencees, HIV/AIDS drugs reach 95 developing countries.⁴⁸

Registration

Medicines are products that require special handling, and need to meet specific standards if they are both to protect the users from harm and reach the claimed efficacy level. There-

fore, manufacturers are required to submit a long dossier to the authorities to win approval to market and distribute their product. The registration process can turn into a lengthy and resource-intensive process for pharmaceutical manufacturers in low- and middle-income countries, due to insufficient institutional capacities, non-transparent or badly harmonised processes, poor documentation, and a lack of regulations or enforcement.

Manufacturing

Ensuring the production of efficacious, safe and high-quality medicines requires standardised and very well-documented processes. These are often grounded in the GMP described by the FDA or WHO, collectively the most influential set of standards. Aside from distribution costs, costs for manufacturing are the key variables in setting prices for generic medicines. Therefore, a main focus for manufacturers is to seek efficiencies in producing a drug. There are various ways to do this.

Pharmaceutical companies operate their own plants and/or work with contract manufacturers, especially for the production of active pharmaceutical ingredients (APIs) – the effective components of medicines, and typically the most expensive elements. Given the need for a well-established and functioning infrastructure and skilled personnel, the major producers of APIs are based in industrialised countries, China, India and South Africa.

To reduce costs, shorten delivery distances, and build local capacity and income, large originator and generic companies have established manufacturing plants, mostly for final drug products, in selected low- and middle-income countries. In these facilities, APIs are fashioned into their final dosage form and packaged. A local pharmaceutical industry has also been evolving in selected LDCs, especially in Bangladesh and some countries of the East African Community, but mostly without the capacity for API production. The biggest challenge for local manufacturers in developing countries has been to meet the GMP standards. If they do not comply with these standards, they cannot obtain a registration and marketing authorisation, and are excluded from large tenders by institutional buyers. Supporting the development of local manufacturing to meet GMP standards has been the focus of international aid efforts in selected countries, led by groups such as the United Nations Industrial Development Organisation (UNIDO) in collaboration with Germany’s BMZ and GIZ.⁴⁹ The Deutsche Investitions- und Entwicklungsgesellschaft GmbH (DEG)⁵⁰ has invested in several local manufacturers that have subsequently been able to meet GMP standards.

However, there has been an ongoing debate as to whether local manufacturing in each country is a desirable goal, or whether imports are for some countries a better alternative, so as to ensure economies of scale and lower prices within this highly specialised, resource-intensive industry.⁵¹

**SEE PAGE 48 ONWARDS,
“AFFORDABILITY”

***SEE PAGE 19, CASE STUDY “SANOFI AND DNDI”

****SEE PAGE 29, CASE STUDY “GILEAD, CIPLA”

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Acceptance



This woman is holding the medicine she needs to treat her disease. Selling medicines to low-income consumers means developing products they find acceptable.

Photo: Fotolia

Low-income patients' living conditions make taking or maintaining a course of medication difficult. Lack of clean water poses risks for those taking pills; lack of electricity prevents the correct storage of medicines that require cool and dry conditions; and complicated drug regimens may be challenging for those who are illiterate.

Companies aiming to design products that are acceptable to the target group need to achieve two things:

Understand the market context: Developing an understanding for this target market goes beyond gathering and analysing statistics. Companies need to learn about the living conditions and the constraints their target group faces on a daily basis. Local partners can help gain an understanding of local health systems and the infrastructure available, as well as their target group's beliefs, habits, social norms and cultural traditions.

Adapt products: With a deep command of their market's needs, companies are well positioned to adapt their products to low-income patients' requirements. For example, they can adapt formulations, size and packaging, and thus make their products more suitable to local tastes and conditions.

CASE STUDY 4

Gilead, multiple countries and Cipla, India

Improving lives by simplifying treatment

Non-adherence is a major issue for low-income consumers who need to take drugs regularly. One factor in this lack of compliance can be a complicated drug regimen: Patients who have never taken drugs before or are illiterate face difficulties in remembering when and how often to take their pills. Others might simply lack access to enough food or clean water allowing them to take the medicine multiple times a day without suffering adverse side effects from consuming it on an empty stomach. Companies who understand these hurdles have found ways to adapt their products to these consumers' unique needs, including one solution called fixed dose combinations (FDCs).

FDCs combine standardised doses of two or more drugs into a single tablet, injection, or suppository. The simplification of a regimen may result in better patient compliance and simpler titration for doctors. Both originator and generic manufacturers have had success in the development and sales of FDCs.

Gilead's most popular HIV combination medicines are Atripla and Truvada. Atripla is a once-a-day HIV regimen that combines three medicines in one pill and was developed in partnership with Bristol-Myers Squibb. Truvada is an anti-HIV drug that combines two medicines and is taken once a day with or without food.

Cipla, an Indian generic pharmaceutical company, has also pioneered FDCs for HIV/AIDS. Their FDC, Triomune, combines three anti-retroviral drugs (ARVs). They have additionally developed generic FDCs of medicines for HIV-infected children, called Pedimune Baby and Junior.

Sources:
Gilead: Truvada website. <http://www.truvada.com/>;
Atripla website. <http://www.atripla.com/>;
<http://jac.oxfordjournals.org/content/59/1/92.full>
Cipla: Access to Medicine Index 2010, p. 184

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Understanding the market context

What does the customer need and want?
What are the conditions in which my product will be placed?

CHALLENGES ...

Data availability

- When aiming to tackle the low-income market, companies often lack basic information, such as statistics on the prevalence and incidence of diseases. Low-income patients are often not covered by national statistics, meaning diseases go unreported; there is no reliable way to organise or aggregate patient data and drug purchases are not tracked.

Local insight

- Companies often also lack a proper understanding of how local health systems operate, including how many health care professionals work in a particular community.
- To develop appropriate products, a good understanding of local traditions and norms is vital. At times, they conflict with drug use (e.g., a belief that disease is punishment for bad deeds, that children cannot leave the house for the first year of life in case they catch the evil eye; or the existence of spending hierarchies within families where men have priority).

Invest in understanding the market context

- The development of products for low-income markets is not business as usual. Market research may need to be re-thought, as data collection is challenging in low-income countries. Companies may need to hire (local) specialists, such as former NGO workers or anthropologists familiar with a corporate environment and, of course, with conditions in low-income environments.
- Some companies establish special business units that focus on knowledge creation concerning low-income markets with the ultimate aim of creating more suitable products and business models. *SEE CASE STUDIES ON PAGES 11 "AROGYA PARIVAR", 19 "SANOFI/DNDI" AND 55 "GSK"*

Cooperate with local partners

- Cooperation with NGOs and other local partners who have a deep understanding of local consumers, their needs, cultural and social norms, infrastructure limitations, and the local health care system is an efficient way to gain an understanding of the market. Besides having a strong involvement in the target community, the local partner should ideally have experience working with corporate partners.
- Engaging people from local communities can provide important insights. NGOs can be a good entry point when they have the trust of local communities. Community heads, local peers, opinion leaders or other influential community members may offer a good understanding of local conditions and needs in the community.

Leverage technology

- Competent market-research partners that work with new technological solutions such as mobile applications, can be an invaluable resource for the collection of data.

SEE CASE STUDY ON DATADYNE

... AND PROMISING APPROACHES

ACTORS

Companies that aim to enhance their understanding of low-income markets can invest resources into conducting their own market research or cooperate with partners. Often, NGOs* and international organisations have a good understanding of local conditions, the real needs of the target group and the best way to adapt offerings to suit their living conditions. Also, they often benefit from having gained the trust of the community, which can facilitate research. Sometimes, people from communities – such as village heads or local opinion leaders – can provide valuable insights. Market research firms that specialise in low-income markets may be suitable partners. However, only a few** exist to date.

**SEE PAGE 62*

***SEE PAGE 61*

CASE STUDY 5

DataDyne, multiple countries

Reliable market data from a basic cell phone



A health official uses EpiSurveyor to collect data needed to monitor the progress of a polio campaign in Kenya. Photo: DataDyne

DataDyne is a social business based in Kenya, Chile, and the United States that creates web and mobile software aimed at increasing the quantity and quality of data available. It is applicable to many sectors, including health care. Customers include businesses, NGOs, governments and researchers.

EpiSurveyor, their main product, is a secure mobile data solution that allows users to rapidly design mobile forms for data collection, fill out forms on any cell phone (using either an application or standard SMS messages), and upload and analyse data in real time. No special expertise or knowledge of computer programming is needed.

Nearly 6,000 users in over 170 countries use EpiSurveyor today. The International Federation of the Red Cross uses EpiSurveyor to evaluate anti-malarial bed net distribution. John Snow, Inc. and USAID have used it to manage information on malaria treatment supply chains in Africa.

Sources:
DataDyne website. www.datadyne.org/episurveyor;
UN Foundation website. www.unfoundation.org/your-role/partners/organization/datadyne.html

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Adapting products and packaging

How should products be adapted to suit low-income patients' needs and living conditions?

CHALLENGES ...

Education and knowledge

- Patients are often illiterate. For example, nearly 60% of rural Indians cannot read or write. They can't read package leaflets and thus may find it difficult to understand and adhere to more complex treatment regimes.

Infrastructure

- People who live in poverty lack the basic infrastructure required for proper administration and storage of medicine – such as clean water and access to energy for refrigeration. For example, 465 million people in rural sub-Saharan Africa lack access to electricity.⁵² This applies not only to patients, but also to health care professionals and the pharmacies that store medicines. Transportation also becomes an issue as some medicines need a complete cold chain.

Tailor products

- Develop special formulations: fixed dose combinations^{*} and medicines that can be taken without food or water, have a pleasant flavour, are heat resistant or suitable for pregnant women and pediatric patients are all vital for compliance and proper treatment regimes in low-income settings.
- Taking local tastes into account may help patients to better accept products with a clear medical benefit. In areas where herbal and ayurvedic medicines are deeply entrenched in local culture, the synthesis of such products may be useful.

Deskill packaging

- Developing packaging and materials for the low-income market^{**} – for example, using pictograms and colour-coded blisters for illiterate patients – can reduce frustration and misuse brought about by a lack of understanding on the patient's part.

* SEE PAGE 29, CASE STUDY "GILEAD AND CIPLA"

** SEE CASE STUDY

ACTORS

The basis for adapting products is a solid understanding of the market context. Product and packaging adaptations are usually done by pharmaceutical companies. However, NGOs can facilitate this process, for example by outlining recommendations for developers. Some NGOs have created platforms with other actors for developing their own new products.

*SEE SPOTLIGHT "BEYOND OUR SCOPE" ON PAGE 26

... AND PROMISING APPROACHES

CASE STUDY 6

Optimize – a WHO/PATH collaboration, multiple countries

Filling essential knowledge gaps for manufacturers



The initial rotavirus vaccine with a full course of 330cm³ required not only more space but also extra time for staff to mix the active ingredient with the vaccine solution.

Photo: WHO

The Global Alliance for Vaccines and Immunisation Alliance (GAVI) established the Vaccine Presentation and Packaging Advisory Group (VPPAG) in 2007; a year later, the WHO took over responsibility. The VPPAG includes representatives from private industry and the public sector, including PATH, an international NP dedicated to creating culturally relevant solutions to health issues. Optimize, a WHO and PATH collaboration, is providing support to the VPPAG as part of its efforts to work with stakeholders and ensure that future vaccine products and delivery technologies are designed with characteristics consistent with developing country needs.

VPPAG has developed a generic preferred product profile (gPPP) as a reference document for vaccines in development for use in low- and middle-income markets. The document outlines various specifications and recommendations for developers, such as minimising

volume and weight of secondary and tertiary packaging, labelling vaccines to reflect their true heat stability, including preservatives, and/or limiting the number of steps needed to prepare and administer the medication to avoid error.

Sources:
Interviews Michel Zafran (WHO) and
Simona Zipursky (PATH)
WHO vaccine volume calculator, 2009

The latest rotavirus vaccine requires one-tenth of the space and can be "given directly".



Photo: GSK

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Awareness



Arogya Parivar's health educators play a crucial role in raising awareness in Indian villages about prevention and in the accurate diagnosis of diseases.

Photo: Arogya Parivar

In low-income markets, people often lack awareness on illnesses, their causes and options for treatment. They have limited means with which to inform themselves on topics such as disease prevention, or what to do if they find themselves sick. A low level of education means that basic medical concepts – What is a germ? What is an infection? – are often poorly understood. Also, traditional beliefs may hinder people from seeking treatment. Health care providers often lack proper training or are not up-to-date with medical knowledge

Ensuring awareness requires two kinds of tasks: information provision and education. For both tasks, it is important to work with neutral partners such as NGOs or governmental bodies to protect patients from biased information.

Information on health topics is usually provided via mass media, in particular newspapers and TV. In low-income markets, companies may use rather unconventional means to reach even those in remote areas – such as radio, street theatre, or health camps and word-of-mouth campaigns. However, they need to ensure that they remain compliant with local regulations concerning the type of medical information that can be shared with patients and the type of information that is strictly for health care providers (HCPs). Mobile phones also offer a direct communication channel with most low-income consumers.

Education on how to navigate the health system or how to prevent and identify illnesses is traditionally provided by the family and school system. In low-income markets, companies can invest in the education of patients, HCPs and pharmacists. Alternatively, they can partner with NGOs and community-based groups to enhance health education or raise awareness on certain diseases in cooperation with the government or NGOs.

CASE STUDY 7

Novo Nordisk, China

Changing diabetes using a local touch

Novo Nordisk found that in China the diagnosis rate for type 2 diabetes is between 10% and 15%, compared to about 50% in Europe. These low diagnosis rates are due in large part to a lack of information and education about diabetes. To address this gap, Novo Nordisk has introduced many programmes aimed at training medical professionals.

In one such programme, Novo Nordisk collaborated with the Chinese Ministry of Health in launching the National Diabetes Management Project (NDMP), which aims to provide education and training to health care providers. The project has to date provided continuous medical education for 35,000 doctors and established 70 patient education centres in hospitals in 47 cities. Each is staffed by nurses and doctors and serves about 50,000 patients each year. Novo has also worked with the media to spread the word about diabetes. In 2002, these partnerships resulted in 22 television programmes and 40 na-

tional radio programmes, and more than 150 mentions in print media. In order to reach all strata of the population, Novo Nordisk has sponsored over 100 free diagnosis clinics, often in heavily frequented parks, as well as 10 mobile clinics with the ability to reach communities that lack diabetes clinics.

Though not a business case per se, the project illustrates how to create awareness through education and information. The resulting higher diagnosis rates help create a stronger market presence for Novo Nordisk in future.

Sources: Novo Nordisk website. http://susrep2002.novonordisk.com/sustainability/sustainability_strategy/china_tbl.asp

Providing information

What are the best ways to inform low-income patients about health-related issues and keep HCPS up to date with new drug and treatment options?

CHALLENGES ...

Communication channels and infrastructure

- Many people who live in poverty may not have a postal address or a TV – both traditional ways of receiving information about over-the-counter products. They may not have regular access to other information sources, such as magazines or the Internet, and thus remain uninformed about diseases, their symptoms and their treatment. This does not apply to prescription medication, the promotion of which is forbidden in most countries.
- Pharmaceutical sales representatives traditionally target HCPs and pharmacists to inform them about new medicines. However, they may face difficulties in identifying the professionals who serve low-income populations and find reaching out to them cumbersome and costly without modern infrastructure like the Internet, especially when they are located in remote areas.

Regulatory environment

- Safe drug marketing and promotion requires appropriate legislation, as well as an adequate administrative structure to enforce regulations that protect the patient. In many developing countries, these capacities may be limited or entirely lacking.

Adapt communication means to local conditions

- Communication methods that meet local conditions and tastes, such as street theatre or radio dramas, capture the attention of the target group more easily and provide an interesting way for even illiterate consumers to gain knowledge. Placing ads or billboards at carefully selected, highly frequented places, such as railway stations, can be a good way to inform patients.
- Mobile health camps or health fairs can be organised to address an entire community at once, encouraging discussions and word-to-mouth communication.
- Printing communication material in the local language, or using visualisations or comic book-style pictures makes the information much easier to understand for patients.

Leverage technology

- SMS's promoting health messages – like mass texts including information on disease and treatment options – are a great way to take advantage of wide mobile-phone coverage, even in rural parts of developing markets. They also allow patients to ask questions in return. Companies can work with partners such as the government and/or a mobile phone operator, always ensuring, of course, that the mobile client has agreed to the service.

Engage in policy dialogue

- By engaging in a policy dialogue with governments to ensure safe drug marketing and promotion, companies ensure both that patients are properly informed and that fair competition is guaranteed for originator companies and generic manufacturers of quality products.

... AND PROMISING APPROACHES

ACTORS

To reach out to low-income patients, companies can rely on various neutral partners. They ensure that information on health topics is conveyed adequately, and in compliance with local standards and guidelines: for country-wide information campaigns, local authorities – such as the ministries of education or health – or development organisations may be suitable partners. Collaborating with social marketing organisations or NGOs, companies can leverage their local knowledge to inform both patients and HCPs. Additionally, other private enterprises that offer health-related products or run local media outlets, such as radio stations, may be interested in joining forces to create awareness.

CASE STUDY 8

Abbott, India

Health fairs connect consumers to knowledge



Abbott's Indian division, Piramal Healthcare, works to expand access to health care among India's rural villages and urban poor. To this end, Abbott makes use of unconventional communication means, sponsoring a wide range of educational events and health fairs. Allowing locals to learn first-hand about important health topics in their na-

Educational events and health fairs increase awareness of common diseases. Photo: Endeava

tive language has proven more effective than relying solely on advertisements or billboards that require literacy. These fairs also bundle services: Free diagnostics tests, screenings, and advice for both acute and chronic diseases are offered. They are often sponsored in conjunction with a local partner, such as the Indian Epilepsy Society, to raise awareness of specific diseases and provide solutions for pa-

tients. Aiming to provide education and information rather than market specific products, these fairs, funded by Abbott's Global Citizenship department, are not part of a business model. They do, however, lay the foundation for market creation.

Source: 2010 Abbott Global Access Report

Education

What's the best way to educate consumers about medical concepts and teach them how to navigate the health system?
How can firms ensure that health care professionals who dispense drugs have adequate qualifications?

CHALLENGES ...

Education and knowledge of patients

- Patients may not know that they are sick and may not seek help in a timely way. Non-communicable diseases such as diabetes or cancer are often not recognised.
- Patients may choose not to see an HCP or prefer traditional healers. This may be due to a lack of awareness about the effectiveness of medical treatment. Also, cultural beliefs and a lack of education on basic medical concepts are big hurdles. For example, many low-income patients prefer injections, as they believe medicine should be delivered directly to the blood.
- Illiteracy creates challenges to ensuring adequate consumer protection. For example, if patients cannot read package inserts they won't understand how to follow treatment regimens.
- Patients may lack awareness about the importance of adherence. Using only half the dosage to make expensive products last longer, patients may experience adverse or ineffective results and lose trust in all pharmaceutical products.

Skills and knowledge of HCP and pharmacists

- People who call themselves doctors, pharmacists or healers often do not have any formal medical degree since professional training is often conducted in far away locations and may be unaffordable.
- Professional HCPs and pharmacists may lack skills to provide diagnosis and treatment options that meet proper standards or seek more lucrative working conditions in urban areas or abroad.

Regulatory environment

- Counterfeit products are commonplace in low-income markets. Counterfeits can be sold to an unsuspecting consumer who has limited knowledge of how to identify and avoid them. After paying for a counterfeit product, taking it, and experiencing adverse or ineffective results, consumers may lose trust in all pharmaceutical products.

Partner to educate patients and develop a strong brand

- By cooperating with reliable and neutral partners,* companies may invest in enhancing health education for patients, for example, by establishing education centres or by launching mass media campaigns in association with government authorities. However, companies need to be sure that they consider national regulatory standards and guidelines. **SEE PAGE 25, CASE STUDY "BAYER / GIZ"*
- A company may cooperate with technology partners to provide innovative ways to enable patients to check if medicines are authentic or counterfeit, such as adding SMS-verifiable codes to packaging.
- Particularly in low-income markets, consumers are inclined to buy branded products, as the risk of wasting money on products that don't work is too high. Companies should work to develop a strong brand image that can be trusted.

Leverage partnerships and technology for HCP training

- To ensure that products are dispensed properly, companies may invest in training for HCPs, pharmacists** or even actors in the informal sector, such as local sellers of products. They can build on the strength of appropriate partners, such as NGOs.
- Although the technique is at a very early stage of development, teletraining conducted by specialists may be a viable option to make up the shortfall of qualified HCPs in rural areas. Alternatively, HCPs can use of mobile phones, which allow them to communicate and send pictures to specialists for remote diagnoses and decision making. ***SEE PAGE 35, CASE STUDY "NOVO NORDISK"*

Engage in policy dialogue

- Companies may raise awareness for certain diseases within the government or team up with authorities to launch education campaigns. This may be particularly relevant for non-communicable diseases like diabetes that are assumed to be diseases of affluence.
- Proper regulation and enforcement in favour of medicine quality helps ensure proper treatment for a patient, not further damage. Advocacy to influence legislation against counterfeit products may be a long-term solution.

CASE STUDY 9

Sproxil, multiple countries

One SMS, instant quality check

Counterfeit drugs are a widespread problem, particularly in low-income markets. These products either lack active ingredients or contain incorrect or inaccurately measured ingredients. Patients are often unaware of the existence of counterfeits or lack the means to distinguish them from quality products. They suffer from the consequences, in some cases fatally. Pharmaceutical manufacturers, in turn, lose market share since counterfeits are sold for less and contribute to a lack of trust in their products and services. Exacerbating the problem, proper drug legislation, regulation and enforcement are often lacking.

Sproxil is a social enterprise that supports pharmaceutical companies in addressing this challenge with an innovative service: an SMS verification system. To verify the authenticity of a drug, customers scratch off a silver panel to reveal 12-digit code on each blister, which is sent via text message using any cell phone. The customer gets an instant response confirming the brand's authenticity. The service is free for users.

In cooperation with Sproxil and Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), GlaxoSmithKline (GSK) has successfully applied this service for its antibiotic Ampiclox, which sells a couple of million units a year in Nigeria. Expansion into additional markets in Africa is being considered.

Source: Interview with Ashifi Gogo, Sproxil

ACTORS

Education is usually the sphere of the government. Companies may cooperate with the ministry for education, for example, to launch educational campaigns in local schools. NGOs may be suitable partners for organising educational events such as health camps in target communities. Free diagnoses and consultations offered by NGOs can contribute to raising awareness. Education of HCPs is a major issue. Governmental and non-governmental organisations may also be suitable partners in enhancing qualification and training.

... AND PROMISING APPROACHES

Availability



Basic health care infrastructure is often lacking in low-income areas. Initiatives such as the community health camps, conducted by Grameen Kalyan in Bangladesh, are one way of providing basic health care to harder-to-reach rural populations.

Photo: Solveig Haupt

Medicine and health services are not always available in close proximity. However, low-income patients cannot afford to spend a day traveling each time they are in need of medicine or medical attention. If a clinic, health services centre or pharmacy is reachable, low-income patients often face the frustrating situation of low or no stock, expired or badly kept drugs, and scarce, untrained or inattentive care providers.

Companies that aim to make their products available in low-income settings need to address two tasks:

Distribution: To ensure that patients can get the drugs they need, at the right place and time, they have to make medicine physically available close to where the patients are, and provide support for proper stocktaking and storage. Companies can work with local partners or take advantage of existing distribution channels of partners who understand the special handling that particular medicines require. This is particularly useful for overcoming the challenges along the “last mile” of distribution.

Dispensing: Besides the physical availability of drugs, companies need to make sure that patients get the right drugs, in combination with proper counselling. Investments in the training of locals and direct delivery to skilled HCPs, who also have appropriate diagnostic skills, may contribute to avoiding dangerous self-medication or misdiagnosis.

CASE STUDY 10

Square Pharmaceuticals, Bangladesh

Delivering drugs directly to dispensing outlet

Underdeveloped technology and infrastructures in low-income markets may make it more difficult to track products through middlemen, or the incorporation of a third party may simply add costs that make consumers less able to buy products. One possible approach to avoiding this problem is to cut out the middlemen and instead supply pharmacies and other dispersion points directly. This can also make sure that only trained professionals dispense medicine.

Square Pharmaceuticals' objective is to supply the right products at the right place at the right time. To fulfil this aim, Square set up a series of depots, including a central depot in Pabna, Bangladesh, that deliver products directly to pharmacies using a fleet of small trucks. This model works well due to the region's high population density and relatively well-established road system. By working in partnership with doctors, Square is able to provide products directly to the pharmacies associated with them and ensures the reliability and quality of its supply chain.

Square hires a number of distribution assistants (DA) and data entry operators (DEO) who take part in a training programme following recruitment and participate in a refresher course each month. Square has been building its distribution channel since 1995 and it is today well established.

Source: Square Pharmaceuticals website. <http://www.squarepharma.com.bd/DistributionChannel.html>

Ensuring proper distribution

How do companies ensure that patients get the drugs they need at the right place and time?
How do they overcome the challenges of “last mile” distribution?

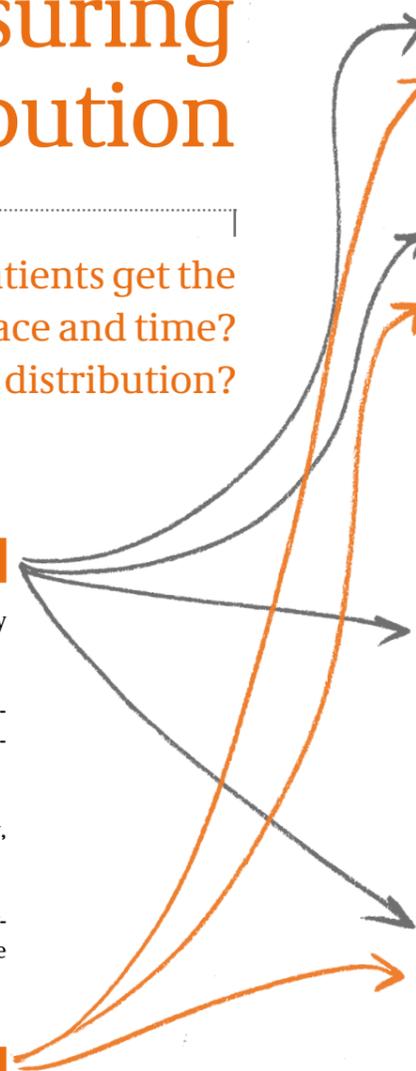
CHALLENGES ...

Efficient distribution channels

- Lack of infrastructure – such as roads and electricity – makes distribution, especially for the last mile and to rural areas, a challenge.
- Few wholesalers reach out to low-income communities; when wholesalers are present, they may apply unreasonable mark-ups when distributing to low-income communities.
- Counterfeit products can enter the distribution channels due to a lack of technology, expertise or incentives to validate the originator’s medicine.
- Skilled experts in the logistics and management of medicines are hard to find in low-income communities. This may not only lead to inefficiencies, but also to compliance issues such as inappropriate documentation and handling of medicines.

Inventory control and storage conditions

- Without appropriate technology and training, it is challenging to control inventory, forecast when stock will run out, and properly dispose of expired medicines. This is aggravated by the fact that information on disease prevalence or dispensing histories are either difficult to find or nonexistent in some communities, making it hard to decide which drugs to stock in what quantity.
- Storage conditions may vary from medicine to medicine but are essential to ensuring the efficacy of the product. Minimum conditions such as cool and dry storage can often not be guaranteed, especially in tropical areas. Some medicines require refrigeration, which is frequently not possible due to the lack of refrigerators or power outages.



Leverage internal, existing distribution channels

- Use synergies by leveraging existing internal distribution channels from the company’s core business, if available.

Cooperate with partners that have established distribution

- Granting licences to local manufacturers or local distributors who are well established in a country is an effective way of ensuring distribution of a company’s products.
- Institutional buyers have usually had a presence in a country or community for a long time and have knowledge of local distribution channels and demand. Selling to them may help get drugs to those who really need them.
- Selling to micro-franchise pharmacies, social marketing companies and other new businesses that directly target the poor puts a company’s products into the hands of professionals who understand low-income markets.

Use locally suitable means for last mile distribution

- By observing what is not available (e.g., proper roads), and what is available (e.g., motorcycles,* bicycles), companies can make use of the existing means to get their products to the consumer, or partner with others that do the same. However, these means are only suitable for medicines that don’t require prescriptions or storage conditions such as cooling. Obviously, prescription medication must be dispensed only by a qualified professional.

**SEE PAGE 97, CASE STUDY ‘RIDERS FOR HEALTH’*

Leverage technology

- A company can use simple but effective technology, such as SMS on basic cell phones, to control and forecast inventory or detect counterfeits.

... AND PROMISING APPROACHES

ACTORS

Companies without a local presence may rely on building partnerships with local manufacturers or explore possible relationships with institutional buyers who have functioning distribution chains. To distribute products properly, companies may also cooperate with a variety of unusual partners. When wholesalers do not reach out to low-income markets, suitable partners may include micro-franchise pharmacies, social marketing companies, hospitals or health care centres. NGOs with a focus on health-related issues may support last mile distribution.

CASE STUDY 11

Novartis, Tanzania

Novartis SMS for Life – taking stock with an SMS

Novartis’ SMS for Life pilot project is a PPP with the Roll Back Malaria Partnership, Vodafone, IBM, Google and the Ministry of Health in Tanzania. Its objective is to minimise stock-outs of life-saving malaria drugs, utilizing mobile phones, SMS, Google mapping, and easy-to-use websites to track and manage the supply of drugs. The project is not reliant on Internet access; it is 100% mobile-based, a crucial feature when Internet connections are unreliable. It enables stock tracking and reporting from the central medical store all the way to individual health facilities, ensuring that life-saving medicines are available as needed. A forecasting function uses malaria incidence projections to help determine when a medical store will run out of stock.

SMS for Life rewards health facilities for timely response to weekly stock requests with free airtime, and uses a simple code to relay information. To ensure sustainability, an annual subscription to the service has been developed with an affordable fixed \$100 price point for each health centre. This fee allows providers to cover their costs and helps

Novartis improve their manufacturing forecasts while reducing the frequency of expensive emergency airfreight deliveries to Tanzania.



Educational materials help pharmacists understand how SMS for Life works. Photo: Novartis

In pilot districts, stock-out rates have been reduced from 87%–93% to 0%–47% within 21 weeks. Supported by the Swiss Agency for Development and Cooperation, the Medicines for Malaria Venture (MMV) and Novartis, the system has been rolled out nationwide in Tanzania and is today used by over 4,600 health facilities on a weekly basis. Pilots supported by Swiss Tropical Health Institute and Novartis are ongoing in Ghana and Kenya.

Source: Interview with Jim Barrington, Novartis SMS for Life case study. <http://www.rbm.who.int/psm/smsWhatIsIt.html>

Ensuring proper dispensing

How do companies ensure patients receive proper counselling and that drugs are dispensed by qualified HCPs?

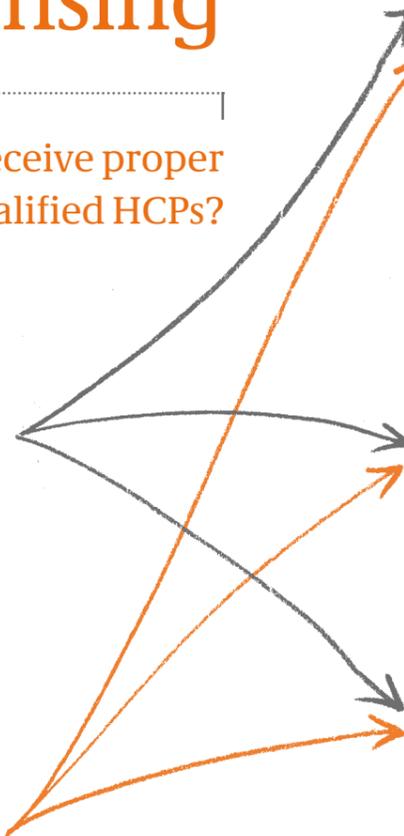
CHALLENGES ...

Dispensing points and personnel in proximity

- A low-income patient with no local clinics, diagnostics, or skilled HCPs will probably go without treatment or receive inappropriate treatment.
- Even when health care facilities exist in proximity, they often lack qualified staff.
- Self-diagnosis or misdiagnosis by unqualified persons, like shop owners, may lead to misuse of drugs, resulting in inefficient or dangerous results: for example, the condition of the patient may worsen or, in the case of infectious diseases, may build up drug-resistance.

Regulatory environment

- There is little or no enforcement of regulations surrounding dispensing of prescription medicine by professionals. Many dispensing points for medicines operate in the informal market.



Build upon existing health infrastructure

- Traditional health care providers – such as healers or midwives – usually enjoy the trust of the community. However, they are often poorly skilled when it comes to modern medicine. Providing training to traditional HCPs to incorporate modern diagnoses, products, and services into their work helps build on local knowledge and trust in an established provider. Similarly, locals – such as community health workers – can be trained to be HCPs with basic diagnostic capacity, with the ability of recognising when referral to a medical doctor or specialist is needed. Both approaches have the advantage that locals are more likely to stay in the community, while other trained professionals often relocate to urban areas (brain drain). Of course, companies can and should not do this on their own; they can build on a trusted and neutral partner, such as an NGO with a focus on capacity building for HCPs.

Collaborate directly with partners that offer dispensing points in proximity

- Micro-franchise pharmacies and health care centres have emerged in many countries that particularly target people living in poverty. They have formalised many of the informal actors. Some of them have scaled considerably. Manufacturers can deliver products directly to them, or establish small district warehouses. This approach not only cuts out middlemen, but also ensures that only qualified professionals dispense drugs.

Leverage technology

- Although still in its infancy, telemedicine could become a viable approach in overcoming a lack of specialists in rural areas. This may be particularly relevant for patients suffering from diseases that require a more advanced diagnosis by a specialist, who would otherwise be unreachable for low-income patients. Issues like working technology, electricity, broadcast quality and acceptance by patient or doctor have hindered the utilisation of its full potential up till now.
- Similar pilots exist for lab diagnostics via mobile phone where blood, stool, saliva, or sputum samples are collected, photographed under a microscope and sent to a specialist for diagnosis. This has the potential to improve diagnostic accuracy but is still in its infancy.

... AND PROMISING APPROACHES

ACTORS

Micro-franchise pharmacies and health care centres are often the front line of health care, especially in rural areas, where access to hospitals may be limited, and self-medication prevails. NGOs that specialise in last-mile distribution of drugs may be suitable partners when it comes to ensuring that patients receive counselling and that products are properly dispensed. Further, community health care workers may support proper counselling. Engaging in a policy dialogue with the government may ensure that product dispensing is regulated properly.

CASE STUDY 12

La Farmacita Nacional, Mexico

Bringing pharmaceutical products and services closer to urban dwellers

Mi Farmacita, a micro-franchise pharmacy, aims to bring high-quality, affordable medicines to low-income communities. Normally, these products are not readily available in Mexico due to the country's loose pharmaceutical regulations and poor distribution channels for generic medicines. The health system is heavily overtaxed, meaning that low-income patients may wait several weeks to

see a doctor. To address these issues, Mi Farmacita offers additional services, such as doctor's consultations costing about \$2, purified water, and Internet and phone services.

A classic franchise model has allowed Mi Farmacita to grow successfully throughout Mexican cities since its 2003 inception in Tijuana. By 2007, 57 franchises in over 15

states in cities both small and large had been established. At this time, at least 16 franchises were registering more than 90 sales transactions per day or 2,400 service transactions a month. The number of franchises doubled on a yearly basis from 2003 to 2007.

Mi Farmacita has a joint partnership with Grupo Farmacéutico and Laboratorios Colins, respectively a well-established distribution company and a generic medicine manu-

facturer. These partnerships have allowed Mi Farmacita to offer high-quality medicine and sell products at low cost by using wholesale pricing, thus scaling quickly. The network also uses an online digital inventory system, eMaksimus, allowing franchisees to communicate, track inventory and adjust prices.

Source: Next Billion blog. <http://www.nextbillion.net/research/mi-farmacita-nacional-enabling-good-health-among-mexicos-bop>



A Mi Farmacita franchise store offers not only access to drugs, but also health services, purified water and ICT. Photo: Lourdes Ferreira

Why Coca Cola is readily available and why essential medicines are not

An inhabitant from a rural, low-income village may not have sufficient access to his malaria medication, but he will be able to treat himself to a Coca-Cola after a long day's work. It may, at first glance, seem strange that sweet, fizzy drinks are able to reach even the most rural of places, while essential medicines are not.

The building and maintenance of secure distribution channels in any low-income market are critical concerns and great challenges to companies. Given the nature of pharmaceutical products, distribution channels must be cared for, regulated, and monitored by skilled persons from their point of origin till their dispensation to the patient by a trained pharmacist.

The differences are immediately obvious at nearly every stage. During transport, beverages do not require storage at a certain temperature, whereas pharmaceuticals require stable, sometimes refrigerated, temperatures for storage at every step. Beverages can be sold at a variety of places – restaurants, bars, supermarkets, and kiosks – while medicine needs to be dispensed by a professional, and often at one of few regulated locations. Distribution of pharmaceutical products is considerably more complicated, because companies are frequently limited to state-owned distribution channels, products must be traceable, and may require separate and specially constructed warehouses. Even the end-of-life stage is distinct: a leading soft drink brand doesn't have to worry much about their products being properly disposed of – glass bottles are easy to collect, and a person who drinks coke that has passed its expiry date is unlikely to become ill from it. On the contrary, pharmaceutical companies must put reverse logistics into play to dispose of drugs, as out-of-date medications can be deadly.

Despite these differences, pharmaceutical companies can still learn from cross-industry peers. For example, they can use a third party to gather reliable information about the market like Optimize, a project run by PATH and WHO, which has identified specifications for vaccines being sold to the low-income market. Emphasis on building sales volume, as seen in the incentive structure of GSK's Global Access Unit,* may eventually lead to economies of scale. Some pharma-related companies have managed to successfully and creatively tap into distribution solutions: VillageReach** established a gas company and bundled medical deliveries with essential energy. Bundling of services with other health-related products like water or bed-nets, as done by Arogya Parivar*** can bring benefits for the seller and the customers. Riders for Health worked with people with good local knowledge to assist their health care providers with last-mile distribution – in this case, on the back of motorcycles well suited to the harsh African landscape.

*SEE PAGE 55, CASE STUDY "GSK"

**SEE OPPOSITE PAGE, UPPER CASE STUDY

***SEE PAGE 11, CASE STUDY "AROGYA PARIVAR"

CASE STUDY 13

VillageReach & VidaGas, Mozambique

Overcoming the last mile using cross-sector partnerships

VillageReach applies a unique logistics model to the problem of "last mile" delivery and the tracking of vaccines in remote settings. The NGO has drawn on the UPS package delivery model to develop its own delivery logistics system. It has established fleets of trucks and field coordinators tasked with managing vaccines and other commodities, and produces reports detailing precisely what has been distributed and what inventory remains at rural health centres.

When it first developed this approach in Mozambique, VillageReach quickly realised that one of the most significant barriers to successful delivery was ensuring reliable fuel supply, which is necessary if vaccines are to be kept adequately refrigerated. Seeking to solve the problem in a sustainable way, the organisation partnered with the Mozambique Foundation for Community Development to establish VidaGas, which has grown to become the largest propane distributor in northern Mozambique. This model has proven successful, according to a recent independent project impact evaluation; the monthly incidence of stock-outs in rural health centres have decreased from 80% to 1%, and the average paediatric vaccine coverage rate has increased to 92.8%, among other findings.



When distributing vaccines that require refrigeration, a reliable gas supply is vital. Photo: VillageReach

Source: Interview with Leah Hasselback, Village Reach

CASE STUDY 14

Riders for Health, Africa

Delivering goods and services by motorcycle



Due to harsh African landscapes, motorcycles are often the best – or only – way to deliver life-saving drugs to remote areas. Riders for Health are welcome guests in rural communities. Photo: Riders for Health

The NGO Riders for Health supports the delivery of health care and other vital services to rural areas. The group manages fleets of motorcycles and four-wheeled vehicles across Africa. Motorcycles offer a cost-effective, reliable way of supporting health care interventions in even the most isolated villages. They are well suited to the harsh African landscape, where roads are often non-existent or in terrible condition.

Reliable transport increases health worker productivity and means more patients can be diagnosed and treated. Health workers can visit patients more regularly, providing crucial assistance with issues like HIV/AIDS. For example, after Riders began working in the Gambia in 2002, there was a 261% increase in diagnoses of diarrhoea, a 75% increase in diagnoses of acute respiratory infection, and a 55% increase in diagnoses of malaria compared to 2001.

Riders works with governments and local partners to ensure that both sectors' needs are met, and that programmes are sustainable. They may also prove a suitable partner for pharmaceutical companies, providing a last mile delivery solution able to reach even remote regions, combined with professional health care services.

Source: Riders for Health website. www.riders.org/us/map_list.aspx?country=kenya

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Affordability

Setting affordable prices is important not only for the individual consumer, but also for local pharmacies looking to keep medicines in stock. Here, a local pharmacist in a Bangladeshi village orders new stock.



Photo: Solveig Haupt

Low-income consumers have to make difficult decisions every day to prioritise their spending: buying food, clean water, paying for energy or sending their children to school. In fact, people living in poverty are active money managers who apply a variety of financial strategies to stretch their small and often irregular incomes.

Companies that venture into the low-income market have to consider two factors:

Pricing: They should adjust their pricing to make products affordable to low-income patients. An expensive drug regimen may mean that treatment is forgone in favour of other, seemingly more pressing needs. Pharmaceutical companies that aim to enter the low-income market need to think of creative and sustainable ways to help offer medicines at reduced prices. For example, they may apply differential pricing schemes or discount systems.

Financing mechanisms: They can also contribute to making adequate financing mechanisms available to their target group. These are badly needed when serious health events that require solutions far beyond basic medical treatment occur. In these cases, low-income patients may not be able to

cover a high lump sum out-of-pocket. These emergencies are often addressed by selling assets, drawing down savings and borrowing from friends or moneylenders.⁵³ This turns health problems into serious financial problems. Even if patients recover, they are faced with high debt, pushing them further into poverty. Adequate financing mechanisms, such as health insurance, would address their vulnerability but are rarely available.

Likewise, wholesalers, pharmacists, and health care providers need financial support to purchase and keep a diverse selection of drugs in stock, or run their facilities in a reliable, high-quality way.

CASE STUDY 15

Novartis, Philippines

Kaagapay – tapping into remittances

In 2010, overseas Filipino workers (OFW) sent home over \$18.5 billion in remittances⁵⁴. Novartis took notice of this strong remittance culture in the Philippines, tapping into it to allow for better flexibility and ease of payment for patients.

Novartis' Kaagapay Health Connect remittance programme allows OFW relatives to provide direct support to family members, enabling them to afford medication. Doctors in the Philippines inform patients about the programme at the same time as prescribing a Novartis medicine. Patients receive a card, allowing them to register with a network via a hotline. OFWs then remit a minimum of PHP 2,500 (\$59) through an authorised remittance centre. This balance can be consumed as needed by the relatives to purchase their medication.

Kaagapay offers additional benefits, such as a 20%–35% discount on participating Novartis products, free health education materials and SMS alerts, free delivery of medicines nationwide, and 24-hour access to the Kaagapay hotline.

Source: Novartis website. http://reactrials.com/KHC/avail/avail_content.shtml

How can companies adjust prices to low-income patients' budgets or leverage other financing sources, such as remittances?

CHALLENGES ...

Cash availability and adherence

- By definition, low-income consumers earn very little and often on an irregular basis.
- They don't have insurance mechanisms to share risks and spread high treatment costs.
- High out-of-pocket payments for health generate greater volatility in a consumer's spending habits, and they will often forego drugs in order to buy food or pay for energy when times get tough, thus interrupting and rendering useless their long-term therapy.
- When costs for treatment exceed the cash that is available at a particular moment, low-income patients often have to spend their savings or sell their assets to ensure adherence, pushing them even further into poverty.

Regulatory environment

- Lack of transparency, the high prevalence of intermediaries in low-income markets, or unregulated mark-ups can increase the price of medicines significantly.
- Pharmaceutical companies are reluctant to provide differential pricing schemes or discounted systems which could better meet the needs of low-income consumers, due to the high risk of product diversion, in which discounted products intended for low-income people spill over into regular markets, jeopardising the overall price structure.



Adjust prices

- The creation of a differential pricing system ("tiered pricing") for key drugs can help manufacturers maintain a profit margin by offering products at levels that each country can afford.
- Pricing can be differentiated between high-, middle- and low-income countries, and within countries for different customer segments. Tiered pricing allows the company to profit from consumers with more purchasing power, who often live in urban areas, while still offering more affordable prices to those with less income. Companies must consider measures to prevent spillover from one market into another, such as different pill size or colour, special packaging or different branding.
- A company may offer coupons, vouchers, or loyalty programmes – where authorised – that offer discounts to consumers while educating them about their ailment and helping to ensure long-term adherence to treatment.

Tap into remittances

- In some countries, overseas workers send home a considerable income in remittances. Specific schemes can help migrants support their families' health care and treatment regimens.

Engage in policy dialogue

- With government help, companies can increase transparency in the supply chain and prevent high mark-ups through intermediaries.

... AND PROMISING APPROACHES

ACTORS

Most drugs that are sold in low-income markets are paid for out-of-pocket. To make their products affordable for low-income patients, companies can draw on their innovative capacities to find new pricing models. However, drug prices are often a systemic problem, due to high mark-ups by middlemen, for example. Companies can engage in a policy dialogue with the government to increase transparency in the supply chain. They can also partner with institutions that enable payment – such as remittance centres.

CASE STUDY 16

Pfizer, multiple countries

Loyalty cards enhance patient adherence



An important element of sales volume gains in emerging and developing markets is drug adherence – an issue that must be addressed in countries where large numbers of patients pay for drugs out of pocket. To deal with this issue, Pfizer launched the eCard. This functions similarly to a retail loyalty card. In this case, the customer receives discounts as rewards for adherence to Pfizer's medicines. The level of discounts is determined by how well the patient adheres to the drug regimen, as tracked by the supplying pharmacist.

Loyalty cards help patients reduce their out-of-pocket expenses and can facilitate better adherence. Photo: Smangostock, Fotolia

The eCard is free to patients, but can be given only at the discretion of a prescribing doctor and is available at participating pharmacies. The eCard programme affords customers a 30% – 60% discount on prescription medicine, and also includes educational materials aimed at helping a patient understand and manage their conditions, as well as to understand the importance of adherence.

Designed as a programme for emerging markets, the eCard was launched six years ago in the Philippines, where 2.2 million patients are now in the system. It was subsequently replicated in Indonesia and Malaysia, where it respectively reaches 110,000 and 18,000 customers today. Future areas of planned expansion include Russia, Mexico, Brazil, Venezuela and Ukraine.

Source: Financial Times, February 8, 2010. www.ft.com/intl/cms/s/0/503e764c-1414-11d1-8847-00144feab49a,s01=1.html#axzzIZiPUvbTw

Financing mechanisms

How can companies provide financial support to pharmacists or health care providers to keep medicine in stock?
How can they connect patients to micro-insurance?

CHALLENGES ...

High costs, weak or absent safety nets

- The poor not only face the cost of treatment, but also a series of incidental costs. These include transport to and from treatment centres or hospitals, accommodation for family members accompanying them, costs for diagnostic tests and doctors' fees.
- Governments and institutional payers in low-income countries often lack the financial resources needed to provide public insurance schemes or to finance a functioning health system.
- Publicly funded, "free" systems are especially vulnerable to corruption. Due to a lack of regulation, bribes to health service providers are common practice, making services and treatment unaffordable for the poor.

Adequate loans

- To pay for serious health events, patients may take out a loan from relatives or money-lenders. The latter often charge high interest rates, increasing the borrower's vulnerability even further, as a health emergency simultaneously diminishes the ability to repay loans.
- Wholesalers and pharmacists cannot afford to keep medicine in stock. HCPs and clinics cannot perform at full quality standards and may have equipment that is very out of date.

Health insurance

- Instead of paying high sums out-of-pocket, insurance arrangements could permit low-income patients to pay smaller amounts, on average. While insurance could be a solution, it is rarely available, as providers often find it difficult to provide health insurance for the poor. It requires high quality actuarial analysis and careful pricing policies. Further challenges lie in the high transaction costs and problems such as adverse selection and fraud committed both by providers and clients who tap unwarranted benefits from the system.

Connect patients to micro-insurance

- Viable health insurance schemes still remain at the pilot stage and require further exploration. Besides insurance companies, established and mature Micro-finance Institutions (MFIs) providing savings and micro-credit services are well positioned to engage in health micro-insurance. They have large distribution networks and understand their clients' needs and payment capacities. Pharmaceutical companies aiming to make their products more affordable to a large, untapped client base could explore partnership opportunities with health micro-insurance providers.
- Sometimes, communities establish their own insurance scheme, paying for health expenses from a common fund. This community-based health financing approach has only one downside: large claims easily exceed a fund's resources. But in some cases these larger claims are re-insured by a bigger insurance provider. The health mutual offers several advantages. For example, the community collects premiums. Also, the risk of moral hazard and fraud are mitigated by social control.
- Governments can work with partners to come up with innovative health insurance schemes to target people living in poverty. For example, the Indian government launched a national health insurance scheme designed to meet the special requirements of families working in the informal sector and living in poverty. It explicitly encourages private partners to participate in its implementation.⁵⁵

Connect patients to micro-finance

- Where private insurance is unavailable, and organisations lack the required skills to set up functioning finance schemes, loans may be the only option for low-income patients. They can be adapted to serve people affected by serious health problems – for example, in the form of an emergency loan. If provided at more favourable conditions than those of the informal market – above all regarding interest rates – loans can be a short-term alternative for patients.

Connect HCPs to micro-finance

- Larger MFIs and other financial service providers may explore pharmacists and doctors as their target group. Loans suited to their needs can ensure that drugs remain in stock where they are most needed. In this scenario, pharmaceutical companies could explore partnerships with MFIs to ensure product availability in low-income environments.

CASE STUDY 17

UpLift, India

Micro-insurance in the community's hands

Uplift India Association, an association of NGOs established in 2004, implemented the Uplift Health Mutual Fund (HMF), which has successfully tackled some of these challenges. The fund decreases the financial shock of an unexpected health emergency for community members through community risk-pooling. The scheme allows people to share risk by contributing a small amount (\$2 per person per year). When an emergency occurs, a lump sum amount (max. \$334) can be made available to meet the hospitalisation expenditure and to

smooth the financial shock. The success of the system relies strongly on the community, which is responsible for setting up the fund. Communities also handle claim management, a model that has been shown to lower transaction costs and reduce the risks of adverse selection, moral hazard and fraud. Uplift's model relies on being healthy and taking preventive care so that the health risks are minimised. This includes a 24x7 helpline and preventive talks. The programme works with over 300 health care providers including public and private hospitals and has an ongoing membership of more than 120,000 people. Partnerships with NGOs, a Mutual Insurance Company and an IT company have helped the programme's evolution.

Source: Uplift website. <http://www.upliftmutuals.org>

ACTORS

The adjustment of prices alone cannot ensure the affordability of medicines. Drugs have to be dispensed by professionals, whose services need to be paid for. These doctors or pharmacists, in turn, need to have the financial resources to keep the drugs in stock. Further, expensive treatment cannot be covered out-of-pocket over a longer period of time. Like the other "As", affordability is a systemic problem that needs to be addressed by various actors. The government plays a key role when it comes to creating a safety net for its citizens. When no public insurance scheme is in place, private insurers may address low-income markets. However, they often face difficulties in assessing risk in low-income situations. Larger, established micro-finance institutions and NGOs may be in a good position to bridge this gap by serving the poor with new business models.

... AND PROMISING APPROACHES

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Getting set up



Getting your business off the ground requires the right vision, strategy and leadership. However, the hands-on collaboration of multiple stakeholders is also vital. Here, Village Reach employees in Mozambique unload needed medicines.

Photo: VillageReach

Venturing into low-income markets: Using the 4As+1 tool, pharmaceutical companies can develop and deliver an attractive value proposition for low-income patients while making a profit. However, inclusive business is far from business as usual. All marketing processes need to be significantly rethought, products adjusted and new partners identified and integrated. In fact, the business is embedded in an ecosystem that is very different from those in established markets.

It is therefore not surprising that companies cannot simply work with established internal structures and processes to get inclusive business models off the ground. Given the discipline required for a product as sensitive as medicine, pharmaceutical companies are typically quite rigorous in their internal processes. This rigour and established routine often runs counter to the requirements for developing inclusive business models, which need experimentation and flexibility, different viewpoints and wholly new approaches.

This final chapter provides some ideas as to how to get started internally. It looks at:

- Creating a vision
- Making a plan
- Securing financial resources
- Creating an organisational structure
- Building teams
- Setting up partnerships

With these in place, the company is ready to venture into the low-income market.

CASE STUDY 18

GSK, global

New strategic priorities and organisational structures: diversifying GSK's global business

When Andrew Witty became CEO at GSK in 2008, he defined three strategic priorities for the company, translating its vision into tangible goals. One was to “grow a diversified global business”, thus highlighting the companies’ intention to move away from reliance on Western markets by making more substantial investments in developing and emerging markets. However, the company acknowledges that a longer time frame will be needed to tap the potential of new markets. Market share needs to be created through new business models so that volume, sales and profit can follow. One result of this approach was the creation of a new Developing Countries and Market Access unit. Its objective is to increase access to medicines and vaccines in the world’s 48 least developed nations, as defined by the United Nations.⁵⁶ The business model is high-volume and low-margin.

The creation of the business unit was triggered by the company’s valuable experience in the vaccine business. In building this business model, GSK experimented with innovative approaches: To help drive access, GSK replaced revenue incentives with volume incentives and capped prices at no more than 25% of the prices in developed countries. In addition, the unit has a relatively long-term investment horizon, so that instead of seeking a return on investments in just one- to two-years, it is planning for three- to four-year time horizons, and perhaps even longer for large programmes. Recognizing that a weak health care infrastructure is a significant barrier to access, the business unit reinvests 20% of its profit into host countries’ health care infrastructure, through partner NGOs such as Save The Children, the African Medical and Research Foundation (AMREF), and CARE.

Source: Interview Jon Pender, GSK

Creating a vision

Inclusive business is new to many pharmaceutical companies – especially those from industrialised countries. How can pharmaceutical companies deal with a new market that differs from their traditional, familiar markets?

Creating a vision is about understanding the role of this new market for the future of the company. It is also about developing a clear picture of the services the company can provide for low-income people. The vision needs to build on strengths the company can leverage to create value for this new target group, be it products, networks, or capabilities. Long-time business, political and cultural ties to low-income markets can be key drivers for pharmaceutical companies, as can a product portfolio that addresses the needs of low-income consumers, such as malaria and HIV/AIDS.

Ideas for concrete projects can come both from within and outside the company:

Scientists, CSR managers, marketing specialists, sales representatives or any other employee can be an innovator when it comes to new business models. Some companies provide programmes that enable their employees to explore low-income settings. Volunteer schemes such as Pfizer's Global Health Fellow Program and GSK's Pulse Program send employees to work for an NGO in a low-income market. In summary, employees need access to supporters and promoters within the organisation so that they can develop and implement their ideas.

By taking inspiration from customers and partners, such as health care providers, international health organisations or NGOs, companies can find ideas for inclusive business models. Systematic engagement with these partners can speed up and improve the innovation process.

Senior leadership support is crucial for inclusive business model development, as profit margins are lower than in high-income markets and a long-term commitment is required to succeed. For example, Novartis established a leadership development programme that strengthens the abilities of executives to design and implement inclusive business models. Understanding the challenges and opportunities of tackling lower-income markets helps future leaders to identify unmet social needs and use their analytical skills and business acumen to recognise future opportunities.

Making a plan

With a clear vision in mind, a project can be created. In order to plan a new business development in the context of the low-income market, it is critical to maintain a high degree of flexibility. Projects may take longer than expected, change course in the process and require more or different resources.

Clear goals need to be set that take into account the commercial and social value that the project aims to provide. Social results measurement is not only crucial for a dialogue with governments and other partners, such as NGOs, but also for the credibility of the project and the company. Specific key performance indicators, such as products dispensed, market share, or how many people are reached, need to be put in place from the beginning to assess progress towards goals.

Planning will probably involve less available data than in traditional business planning – for example, unclear numbers of prescriptions written by health care providers. Teams will need to work with rough business model sketches rather than with fixed projections. Top-level management needs to understand and accept the greater uncertainty. To set up the project, a head count, goods and funding need to be laid out. Contingency plans should specify what happens when the project direction changes or when more resources are required. The time frames should be realistic. New business model development for low-income populations is experimental. Experts in the field suggest a minimum of two to four years to show measurable results and to become sustainable.

Securing financial resources

Inclusive business development cannot typically compete with other projects in terms of return rates and timelines or risk. It is important to specify the total added value for the company, such as positive impact on the company's image and, more importantly, the development of new markets. Internal resources can come from the business unit, but also from the CSR department or the foundation, if they exist. These funds may allow for more experimentation and greater uncertainty.

The mobilisation of resources can also be done externally. They can either come from other private partners, as in the case of SMS for Life^{*} in Tanzania or from private foundations like the Bill and Melinda Gates Foundation, or via public funds. Public funds can come from bilateral donors such as BMZ,^{**} USAID or DFID,^{***} amongst many others. Further public funding is available through the International Finance Corporation (IFC) and their regional institutions, and national development banks. Lastly, the government in the target country may provide funding if the project contributes to the overall societal development such as health infrastructure or education.

^{*}SEE PAGE 48, CASE STUDY "NOVARTIS"

^{**}SEE PAGES 24/25, SPOTLIGHT "DEVELOPP.P.DE"

^{***}SEE PAGE 62, "FINDING SUPPORT"

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Creating an organisational structure

Corporate projects that tackle low-income markets need a supportive organisational setting. Internal processes and regulations often do not allow for new business model development. Externally, non-harmonised legal and regulatory standards across different countries make it challenging for global actors to manoeuvre in this complex sector. It takes a careful balance to give the pilot team some flexibility to experiment with new business models, while being compliant with external regulations.

Some potential solutions include forming a separate legal entity (“spin off”) or a new business unit, embedding the project into an existing business unit like “Established Products” or “Emerging Markets”, or working through external partners like NGOs. While a separate legal entity offers the greatest flexibility of all these solutions, it also requires the biggest resource commitment. Working through an existing business unit gives the project team access to readymade resources and a knowledge pool, but means competing with other teams for resources and results in less flexibility. The last option, of working through external partners, is only recommended for project-based work in an early, exploratory phase. It enables companies to tap into the expertise and network of an external partner to explore specific issues.

Building teams

Given the complexity of expertise needed, the project development team should bring together a diverse set of knowledge and skills. Key functions to consider are commercial, scientific and medical skills, market research, knowledge of developing and emerging markets, regulatory environments, legal experience, CSR and IT. More unusual skills, like knowledge of anthropology, can be a great addition to market insights. Employees and experts from NGOs or related industries, such as consumer goods, with experience in low-income markets, can be real assets to your team. A good mix of internal and external (hired or consulting) members is recommended. At the same time, a manageable team size, especially in the early stages, should be assured.

Every implementation project in the low-income market also requires local staff. Word-of-mouth has been shown to be an effective method of identifying talent in rural or slum areas. Recommended competencies are trustworthiness, human capital in form of connections, literacy, and a minimum level of business savviness.

During the early stage, the intrinsic motivation of a few selected employees is often the driver. In the long run, a proper incentive structure needs to be in place to ensure commitment along all levels of operations. For inclusive business models to thrive, they need to become a priority of inline management and be attractive enough to engage the firm’s best talents. Employees of GSK, for example, are rewarded for increased volume share instead of profit. The Novartis leadership programme recognises low-income market experience as an asset for an employee’s career development.

Setting up partnerships

Partners are often critical to the success of inclusive businesses, as this study has shown, but every new partner also increases the complexity of the project. Therefore, it is important to select the right partners and partnership structure.*

- **Commonalities:** Both partners need to share a fundamental vision and a common objective. Tensions may arise when both partners do not pursue goals with the same urgency. Depending on the scope of the collaboration, aligning objectives should be done in the short-, mid-, and long-term.
- **Complementarity:** Partnerships should be formed to supplement or add to each other’s skills and assets. Collaboration can easily fail – especially between private and public partners – if the partners are not explicit about what skill or asset they expect from the other side. The collaboration has to be mutually beneficial to succeed, and the incentives for each partner should be attractive.
- **Compatibility:** Partners should be confident from the start that they really fit together. Is the partner’s culture compatible with yours? Are management structures, decision-making, operational practices and record-keeping transparent and compatible? Does your partner enjoy acceptance and credibility within your stakeholder group? Openly asking and answering these questions can contribute considerably to a partnership’s success.
- **Capacity:** Specific goals, project timelines, assets, deliverables and governance structures have to be set, clearly communicated, accepted and tracked by the partners. Mutually binding agreements about the ownership of the project, the outcomes and losses, if applicable, need to be put in place. However, contracts do not always send the right signal in a low-income setting – one’s word, trust, or simple agreements may do. Legal guidance from local experts is needed here.

Needless to say, not all partnerships will work out. Therefore, an exit strategy should always be in place.

With these steps taken ...

... the project is ready to get underway. The creation of inclusive business models for pharmaceutical companies is a complex and challenging process.

We are, however, now better equipped to deal with these dilemmas and bring medicines to low-income patients in a way that is truly acceptable, available and affordable. Companies need determined and experienced leadership to succeed, but over time, as more and more models are tried and trusted, best practices will be established, and companies will be able to draw a better map of inclusive business models.

For now, we hope that this study helps companies navigate the challenges more effectively as they tap into the growth potential of low-income markets by bringing quality health care solutions to an entirely new market of patients.

*SEE PAGE 19, CASE STUDY “SANOPI / DNDi”

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Finding support

Health staff at a Grameen Kalyan health centre in Bangladesh draw a map of the community, seeking insight from their team. Cooperating with local partners is a good means of accessing the local resources and knowledge crucial to inclusive business models.



Photo: Solveig Haupt

Working with partners is crucial to building a sustainable, profitable business model in a low-income setting. Potential partners in the private and public sectors can help companies gain a deeper understanding of the market, facilitate operations by providing the appropriate technology for low-income markets, and provide companies up-to-date access to trends in medicines.

The following list is intended as a springboard for companies seeking to locate potential partners for current and future endeavours. Of course, the list names only a selected number of actors and is not exhaustive. In addition, a list of suggested further reading provides links to useful documents and websites.

Understanding the market context

Both public and private institutions can help companies better understand the targeted market by providing useful data or assistance in designing and executing market research.

PRIMARY DATA PROVIDERS

DataDyne

Social business whose mobile data collectors improve data quality, allow for information aggregation and analysis, and decreased costs
www.datadyne.org

Mobile Metrix

Market research in low-income markets
www.mobilemetrix.org

IDEO

Award winning design firm that developed a tool kit to capture market insights in the field and develop human-centred design
www.ideo.com/work/human-centered-design-toolkit

SECONDARY DATA PROVIDERS

Business Monitor International

Independent provider of proprietary data, ratings, and forecasts for 175 countries and 22 industry sectors, integrating analysis with industry research to facilitate decision-making
www.businessmonitor.com

Gapminder

Comprehensive data base fed by WHO, World Bank, World Resource Institute displaying impactful graphics
www.gapminder.org

IMS Health

Leading market research and consulting company for pharmaceutical sector specialising in secondary data collection
www.imshealth.com

Kaiser Family Foundation Global Health

Comprehensive resource on global health data inclusive health systems and structures
www.globalhealthfacts.org

World Health Organization (WHO)

The leading and coordinating authority for health within UN system; responsible for leadership on global health matter, setting norms, articulating evidence-based policy options, and monitoring and assessing health trends
www.who.int

Implementation support

Partners with a local presence have deep knowledge of the target group and can prove invaluable in several ways. This includes awareness-building and health education, enabling availability by setting up distribution channels, and ensuring affordability by providing micro-insurance and -financing options to the consumer.

African Medical and Research Foundation (AMREF)

AMREF's mission is to ensure that every African can enjoy the right to good health by helping to create vibrant networks of informed communities that work with empowered health care providers in strong health systems www.amref.org

CARE

A humanitarian organisation fighting global poverty with a special focus on women; other foci include the expansion of economic opportunity, preventing the spread of disease and private sector development www.care.org

Jon Snow International (JSI)

An international non-for-profit organisation dedicated to improving the health of individuals and communities throughout the world through innovative solutions in management, research, education, information and training www.jsi.com

Mary Stopes International (MSI)

Leading NGO in family planning and sexual health with operational services around the globe www.maristopes.org

Medecins Sans Frontieres (MSF)

An international and independent medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, health care exclusion and natural or man-made disasters www.msf.org

PATH

An international non-for-profit organisation that creates sustainable solutions for global health problems www.path.org

PlanNet Finance

Non-profit organisation dedicated to alleviating poverty through the development of micro-finance www.planetfinancegroup.org/EN

PSI

International non-for-profit global health organisation with programmes targeting malaria, child survival, HIV and reproductive health www.psi.org

TransAid

Non-for profit organisation that aims to reduce poverty and improve livelihoods across Africa and the developing world by creating better transport for essential items such as medicine www.transaid.org

Village Reach

A non-for-profit where social enterprise, technology and logistics meet global health and development. Offers expertise in last-mile distribution www.villagereach.org

Financing and technical assistance

This section provides an overview of several financing options available to companies working in developing countries' health sectors.

PUBLIC DONORS

BMZ

The German Federal Ministry for Economic Cooperation and Development (BMZ) is responsible for formulating the principles and strategies of German development policy. These then form the basis of the cooperation projects and programmes developed together with its partner countries and with international organisations. www.bmz.de/en

DANIDA

Danish International Development Agency for coordinating humanitarian and assistance in developing countries. www.um.dk/en/danida-en

DFID

UK Development agency for promoting development and reducing poverty www.dfid.gov.uk

USAID

Government agency providing U.S. economic and humanitarian assistance worldwide www.usaid.gov

SDC

The Swiss Agency for Development and Cooperation, responsible for the overall coordination of development activities and humanitarian aid delivered by the Swiss Confederation www.sdc.admin.ch/en/Home

SIDA

The Swedish International Development Cooperation Agency, responsible for the bulk of Swedish development assistance to developing countries www.sida.se/English

PRIVATE FOUNDATIONS/FUNDS

Acumen Fund

A non-profit global venture fund that uses entrepreneurial approaches to solve the problems of global poverty www.acumenfund.org

Bill & Melinda Gates Foundation

This foundation is the biggest funder in global health and works to help all people lead healthy, productive lives while focusing on health in developing countries www.gatesfoundation.org

Health Impact Fund

An initiative encouraging firms to register new medicines with the HIF. By registering, companies agree to provide drugs at cost wherever needed and are rewarded by receiving HIF's assessment of a drug's global health www.yale.edu/macmillan/igh

Rockefeller Foundation

The Foundation works to promote growth with equity by granting the poor greater access to life-improving opportunities and by enhancing community and institutional sustainability in the face of crises and chronic stress www.rockefellerfoundation.org

Wellcome Trust

Provides support in conducting research, accelerating its application and exploring biomedical science in historical and cultural contexts www.wellcome.ac.uk

Product development, advocacy and networking platforms

Acting as platforms, some organisations conduct advocacy and facilitate networking or leverage the potential of a platform to develop products.

PRODUCT DEVELOPMENT, ADAPTATIONS AND ADVOCACY

Drugs for Neglected Diseases Initiative (DNDi)

A collaborative non-profit drug R&D organisation that is developing new treatments for neglected diseases www.dndi.org

Global Alliance for TB Drug Development (TBA)

Not-for-profit organisation dedicated to addressing gaps in drug development for TB by bringing together scholars, government actors and private sector players www.tballiance.org

Innovations in International Health (IIH)

Aims to accelerate the development of global health technologies in a multi-disciplinary research environment, and works to enhance the sustainability of technologies by bridging the gap between invention, funding and clinical trials iih.mit.edu

OneWorld Health

Develops new treatments and interventions appropriate for people with infectious disease in the developing world, works with regulatory agencies to test drugs and work with governments, and trains local HCWs and doctors www.oneworldhealth.org

Medicines Transparency Alliance (MeTA)

Pilot multi-stakeholder alliance working to improve access and affordability of medicines for the poor by compiling information about medicine supply chains and fostering discussions of the issue with major stakeholders in government, private industry and civil society www.medicinestransparency.org

Medicines for Malaria Venture (MMV)

A private-public partnership dedicated to discovering, developing and delivering new and affordable anti-malarial drugs through effective partnerships www.mmv.org

TB Alliance

Seeks to develop and ensure equitable access to new tuberculosis drugs. Amongst its features are organisation information, disease information, and new drug development. www.tballiance.org

ADVOCACY AND NETWORKING

Business Fights Poverty

Business Fights Poverty is an open, positive and informal platform for practitioners and experts around the world to actively share ideas and interact with their peers www.businessfightspoverty.org

Global Business Coalition on Health (GBC Health)

GBCHealth serves as a hub for private sector engagement on the world's most pressing global health issues www.gbchealth.org

Pharma Futures

A multi-year, investor-led dialogue between the pharmaceutical industry and its investors about how to manage a rapidly changing operating environment to deliver long-term value both to society and to shareholders www.pharmafutures.org

Leveraging technology

Technology, in particular information and communication technology (ICT) can help health service providers succeed in low-income markets by aggregating patient data, tracking the prevalence of disease, ensuring reliable stock-taking, and providing direct care via telemedicine.

EMIT

Cloud-based service allowing text data to be gathered via Java-based handsets www.emitmobile.co.za

Global Pharma Health Fund

Developed a MiniLab for rapid drug quality verification and counterfeit detection www.gphf.org

Massachusetts Institute of Technology D-Lab

Fosters technologies and sustainable solutions for international development. <http://d-lab.mit.edu>

Medic Mobile

Makes use of open source software to support health services worldwide. Software available as an online download <http://medic.frontlinesms.com>

Mobenzi Researcher

Cloud-based service that enables data collection via SMS, wireless application protocol, and/or HTML www.mobenzi.com/researcher

Mobile Active

A non-for-profit that is a leading network and resource on the use of mobile technology for social impact www.mobileactive.org

Mobile Diagnosis

Non-for-profit organisation that developed technology to diagnose a list of infectious diseases with basic cell phone technology and trains www.mobilediagnosis.net

Nokia Data Gathering Toolkit

Allows for text and GPS data collection via handsets; also incorporates tools to create “virtual” quarantine zones and monitor the spread or contraction of disease
projects.developer.nokia.com/ndg

Sproxil

Company providing anti-counterfeit solutions.
www.sproxil.com

RapidsMS

The underlying open-source and customisable framework used to build enterprise-level, SMS-based applications for data collection, logistics and communication
www.rapidsms.org

Voxiva

Leverages cell phone technology to enable access to an online database of symptoms and communication with specialists about outbreaks
www.voxiva.com

Further reading

This section lists a selection of publications that help to understand the broader context of this report, such as how people in poverty live their lives. Some also focus on specific issues related to pharmaceutical business in low income settings, such as pharmaceutical manufacturing.

REPORTS

Access to Medicine Foundation (2010)
Access to Medicine Index 2010
Ranking of the world’s largest pharmaceutical companies on their efforts to increase access to medicine
www.accesstomedicineindex.org/content/index-2010-0

African Union, COHRED, NEPAD (2009)
Strengthening Pharmaceutical Innovation in Africa
International discussion on what is needed to provide better access and local production of medicines in Africa
www.nepad.org/system/files/str.pdf

Banerjee, Abhijit and Duflo, Esther (2011)
Poor Economics: A Radical Rethinking of the Way to Fight Global Poverty
Suggestions on new ways of fighting global poverty; includes case studies and statistical data
Focus: Chapter 3 – Low-Hanging Fruit for Better (Global) Health?
www.pooreconomics.com

BMZ (2009)
Sector Strategy “German Development Policy in the Health Sector”
Gives an overview of the Health Sector in the context of human development and efforts against poverty – and the sector strategy of the German Federal Ministry for Economic Cooperation and Development
www.bmz.de/en/publications/type_of_publication/strategies/konzept187.pdf

DNDi/Health Policy Division The George Institute for International Health (2010)
Registering New Drugs: The African Context
The report discusses current gaps and possible alternatives to register medicines for neglected diseases on the African continent.
www.policycures.org/downloads/DNDi_Registering_New_Drugs-The_African_Context_20100108.pdf

DFID, Human Development Resource Centre (2010)
Product Development Partnerships (PDPs): Lessons From PDPs Established to Develop New Health Technologies for Neglected Diseases
Grace, Cheri. Discusses the nature of investment barriers in the neglected diseases field and how the PDP model overcomes them
www.dfid.gov.uk/Documents/publications/hdrc/Issns-pdps-estb-dev-new-hlth-tech-negl-diseases.pdf

Endeva (2010)
Inclusive Business Guide
A workbook-style report for private firms on accessing low-income markets.
www.endeva.org/fileadmin/user_upload/publications/IBG_final.pdf

Economist Intelligence Unit (2011)
Health Care in Asia: The Innovation Imperative
Provides a status update and outlook on one of the most dynamic health care markets
www.businessresearch.eiu.com/healthcare-asia-innovation-imperative.html

FSG (forthcoming in early 2012)
Competing by Saving Lives: How Pharmaceutical and Medical Device Companies Create Shared Value in Global Health
The report provides an overview of the shared value concept, outlines opportunities of how to apply it in the health sector and gives guidance on how to implement it in an organisation. It includes current health-specific case studies to illustrate the ideas.
www.fsg.org

Harvard University (2007)
The Role of the Health Care Sector in Expanding Economic Opportunity
Discusses the role of multi-national health care companies in improving access to medicines, quality care and economic opportunities for developing countries
www.hks.harvard.edu/m-rcbg/CSRI/publications/report_21_EO%20Health%20Care%20Final.pdf

Oxfam (2010)
International Stop Stock-out Campaign
Oxfam teamed up with Health Action International to run the Stop Stock-outs campaign in order to ensure every hospital and clinic in Africa has the medicines people need to stay healthy.
www.oxfam.org/campaigns/health-education/stop-stock-outs

IFC (2007)
The Business of Health in Africa
Using research and analysis from McKinsey, this report presents the role of the private sector in fulfilling demand for health products in Africa in the next decade.
www.ifc.org/ifcext/healthinfrica.nsf/Content/FullReport

IFC and WRI (2007)
The Next 4 Billion: Market Size and Business Strategy at the Base of the Pyramid
Measures the size of markets at the base of the economic pyramid and provides an overview of successful business strategies in these markets; includes section on health
www.wri.org/publication/the-next-4-billion

ILO (2011)
Sharing Innovative Experiences: Successful Social Protection Floor Experiences
Discusses Social Protection Floors (SPF), tools in reducing social vulnerabilities and making progress toward achieving the Millennium Development Goals
www.ilo.org/gimi/gess/RessShowRessource.do?ressourceId=20840

Monitor Group (2011)
Promise and Progress
Reviews market-based solutions to poverty in sub-Saharan Africa across different sectors
www.monitor.com/Expertise/Geographies/Africa/tabid/87/ctl/ArticleDetail/mid/675/CID/2011230515191415/CTID/1/L/en-US/Default.aspx

United Nations Conference on Trade and Development (2011)
Investment in Pharmaceutical Production in Least Developed Countries
A guide for policy makers and investment promotion agencies
www.unctad.org/en/docs/diaepcb2011d5_en.pdf

WHO (2006)
Public Health and Intellectual Property Rights
This report by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) documents the long road from product discovery to getting a product to the patients and how to ensure innovation and access in a sustainable way
www.who.int/intellectualproperty/documents/thereport/en/index.html

WHO (2005)
Local Production of Pharmaceuticals – Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Further Research.
Summarises issues surrounding local production in developing countries from a policy and public health viewpoint, includes four country-level case studies
www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf

WHO (2011)
The World Medicines Situation Report 2011
Brings together information on 24 key topics related to pharmaceutical production and consumption, innovation, regulation and safety
www.who.int/medicines/areas/policy/world_medicines_situation/en/index.html

WHO (2004)
A Needs-based Pharmaceutical R&D Agenda for Neglected Diseases
Torreele, E et al discuss the burden of neglected disease and provide suggestions on how to improve R&D efforts
www.who.int/intellectualproperty/topics/research/Needs%20based%20R&D%20for%20neglected%20diseases%20EIs%20Pierre%20Martine.pdf

WEBSITES

Action for Global Health
A broad European network of NGOs advocating for Europe to play a more proactive role in enabling developing countries to meet the Health Millennium Development Goals by 2015. This website informs about the way that Europe should be supporting developing countries to enable them to achieve the targets to reduce deaths of infants and children, deaths of mothers during childbirth and pregnancy and deaths from preventable infectious diseases.
www.actionforglobalhealth.eu

Canada’s Access to Medicines Regime
Compiles information that developing countries, NGOs and pharmaceutical companies need in order to take advantage of the programme aiming to provide access to medicines for low-income populations
www.camr-rcam.gc.ca

Center for Health Market Innovations
Identifies, analyzes and connects programmes working to improve health and financial protection for the poor.
www.healthmarketinnovations.org

Making More Health Competition
Seeks to recognise innovative efforts transforming the field of health; sponsored by Ashoka’s Changemakers in partnership with Boehringer Ingelheim
www.changemakers.com/morehealth

Project Optimize
Provides various resources and stipulations surrounding the development of packaging and vaccinations for low-income environments
www.path.org/projects/project-optimize.php

WHO. Global Burden of Disease Project
Information for funders and policy makers on the burden of individual diseases
www.globalburden.org

Goals & methods

The aim of this study is to help companies create successful business models in bringing medicines to low-income markets by providing examples of companies that already operate in these markets. Our examples range from companies with complete business models to those that have just begun their venture into the low-income market or are experimenting with business model components. We have also included the business-oriented approaches of other public and private organisations, such as NGOs or MFIs. The findings derived here can help companies avoid common pitfalls and identify issues to consider from the start.

Our analysis draws on a dataset comprised of more than 100 case studies. Each case study began with a broad document analysis that dived into reports, online documents (e.g., company websites), newspaper as well as academic articles. We then conducted 32 interviews with experts from the private and public sectors using a standardised questionnaire with open-ended questions. In selecting our interviewees, we aimed to speak with those responsible either for low-and middle-income markets or access to medicine. We made concerted efforts to speak with companies that produce generic medicines, but with limited success. Other organisations exploring this topic, such as the Access to Medicines Index,⁵⁷ report a similar lack of responsiveness, which may be due to a lack of resources among generic manufacturers to handle such requests.

The analysis of the cases we identified, as well as the interview results, were guided by a shared research protocol centred around three main topics:

Challenges: What are the main challenges facing pharmaceutical companies in bringing medicines to low-income markets?

Solutions: How do existing business models cope with or overcome these challenges?

Partners: Which role do partners play when aiming to bring medicines to low-income markets? Which partners are out there to support companies in this endeavour?

Our findings to these questions were clustered. The structure of this report follows the clusters.

Case studies

In total, we identified 112 case studies of business models targeting low-income markets to serve as the empirical basis for this report.⁵⁷ The following figures illustrate the diversity of our empirical basis in terms of the regions of implementation and diseases addressed. We sought to include cases addressing both communicable and non-communicable diseases, and we also tried to strike a balance between regions. Some case studies were implemented in multiple regions. The category “other” (Figure 10) is used for cases that do not directly address a specific disease, but provide instead supporting services (e.g., financial or transport solutions).

FIGURE 9
Overview of case studies by region⁵⁸

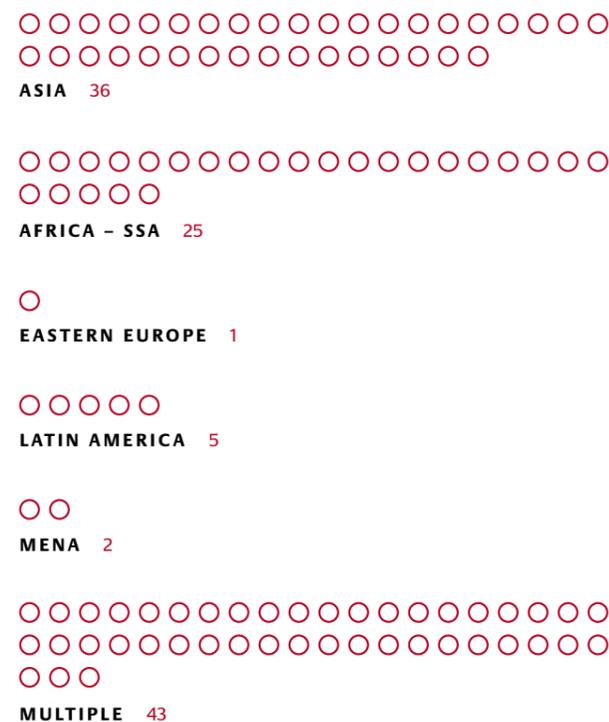
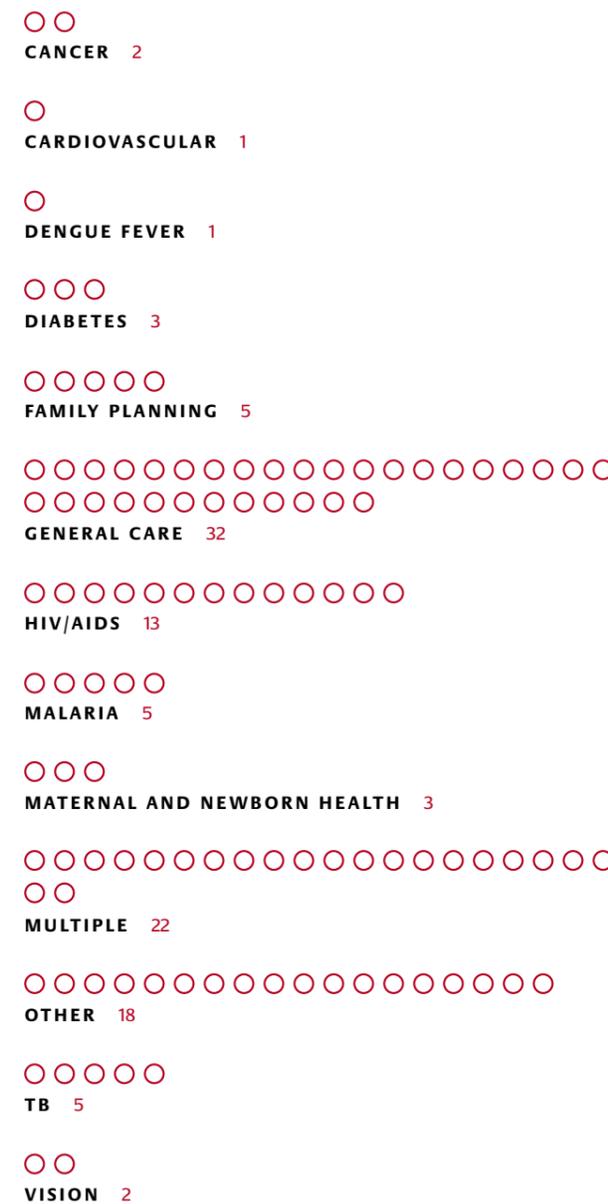


FIGURE 10
Overview of case studies by disease



List of interviews

Organisation	Name
3xBL Consulting	Olivier Jarry
Bayer HealthCare	Klaus Brill; Annette Wiedenbach
Boehringer Ingelheim	Dr. Michael Rabbow
Cinpharm	Salihou Boubakary
Ferring	Silke Humberg
Gilead	Graeme Robertson
GIZ	Representatives of the GIZ's health division
GIZ	Dr. Thomas Walter
GIZ	Rubeena Esmail-Arndt
Grameen Kalyan	Md. Imamus Sultan
GSK	Jon Pender
Kisumu Medical and Education Trust	Sam Owoko
Merck AG	Frank Gotthardt
Novartis	Dorje Mundle
Novartis	Jim Barrington
Novartis	Anuj Pasrija
Optimize (WHO, PATH)	Michele Zaffran; Simona Ziparsky
Pfizer	Dr. Sebastian Fries
PlaNNet Finance	Didier Krumm
PlaNNet Guarantee	Vance Kouassi Abissa
PlaNNet Guarantee	Mathieu Dubreuil
Proyecto Aldea Global	Chester Thomas
Sanofi	Dr. Robert Sebbag
Sproxil	Ashifi Gogo
UpLift India Association	Kumar Shailabh
ViiV	Manuel Goncalves
Village Reach	Leah Hasselback
WHO	Lisa Hedman
World Bank	Dr. Andreas Seiter
World Health Partner	Gopi Gopalakrishnan

Endnotes

- 1 WRI, IFC (2007): The Next 4 Billion, p. 26. Purchasing power parities are a form of exchange rate that takes into account the cost and affordability of common items in different countries. These “international dollars” reflect the purchasing power of local currencies.
- 2 Ibid., p. 35. This number is an estimation calculated by the WRI and IFC. It accounts for the spending of 3.96 billion people in Africa, Asia, Eastern Europe and Latin America and the Caribbean. The number is based on the measured annual household spending on health in the 35 countries for which standardised data exist, which encompasses 2.1 billion of the world’s BoP population.
- 3 Ibid., p. 41.
- 4 Inclusive business models were defined by the UNDP in their 2008 report “Creating Value for All: Strategies for Doing Business With the Poor” as business models “that include the poor on the demand side as clients and customers, and on the supply side as employees, producers and business owners at various points in the value chain”.
- 5 Prahalad, C.K. (2004): The Fortune at the Bottom of the Pyramid; Anderson, J.; Billou, N. (2007): Serving the World’s Poor: Innovation at the Base of Economic Pyramid. Journal of Business Strategy, Vol 28, No.2, pp.14-21. See also the sector strategy on “German Development Policy in the Health Sector” published by the German Foreign Ministry for Economic Cooperation and Development, which mentions three of the 4As (acceptance, availability and availability). http://www.bmz.de/en/publications/type_of_publication/strategies/konzept187.pdf
- 6 Government of India (2011). <http://censusindia.gov.in/>
- 7 Oxfam India website. <http://www.oxfamindia.org/files/resource/factsheet-universal-access-medicine>
- 8 UN (2008): MDG Gap Task Force Report 2008, Delivering on the Partnership for Achieving the Millennium Development Goals. Access is defined by the UN here as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population”, p. 35. <http://www.who.int/medicines/mdg/MD-G8EnglishWeb.pdf>
- 9 See also: WHO (2004): The World Medicines Situation; United Nations (2010): MDG Gap Task Force Report 2010, The Global Partnership for Development at a Critical Juncture.
- 10 WHO (2011): The World Medicines Situation Report.
- 11 WHO (2010): 10 Facts on Essential Medicine.
- 12 WHO (2011): The World Medicines Situation Report.
- 13 United Nations (2010): MDG Gap Task Force Report 2010, The Global Partnership for Development at a Critical Juncture.
- 14 Rajasekhar D. (2007): Assessing Risks and Demand for Micro-Insurance Products in Tamil Nadu. CARE India.
- 15 Planning Commission (2009): Out-of-Pocket Expenditures and Poverty: Estimates from NSS 61st Round. planningcommission.nic.in/reports/genrep/indrani.pdf
- 16 Individual country data on the availability of physicians, nurses and hospital beds can be retrieved at: WHO (2011): World Health Statistics. See “Health Workforce, Infrastructure and Essential Medicines” table on WHO website. <http://www.who.int/whosis/who-stat/2011/en/index.html>
- 17 Economies are divided according to World Bank income groups using 2009 gross national income per capita, which is calculated using the World Bank Atlas method. The groups are: low income, \$995 or less; lower middle income, \$996 – \$3,945; upper middle income, \$3,946 – \$12,195; and high income, \$12,196 or more. See World Bank website. <http://data.worldbank.org/about/country-classifications>
- 18 WHO (2010): Factsheet No. 331 on Pneumonia. <http://www.who.int/mediacentre/factsheets/fs331/en/index.html>
- 19 WHO (2011): The Top 10 Causes of Death.
- 20 WHO (2010): Prevention and Control of Non-communicable Diseases. WHO Information Note, Issue 1. http://www.who.int/nmh/events/2011/information_note_20100723.pdf
- 21 WHO (2008): Global Burden of Disease: 2004 Update.
- 22 WHO (2006): Non-communicable Diseases and Poverty. The Need for Pro-Poor Strategies in the Western Pacific Region: a Review. http://www.wpro.who.int/NR/rdonlyres/1FC8050D-36F2-40D4-88A4-45E819EEF0FB/0/poverty_ncd.pdf
- 23 United Nations (2010): MDG Gap Task Force Report 2010. The Global Partnership for Development at a Critical Juncture.
- 24 See WHO website. <http://www.who.int/mediacentre/factsheets/fs310/en/index.html>
- 25 WRI, IFC (2007): The Next 4 Billion.
- 26 While statistics on access to essential medicines and health services or disease prevalence provide a national perspective (i.e., low-, middle- and high-income countries), income statistics instead focus on the individual or household level.
- 27 The World Bank (2007): Understanding Poverty.
- 28 Cf. footnote 2.
- 29 WRI, IFC (2007): The Next 4 Billion, pp. 35-41.
- 30 Ibid., p. 39.
- 31 Ibid., p. 116, 128, 142. Banerjee, A. and Duflo, E. report a monthly expenditure on health of 5% in rural India (Poor Economics (2011), p. 50).
- 32 WRI, IFC (2007): The Next 4 Billion, p. 39.
- 33 World Bank (2011): Global Economic Prospects 2011.
- 34 UN Population Division (2009): World Population Prospects: The 2008 Revision.
- 35 UNDP (2008): Creating Value for All – Strategies for Doing Business with the Poor.
- 36 Plosmedicine website. <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0020100>
- 37 Banerjee, A. and Duflo, E. (2011): Poor Economics, p. 52; Das, J.; Hammer, J. (2007): The Dire Straits of Medical Practice in Delhi, India. Journal of Development Economics 83 (1).
- 38 WHO (2011): World Health Statistics.

- 38 Given the illegal nature of counterfeit products, including pharmaceuticals, many cases go unreported. Most common sources for counterfeit medicine reporting include the WHO, IMPACT, and UNODC. The statistics contained in this report are based on estimates and are often presented as ranges. In reality, the instances of spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines are likely higher than the figures reported here.
- 39 Prahalad, C.K. (2004); Anderson, J.; Billou, N. (2007).
- 40 CGAP website. <http://www.cgap.org/p/site/c/template.rc/1.26.11415/>
- 41 Jack, A. (2011): Remedies for Drug Development. Financial Times, July 20, 2011.
- 42 Measure of disease burden, including both the quality and the quantity of life lived according to National Institute for Health and Clinical Excellence (NICE) www.nice.org.uk/
- 43 Schneider, E. (2011): Medizin auch für die Ärmsten. TAZ February 25, 2011.
- 44 WHO website. <http://www.who.int/trade/glossary/story034/en/index.html>
- 45 WTO website. http://www.wto.org/english/tratop_e/trips_e/public_health_fa_q_e.htm
- 46 FDA website. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/default.htm>
- 47 WHO website. http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/
- 48 Gilead website. www.gilead.org
- 49 UNIDO (2009): Presentation of the Inter-agency Pharmaceutical Coordination Group (IPC) on Informal Sub-Group Meeting on Local Pharmaceutical Production. http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/1_Reinhardt_UNIDO_IPC%20subcom%20Gen%20300909-UNIDO-V3.pdf
- 50 DEG (2011): Presentation of DEG at International Conference on Local Pharmaceutical Production in Africa, April 4-6, 2011, Cape Town. <http://www.gc21.de/ibt/site/local-pharma/ibt/sulimann.pdf>

- 51 Kaplan, W.; Laing, R. (2005): Local Production of Pharmaceuticals – Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Further Research. http://www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf
- 52 IEA/OECD (2010): Energy Poverty – How to Make Modern Energy Access Universal.
- 53 Banerjee, A.; Duflo, E. (2011): Poor Economics, p. 59.
- 54 Ibid., p. 67.
- 55 GIZ (2010): 56 Million Steps Towards Universal Coverage: RSBY Health Insurance for the Poor in India.
- 56 <http://www.un.org/special-rep/ohrls/ldc/list.htm>
- 57 The Access to Medicine Foundation (2010), Access to Medicine Index 2010, p. 38.
- 58 A complete list of these case studies is available upon request. Please contact the authors of this publication.

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ASAQ	Adapted, Simple, Accessible, Quality
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung – German Federal Ministry for Economic Cooperation and Development
CSR	Corporate Social Responsibility
DNDi	Drugs for Neglected Diseases Initiative
FDC	Fixed-Dose Combination
GAVI	Global Vaccines and Immunisation Alliance
GMP	Good Manufacturing Practices
GSK	GlaxoSmithKline
GIZ	Deutsche Gesellschaft für internationale Zusammenarbeit
HCP	Health Care Provider
HIV	Human Immunodeficiency Virus
IFC	International Finance Cooperation
KMET	Kisumu Medical and Education Trust
LDC	Least Developed Country
MFI	Micro-finance Institution
MMV	Medicines for Malaria Venture
NCD	Non-Communicable Diseases
NGO	Non-Governmental Organisation
PDP	Product Development Platforms
PPP	Purchasing Power Parity
R&D	Research and Development
SMS	Short Message Service
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNICEF	United Nations Children’s Fund
VPPAG	Vaccine Presentation and Packing Advisory Group
WHO	World Health Organisation
WRI	World Resources Institute
WTO	World Trade Organisation

The lead authors

Solveig Haupt has 15 years of experience in the pharmaceutical and health sectors. As Director Global Access for Pfizer Inc., she developed a pilot for maternal health in partnership with Professor Yunus' Grameen's Kalyan organisation in Bangladesh. As a Pfizer Global Health Fellow, she advised the hospital management at Christian Medical College, Tamil Nadu, India, on PR and fundraising activities. As part of her graduate studies in global public health at New York University, she conducted research on bed-net replacement strategies in Uganda in collaboration with the Global Alliance Against HIV/AIDS, Malaria and Tuberculosis and LaFarge. Solveig has been leading the launch of various new medicines globally and locally and has substantial experience in strategic business development in the pharma sector. As a Fulbright Scholar she earned her MBA at Ball State University, Indiana.

Aline Krämer is a founder and director of Endevo and an expert in the field of inclusive business. She has co-authored several reports, including "Fast Growth and Big Impacts: How Emerging Market Multinationals are Advancing Sustainable Development", a study conducted for the BMZ and GIZ, "Towards Triple Impact", a report for the United Nations Environment Programme, and "Corporate Social Responsibility of German Companies Doing Business Abroad", a survey report for the Bertelsmann Foundation. Aline has worked as a consultant for the UNDP Growing Inclusive Markets Initiative, coordinating and reviewing case studies authored by experts and practitioners from Africa, Eastern Europe and the CIS. Aline is currently completing her doctoral dissertation on low-income consumers as a source of innovation at the TUM School of Management in Munich, Germany.



Title Picture

A woman helps prepare syringes with a meningitis vaccine for nurses to administer. Following a 2009 outbreak, hundreds of people in the Gaya region of Niger showed up to receive the vaccine during this campaign.

Photo: Guillaume Ratel

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