ISSUES FOR RESPONSIBLE INVESTORS

PHARMA AND HEALTHCARE IN ASIA

MAY 2010

Kamal Parida  Author
Lucy Carmody  Editor
Responsible Research is the exclusive partner in Asia for RepRisk, a web-based tool which provides insights on environmental and social issues that present financial and reputational risks to companies and investment portfolios. The tool enables commercial and investment bankers, asset managers, and supply chain managers to manage the corresponding risks and to implement effective screening procedures.

About the RepRisk® tool

RepRisk® is a web-based tool that allows you to identify and assess the environmental and social issues which may present financial, reputational and ethical risks. It is used by investment professionals, financial institutions, supply chain managers, multinational corporations and compliance managers, and includes a variety of features enabling clients to monitor risk trends over time, create customized watch lists, tailor alert services and more. The tool plays an integral role in increasing transparency and ensuring compliance with internal and international standards, thereby helping reduce risk exposure.

RepRisk’s comprehensive and relevant database enables you to meet the risk management and compliance challenges in an increasingly complex world. On a daily basis, RepRisk tracks a company’s or project’s environmental and social risk exposure by monitoring independent third-party sources such as all major print media, over 700 NGOs, newsletters, news sites, governmental agencies and blogs. Controversial issues covered include environmental, community relations, labour conditions and employee relations as well as corruption and money-laundering. In particular, all principles of the UN Global Compact are addressed. RepRisk covers all major business languages (Chinese, English, French, German, Japanese, Korean, Portuguese, Russian, and Spanish) and its database currently includes over 13,800 companies and 2,900 projects, and is updated and growing daily.

Please contact info@responsibleresearch.com for more information.
The healthcare industry in Asia is characterized by stark contrasts between developed countries like Singapore and Hong Kong and the emerging economies of India, China and Indonesia. There are glaring differences even within countries that make regional generalisations challenging.

The industry in Asia is growing much faster than that in the west and promises handsome returns. National insurance coverage is expanding very fast in most of the countries, improving affordability, and governments are spending massively to overhaul their healthcare delivery infrastructure. All this potential, however, comes laden with significant, environmental, social and governance (ESG) issues, giving responsible investors a number of additional factors to consider in their investment decision-making process.

This report covers the potential risks to earnings in both the pharma and healthcare industries due to non-financial ESG issues. It covers the ten countries featured in the MSCI All country (AC) Asia ex Japan Index, namely China, India, Indonesia, Philippines, Thailand, Malaysia, South Korea, Hong Kong, Taiwan and Singapore. We also provide a summary of the frontier markets of Pakistan, Vietnam and Cambodia. Several of these countries are also covered in detail in other sections in the report where we highlight ESG risks by using case studies from the region and offer global best practice examples. During our research, we interviewed several key individuals driving the Access to Medicines and Healthcare debate, from organisations such as Oxfam’s Pharma Futures. These interviews provide additional insights for responsible investors in the region.

In order to confirm regional best practices, we ranked 37 of the largest listed companies in the Pharma and Healthcare sector based on their performance according to a comprehensive set of 23 environmental, social and governance criteria. These criteria can also serve as a basis for engagement with companies for investors looking to practice more active ownership in this sector.

The results show that Dr. Reddy’s leads the field in the pharma sector and Fortis is well ahead in the healthcare rankings. These two well-managed companies stand in stark contrast to poor performers such as TTY Biopharma and Shanghai Pharma.

Access to Medicines and Access to Healthcare are the biggest social issues faced by the sector. Unlike Europe and the United States, healthcare financing in Asia is mostly out-of-pocket and, given the significant proportion of the population living below the poverty line, companies are under huge pressure to significantly modify pricing, intellectual property and research and development strategies until government structures are in place to support the ‘bottom of the triangle’. Surprisingly, this holds true for generic drugs manufacturers as well as the MNCs, given that they have slowly but steadily increased their prices dramatically over the last decade. Similarly, given the grossly inadequate healthcare infrastructure (using measurements such as number of hospital beds and medical personnel per person) in countries like India, private sector healthcare providers are encouraged to accept certain responsibilities and expand beyond their traditional profit centres in the Asian mega-cities.

The gravest potential risks to earnings from the ‘Access to Medicines and Healthcare’ issues arises from governments deciding to impose compulsory licensing and pricing caps on drugs. This has happened already in the Philippines and Thailand. Additionally, issues such as product safety, ethical clinical trials and non-discrimination are often not taken seriously by the industry, despite several cases where there have been substantial financial implications for violations. We believe that, as a result of the ASEAN harmonization process, Good Manufacturing Practices (GMP) will begin to be implemented and product quality will improve. Companies that have not put into place policies and guidelines to comply with these practices will face heightened threats of closure actions by regulatory bodies.

Environmental issues such as climate change, energy efficiency, water usage and waste management could pose serious risks to company earnings in the future due to trends such as carbon taxes, emissions trading and increased water pricing. We highlight these risks through the use of case studies illustrating companies like Zhejiang Pharma, which received hefty fines due to water pollution in China. Governance issues continue to affect the Pharma industry, in particular due to conflicting interests from many different stakeholders. The issue of unethical marketing practices is covered and we also focus on the poor standards of corporate governance and the complexity of government relations in the Chinese pharma industry.

Asia is fast emerging as a hub for innovations such as stem cell research and biogenetic manufacturing. Singapore has already established itself as a centre for high-end biotechnological research. There are, however, several ethical and reputational concerns involved for responsible investors, including ethical boundaries, use of cadavers and organ donation.

Complementary and alternative medical systems such as Traditional Chinese and Aryuvedic Medicine, whilst allowing patients to avoid the use of modern pharmacological drugs, still have issues to consider such as the poor training of medical personnel, inadequate long term clinical trials into the long-term side-effects and contra-indications. There are also concerns that the profits from the IP owned by generations of traditional medicine men and women is being exploited commercially with little or no compensation reaching those who developed the techniques and cures. This has resulted in calls for more responsible bio-prospecting in developing countries.

The report ends with a comprehensive discussion on a host of socio-economic health issues which may impact earnings for companies in other sectors. These include issues such as lack of primary healthcare infrastructure, clean drinking water and vaccinations, changing diets, lifestyles and disease profiles, mental health and maternity/paternity leave issues.
INTRODUCTION

A review of Asian healthcare offers an insight into the striking contrasts in healthcare conditions between developed and developing countries. Whilst developing countries such as India, China, Thailand and Indonesia are grappling with some of the poorest healthcare indicators worldwide, more developed countries like Singapore, Hong Kong, South Korea and Taiwan are rated as having some of the most advanced healthcare systems in the world. Even within countries, the heterogeneity of issues can be confusing. As such, the risks to earnings for investors in Asia, whether they specialize on the healthcare industry or not, change dramatically from one country to another and are in need of deeper analysis.

For responsible investors, the Asian healthcare and pharma industry presents a unique opportunity. Not only can investors look forward to above-average growth rates but, through engagement with company management, they can also encourage changes in business models towards balancing short term profitability objectives with that of enabling more equitable Access To Medicines (ATM).

Decreasing infant and child mortality, improving maternal health and combating HIV/AIDS, malaria and other poverty-related diseases are three of the United Nations’ eight Millennium Development Goals. The importance of tackling these crises in Asia cannot be overstated. India and China together make up nearly 10% of the global HIV/AIDS population and over 40% of global tuberculosis cases.

Access to healthcare and life-saving drugs is a key social issue in almost all emerging Asian economies. At the same time, emerging markets are seen as the major growth opportunity for pharmaceutical companies. Some, like India, now have an experienced research and development (R&D) industry and scientific communities offering low cost clinical-trials and manufacturing.

On the other extreme are countries like South Korea and Singapore that face the same problems as the rich world such as type II diabetes, heart disease and infant obesity. With some of the highest life expectancies and lowest birth rates in the world, their demographics may eventually limit the available workforce and increase overall per capita healthcare expenditures which will impact on overall economic growth. “Korea may lose out in the global economic competition due to a lack of manpower. It is actually the most urgent and important issue the country is facing,” Korean Minister of Health, Jeon Jae-Hee, has remarked.

There are also serious concerns in the sector regarding environmental and governance issues. Topics such as climate change, political intervention during natural calamities and local and state-level corruption pose new risks to the entire industry that need to be understood at a local level by investors.

We begin with the Pharma sector and look at most crucial theme that threatens to deliver risk: ATM. We then address global and Asian best practices and also look at what companies can do to improve their ratings on this indicator. We also highlight the chronic diseases that are proliferating rapidly in the region, such as HIV/AIDS, tuberculosis and diabetes and cover environmental risks such as the toxicity of chemical effluents and governance risks from corrupt medical practices.

In the second half of the report we review the ESG risks faced by the listed Healthcare providers in the region. Recent calamities and pandemics have shown that these companies may come under intense government pressure to provide subsidized services during difficult times, which may impact on margins. Demographic trends such as ageing populations in developed Asia and mass migration of healthcare workers away from certain poorer nations also pose risks. Environmental issues, in particular energy efficiency, water usage, waste treatment and governance issues such as board composition, are risks that have also been analyzed.

The report finally discusses regulatory frameworks and prominent healthcare issues which will affect business environments in the future in the 10 countries under coverage, as well as focusing on emerging trends in the biotech sector and the relevance of complementary medical systems like Ayurveda and Traditional Chinese Medicine (TCM).

Our findings end with ratings on the 30 largest pharma and healthcare companies in ten markets namely Hong Kong, China, India, Singapore, Malaysia, Korea, Taiwan, Philippines, Thailand and Indonesia. The companies selected are rated according to selected material environment, social and governance criteria and then classified into leaders, followers and laggards.
THE PHARMACEUTICAL INDUSTRY IN ASIA

Pharma companies in Asia are rapidly building manufacturing capacity. They need to design products, processes and plants with low environmental footprints. At the same time, they need to minimize and manage the adverse impacts of their existing environmental footprint through water and waste treatment, recycling and safe disposal efforts. Sustainability needs to be integrated in two ways, firstly, compliance with the laws and regulations and secondly, going beyond what local laws mandate to reduce risk from future environmental legislation.

The main issues in Asia are energy efficiency, emissions, toxic waste, water usage, bio-diversity and product life cycle. These issues are discussed below with examples of global and Asian best practices.

Pharma companies which do not comply with international standards on environment management face serious risks to their financial performance through enforcement of regulatory provisions as well as political and social mechanisms. Affected communities getting are starting to protest violently against irresponsible companies and politicians are feeling the pressure to take action.

Companies employees are typically resident in local communities and are also affected by the damage to their drinking water sources or air pollution. Lowered staff health and morale is known to have negative impacts on productivity. In the following paragraphs, we discuss Asian cases where companies have fallen foul of environmental non-compliance.
ENERGY EFFICIENCY

Pharma manufacturing is a chemical process involving energy-intensive factory processes. There is a lot of refrigeration, air-conditioning, steam generation and distribution, power transmission, pump systems, lighting, compressed air and fans and blower systems. Most factories in Asia are still way behind their western counterparts in terms of energy efficiency.

GRI recommends reporting on both direct and indirect energy usage. We also recommend that pharma companies employ a third party auditor to analyse areas of efficiency improvements. There are several global certifications, which help validate efforts towards improving energy efficiency such as International Standards Organization (ISO) and Leadership in Environmental and Energy Design (LEED). Companies should review renewable energy sources for in-house energy consumption and, where economically viable, build a proportion of renewable energy into energy procurement contracts.

Financial risks of not improving energy efficiency standards could have substantial bottom line impacts in the future. Emissions trading is becoming more accepted, expected and transparent whilst taxes on carbon emissions in developed markets, in line with the Polluter Pays Principle, seem inevitable. This development will mean that firms will have permanent economic incentives to reduce emission and consume energy more efficiently.

The EU has made several announcements asking member states to implement carbon taxes on imports from polluting companies. Given that several Asian pharma companies export to Europe, this tax could, in the future, be a differentiator between polluting and non-polluting companies that may enable cleaner companies to undercut the competition.

In addition, certain Asian countries are also likely to impose domestic carbon taxes on polluting companies and individuals. Several Nordic and European countries have begun to implement such plans.

CASE STUDY: DR. REDDY’S LABS ENERGY SAVINGS POTENTIAL

In 2007-09 the company initiated Energy Conservation Audits by TERI (The Energy and Resources Institute) across 12 locations. All sites are in the process of implementing recommendations from these audits and improvements in energy efficiency are expected in the coming years.

Energy efficiency improvement recommendations came in the areas of Refrigeration & Air-conditioning Systems, Steam Generation & Distribution and Pump Optimization. A chart depicting savings potential is shown here:

Figure 1: Potential energy and GHG emissions savings at Dr. Reddy’s

EMISSIONS

Carbon dioxide (CO₂), one of the six key greenhouse gases identified in the Kyoto Protocol of the UN Framework Convention on Climate Change (UNFCCC), is emitted during energy generation at pharma facilities, mostly when waste is incinerated and for transport. Other air emissions of materials with global warming potential are volatile organic compounds (VOCs), hydrofluorocarbons (HFCs) and chlorofluorocarbons (CFCs). VOCs can contribute to the generation of ozone at ground level, leading to urban smog. CFCs are both ozone depleters and potent greenhouse gases.

GRI segments emissions from pharma companies into the following areas: greenhouse gas, ozone-depleting emissions and others. It recommends reporting on emissions along the following parameters:

- total direct and indirect greenhouse gas emissions by weight
- other relevant indirect greenhouse gas emissions by weight
- initiatives to reduce greenhouse gas emissions
- GHG reductions achieved
- emissions of ozone-depleting substances by weight
- NOx, SOx, and other significant air emissions.

To illustrate the Global Warming Potential (GWP) potential of an MNC pharma company engaged in extensive sales and marketing we look at the figures for AstraZeneca, below.

Travel and transport emissions are the largest contributor and emissions from imported energy and directly from facilities are also major contributors.

Emissions from ‘inhalation medicine’ products, e.g. asthma medication, could be specific to AstraZeneca and may not apply to most generics pharma companies in Asia, meaning the proportion of the first three would be higher. Of greater concern is the fact that there is not much awareness on this subject and most companies do not yet map their total business emissions.

Figure 2: Global Warming Potential Emissions, Astra Zeneca

Source AstraZeneca 2008

CASE STUDY: DR. REDDY’S LABS ENERGY SAVINGS POTENTIAL

In 2007-09 the company initiated Energy Conservation Audits by TERI (The Energy and Resources Institute) across 12 locations. All sites are in the process of implementing recommendations from these audits and improvements in energy efficiency are expected in the coming years.

Energy efficiency improvement recommendations came in the areas of Refrigeration & Air-conditioning Systems, Steam Generation & Distribution and Pump Optimization. A chart depicting savings potential is shown here:

Figure 1: Potential energy and GHG emissions savings at Dr. Reddy’s

Source AstraZeneca 2008
A significant proportion of pharma waste is classified as hazardous because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients. Other hazardous wastes include lubricants, fluorescent lights and even the carcasses of animals used in research. Responsible companies should eliminate, reduce, reuse or recycle waste and dispose remaining material sensitively. Hazardous wastes should be segregated into different categories for efficient and appropriate treatment. Disposal contractors should be monitored to ensure that they comply with EHS requirements and local regulations.

Most Asian pharma companies are located in high population density areas and discharge effluents directly into nearby rivers or dump them into landfills. This hazardous waste seeps into the underground water and makes it unsuitable for human consumption. This situation can quickly snowball into political conflict. The toxic waste may also impact the ecosystem and fertility of agricultural land.

Using RepRisk®, a company which screens over 14,000 companies globally for reputational risk issues, we have identified several such instances in Asian companies.

**CASE STUDY: RESIDENTS PROTEST AGAINST BIOCON INSULIN PLANT**

BANGALORE: Alleging that the insulin plant of a biotechnology company in Hebbagodi was contaminating groundwater, resulting in the death of livestock, local civil society groups demanded that the plant be relocated to a non-residential area. The company was accused of allowing effluents from the insulin plant of Biocon Ltd. to contaminate the groundwater forcing villagers to stop cultivation. "Animals in Hebbagodi and five surrounding villages that are dependent on groundwater are dying. We are unable to cultivate our land". Villagers claimed that nearly 145 private borewells and 45 government borewells were contaminated and the water is not potable.

**CASE STUDY: AZ REDUCES BUSINESS TRAVEL AND TRANSPORT**

In order to reduce total global emissions, AstraZeneca has instituted some changes to their travel and transport policies.

For goods transport the company selected a few logistic and road haulage companies to partner for the main distribution routes, selecting them on the basis of their safety, health, environment and quality management, the efficiency of their air and road fleets in addition to financial considerations. In 2008 they won a ‘Best in Class’ at the European Outsourcing Awards, in conjunction with their logistics provider NYK Logistics. The award recognized the success of a new concept of co-loading product into vehicles with product from other companies to minimise vacant space and dispatch products more quickly, significantly reducing costs and sharing environmental impact, whilst maintaining the integrity, quality and security of our products.

The company also introduced fleet reporting to track CO2 emissions and, at the end of 2008, data was made available on 18 European markets and 7,500 cars, which gave an average CO2 emission figure of 163g/km. Additional fleet programs are introducing CO2 caps on new car acquisitions in major European markets. Even the marketing companies are setting fairly low emissions caps - at 160g/km CO2 in Italy and 175g/km in Belgium.

The company is also trialing low emission hybrid vehicles at 21 locations across the United States and training staff in fuel economy and fuel efficient driving behavior. These measures should ensure that the US Fleet Services achieve their goal of reducing GHG emissions from vehicles by 12% - about 9,000 tonnes - by 2010.

In New Zealand in 2008 the marketing company changed their fleet of vehicles from large petrol engine vehicles to a fleet of smaller diesel powered vehicles that resulted in an immediate reduction of 40% of CO2 emissions. The Swedish fleet includes around 10% driven by ‘Flex Fuel’, powered by either petrol or E85 (85% ethanol and 15% petrol). Each ‘Flex Fuel’ car can reduce CO2 emissions each year by about 520 tonnes.

**TOXICITY AND WASTE**

A significant proportion of pharma waste is classified as hazardous because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients. Other hazardous wastes include lubricants, fluorescent lights and even the carcasses of animals used in research. Responsible companies should eliminate, reduce, reuse or recycle waste and dispose remaining material sensitively. Hazardous wastes should be segregated into different categories for efficient and appropriate treatment. Disposal contractors should be monitored to ensure that they comply with EHS requirements and local regulations.

Most Asian pharma companies are located in high population density areas and discharge effluents directly into nearby rivers or dump them into landfills. This hazardous waste seeps into the underground water and makes it unsuitable for human consumption. This situation can quickly snowball into political conflict. The toxic waste may also impact the ecosystem and fertility of agricultural land.

Using RepRisk®, a company which screens over 14,000 companies globally for reputational risk issues, we have identified several such instances in Asian companies.
Clean water is a valuable resource that needs to be conserved and protected from pollution. Pharma companies should aim to minimise the amount of water used and the environmental impact of the water that they discharge, especially those operating in less developed areas where water is already scarce.

Pharma companies use water for processing, cooling, cleaning, general site uses, drinking, food services and sanitation. Sites that manufacture active pharmaceutical ingredients use large amounts of water, while R&D sites and offices use less.

The UN Global Compact’s CEO Water Mandate requires companies to develop a comprehensive approach in the six areas identified in the mandate: Direct Operations, Supply Chain and Watershed Management, Collective Action, Public Policy, Community Engagement and Transparency. Sooner or later, pharma companies in Asia will have to fulfil requirements due to regulatory and stakeholder pressure.

In terms of the Global Reporting Initiative (GRI) reporting, pharma companies should report on their total wastewater discharged both into public or in-house treatment facilities, as well as direct discharges and seepages. GRI also requires reporting on biological and chemical oxygen demand (BOD and COD) and presence of elements in water like Copper, Cadmium, Arsenic, etc.

**CASE STUDY: DR. REDDY’S REDUCES WASTE WATER DISCHARGE AND INTRODUCES RAINWATER HARVESTING**

Wastewater-recycling facilities (Zero Liquid Discharge facility) has been installed in several Dr Reddy’s plants since 2002. The objective was to reduce consumption of fresh water as well as avoid discharge of effluent from the plants. For FY 2008-09, three plants achieved the desired status with an investment of around US$1.3m. Additional proposals for investments of around US$4.5m were subsequently approved for installing additional wastewater recycling. Treated water would all be then recycled back into the boilers and cooling towers. Two new facilities at SEZs in Medak and Visakhapatnam, in Adhara Pradesh, will also have waste water recycling facilities installed.

During FY2009, a Waste Water Recycling Facility was commissioned with all effluent is recycled back as cooling tower make-up or boiler feed water. The WWRF is a sophisticated combination of Effluent Treatment Plant (ETP), Reverse Osmosis Plant-1 (RO1), Reverse Osmosis Plant-2 (RO2), Multiple Effect Evaporator (MEE) Plant, Agitated Thin Film Dryer (ATFD) and Sewage Treatment Plant (STP).

Rain Water Harvesting facilities at the largest sites, with a total area of 680 acres are expected to restore 1.34m KL/year of water into the ground which is equivalent to all the groups water consumption during FY 2009.

**CASE STUDY: CHINESE PHARMA COMPANY DUMPS 1000 BARRELS OF TOXIC WASTE AND PAWS THE PRICE**

In January 2010 a Chinese pharmaceutical company was ordered to pay hefty compensation for dumping toxic chemical waste in rural areas. Environmental watchdogs in Anhui and Zhejiang provinces issued the decision after a meeting. Zhejiang Puludebang Pharmaceutical Co. Ltd. has been ordered to pay RMB2.2m (over US$300,000) to two counties in Anhui, where water and soil was polluted. An investigation by environment authorities found chemical waste in over 1,000 barrels was dumped in roadside ditches and a pond. Some of the waste had already spilled from the barrels. A 10km section of the Fuwo River was found to contain traces of methylene dichloride, methanol and methane, which damage the central nervous system. No deaths or illness had been reported in connection with the pollution.

According to local press reports, a garbage dealer was contracted to dispose of the waste by a local man who said it came from a pharmaceutical company in Dongyang City in Zhejiang. The pharmaceutical company relied to accusations by saying it had entrusted a chemical plant to dispose of the chemical waste. However, the owner of the plant disappeared following media reports on the waste dumping. Environmental authorities are holding the pharmaceutical company responsible for the environmental damage caused by the dumping.

Anti-dumping regulations were successfully enforced in this case by the Environmental Protection Bureau in Anhui launched the investigation after local people reported the pollution in December last year. Over 1,000 local people were mobilized to collect the 395 tonnes of waste and polluted soil. A recent water sample test showed the river water quality had already returned to normal, although the EPA did not specify what ‘normal’ levels of pollution are in this county.
**WATER POLLUTION**

Water pollution by pharma companies can have extremely damaging consequences and can seriously impact the lives and livelihoods of local populations and opposition can be fierce.

In order to monitor this risk, Responsible Research partners with RepRisk, a tool that highlights media and NGO criticism towards companies based on environmental and social issues.

**CASE STUDY: ZHEJIANG CHEMICAL PLAN SCRAPPED AFTER FIERCE PROTESTS**

Three protesters were arrested in Xinchang, near Shanghai in 2005, outside a pharmaceutical factory that they say is polluting their water.

A planned pharma chemical disposal facility was scrapped in 2005 as a result of successive protests by local farmers, worried about their crops and their health.

The Jingxin Pharmaceutical plant had been blamed for releasing polluted water into the Xinchang River, polluting the environment and affecting the production and health of locals. News sources stated that around 50 villagers marched to the plant demanding compensation for ruined crops and free medical check-ups. Local government and the plant washed the scene and tensions escalated. Shortly after this Xinchang County ordered the plant to suspend its production until the dispute had been properly settled. The local authorities then decided to dispose of around 1,000 tonnes of chemicals in the plant which were growing dangerously unstable in the summer heat.

Local press reports bemoaned the fact that the pharmaceutical industry used to be the pilla for Xinchang’s economic development but that many companies were polluting their water.

**CASE STUDY: CHEMICAL PLANTS TO BE MOVED OUT OF GUANGZHOU**

The City of Guangzhou, capital of Guangdong, has begun to move out all chemical and other polluting companies with a target of 300 within eight years from 2008. Around 120 have already gone, mostly to be replaced by service industries.

Those to be moved include Guangzhou Baiyunshan Jigong Pharmaceutical Co, a large drugs manufacturer. Most companies to be moved were chosen because they had violated national and local environmental protection regulations relating to emissions, sewage, noise and solid waste, and were seriously affecting living conditions in the urban areas.

The hope is that the pollution is now effectively monitored and regulations enforced in rural areas as well as the newly sanitized urban centres.

**PRODUCT LIFE CYCLE**

Product lifecycle begins with process design and continues through manufacturing to patient use and eventual disposal. Some pharma manufacturing wastes, such as solvents, can be reused as a raw material for other industries, such as paint stripping.

**PHARMACEUTICALS IN THE ENVIRONMENT**

The presence of trace levels of pharmaceuticals in the environment results largely from patient excretion and is an inevitable result of the way most current medicines work. Pharmaceuticals need to be stable enough to have a useful shelf life and oral dosage forms must be robust enough to pass through the stomach intact. Wastewater treatment removes most pharmaceutical residues but small concentrations of active compounds do end up in rivers or in the sea and very low concentrations of some pharmaceuticals are occasionally found in drinking water. In countries where wastewater is not treated, higher concentrations may enter the environment.

**MATERIALS OF CONCERN**

Areas of concern are chemicals where scientific evidence shows probable serious long-term effects to humans or the environment and for which there is, or the potential to be, legislation that may restrict use. These compounds include so-called PBTs (substances that persist in the environment, ‘bio-accumulate’ in animals, fish and plants or are toxic), carcinogens, mutagens, reproductive toxins, substances known to cause asthma, endocrine disrupting chemicals and ozone depleting substances. Multinational pharma companies also use genetically modified organisms and nano-materials during research. Efforts should be made to comply with all international regulations and best practices.

**unused medicines**

When medicines have to be discarded, patients be informed as to how to do so in an environmentally sensitive manner. Companies should work with national and local authorities to ensure that appropriate disposal options and guidance is available, to discourage disposal to the drain or directly to sewage systems and support the use of approved, voluntary take back programmes.

In the European Union there is a Directive recommendation to include a statement on the patient information leaflet about how to handle waste product in the United States, most major drugs companies now support the prescription drug disposal guidelines from National Drug Control Policy and the SMARxT Disposal Guidelines developed by the US Fish and Wildlife Service and the American Pharmacists Association in partnership with the US Pharmaceutical Industry Association, PhRMa. These guidelines are designed to raise awareness of the potential environmental impact from improperly disposed of medicines and to provide proactive guidance through proper disposal alternatives.

**Product lifecycle begins with process design and continues through manufacturing to patient use and eventual disposal.**
PACKAGING

Pharma companies should work to reduce the environmental impact of packaging for their products. GSK’s ‘green packaging guide’ provides guidance for evaluating and selecting packaging. It allows designers and managers to benchmark new and existing packaging designs using five metrics:

- Manufacturing impacts
- Mass of the material
- Biodegradability
- PVC content
- Resource depletion of petrochemical feedstock

GSK highlights the example where they have been able to reduce their packaging impacts through the use of 100% recycled plastic for Ribena bottles, achieved despite the challenge of sourcing sufficient quantities of recycled plastic.45

Unfortunately, in the context of Asian pharma companies, there is virtually no disclosure on efforts to contain any damaging effects from their product life cycle. Dr. Reddy’s talks about their ‘Green Chemistry’ and anti-counterfeiting initiatives in their sustainability report but there is no detail. Awareness levels on product stewardship are significantly low at this point.
ACCESS TO MEDICINES

Access to medicines (ATM) is fundamental for populations to achieve their basic right to health. Getting universal access to existing treatments, and finding new, affordable treatments for diseases are crucial for the overall economic development of low-income countries. Whilst governments have the primary responsibility for ensuring access to health care for all their citizens, the role of the pharmaceutical industry is to provide the vital ingredient – medicines – at an affordable price. As the owner of unique knowledge, technology and infrastructure this carries its own responsibilities. Companies operating in the region, which do not accept these responsibilities, face serious risks to their goodwill valuations and license to operate and may lose the sympathies of the government and judiciary over issues of intellectual property (IP) rights.

The challenge to ensure that millions of poor people get the medicines they need remains huge, given the appearance of new diseases, the re-emergence of ‘old’ diseases, the threat of pandemics and the growing burden of non-communicable diseases in developing countries. Preventable and treatable diseases such as HIV/AIDS, malaria, tuberculosis and many others continue to claim millions of lives every year in developing countries. As many as two billion people globally cannot afford the drugs or vaccines that have already been developed against treatable diseases that are threatening them, or are suffering from devastating diseases for which no affordable remedies are being developed.

In the context of the ten Asian countries covered in this report, we notice stark contrasts between the developed and the developing countries. For instance, the problem of ATM is a major issue for the 350m, 200m and 15m people in India, China and Philippines living below poverty line. The cost of financing health care is still largely out-of-pocket. In other countries, such as Thailand where 1.4% of the population is HIV-positive, the government has had to fight multinational pharma companies to license out ARV drugs to generics manufacturers.

CASE STUDY: ATM Index 2010 – a collaborative success

The global pharma sector has performed well recently as a ‘defensive’ play, despite the recession, declining earnings and concerns over patent expirations. The investment community seems to place great hope on the emerging markets are still growing rapidly. AstraZeneca, for example, has seen 10% growth in emerging markets in recent years vs only 2% in OECD countries.

Around two billion people worldwide have no access to essential medicines and little public health care. These people often go untreated and are a continued burden on their extended families and, thus, on the wider economy. Often families sacrifice their food budget to buy medicine privately as there is no access through the public sector.

There has been a shift in the way the world intends to deal with this, the Global Health Burden. Where once it was seen as the role of governments and charities, now a growing number of stakeholders are involved in the debate surrounding Access to Medicine – including investors and companies. These forward-looking entities believe that solving this crisis means long-term positive returns. If ATM is improved in the Asian emerging markets there will be healthier workers, savers and consumers that will benefit most businesses. The Gates Foundation, for example, reported that, in Kenya, a simple de-worming could increase per cap earnings by over 30% and Indian GNP could increase by US$1.5 billion if they could control Lymphatic Filariasis.

In order to track improvements in ATM an index was published in 2008 that highlights CSR activities, policies and performance within the pharma sector. The ATM Foundation creates the index from data provided by institutional investors, academia, governments, NGOs and the pharmaceutical industry itself. It focuses on drug donations, philanthropy, management and capacity building and highlights good performance and areas for improvement. It seems some pharma companies are now using the measurement criteria to align their own CSR strategies.

As Andrew White suggests in Responsible Investor, “Collaborative dynamics... can be far more effective at producing innovation and change than competition” and this is a great example of this taking place.

The Results of the 2008 ATM Index showing Ranbaxy in 16th place on ATM globally.

CASE STUDY: ACCESS TO MEDICINES AT AFFORDABLE PRICES: THAILAND VS GLOBAL PHARMA

Thailand has made serious efforts to ensure universal access to medicines through a robust public-health system, which charges at most 30 baht (US$0.94) for a consultation at a clinic or hospital. This also includes free medicines, or at least those that are available at an affordable price within the public-health system. In recent years, the high price of new, patented medicines has limited the provision of medicines through the public-health system. For example, the prices of two key anti-retroviral medicines, efavirenz, manufactured by Merck, and Kaletra, by Abbott, threatened Thailand’s ability to ensure care of the existing 80,000 patients on HIV treatment, and to expand treatment to an additional 20,000 patients needing care. Negotiations have been heated between the Thai government and Abbott – the choice for Abbott was to issue so called ‘voluntary’ licenses to other generics manufacturers or substantially reduce the price of its medicines.

Thailand has made serious efforts to ensure universal access to medicines through a robust public-health system, which charges at most 30 baht (US$0.94) for a consultation at a clinic or hospital. This also includes free medicines, or at least those that are available at an affordable price within the public-health system. In recent years, the high price of new, patented medicines has limited the provision of medicines through the public-health system. For example, the prices of two key anti-retroviral medicines, efavirenz, manufactured by Merck, and Kaletra, by Abbott, threatened Thailand’s ability to ensure care of the existing 80,000 patients on HIV treatment, and to expand treatment to an additional 20,000 patients needing care. Negotiations have been heated between the Thai government and Abbott – the choice for Abbott was to issue so called ‘voluntary’ licenses to other generics manufacturers or substantially reduce the price of its medicines.
Abbott did reduce the price of the medicine twice, in 2006, but treatment still cost US$2200 per patient year. Abbott was unwilling to reduce the price further in spite of the fact that its anti-retroviral medicine was ten times more expensive than other first-line treatments and, in spite of warnings from institutions, including the World Bank, that high prices for these medicines would jeopardise Thailand’s much-lauded HIV treatment programme. Negotiations also occurred between the Thai government and Merck for its anti-retroviral, efavirenz.

Thailand eventually issued ‘compulsory’ licenses on both Abbott and Merck for these drugs. In response, Merck negotiated with the Thai government to reduce the price of efavirenz to prices comparable to generic versions. Abbott, however, responded to Thailand’s decision to issue a ‘compulsory’ license by halting registration of seven new medicines in Thailand, including a heat-stable version of Kaletra (which can be used in rural districts with sporadic electricity supplies). According to Associated Press, Abbott said at the time: “Thailand has revoked the patent on our medicine, ignoring the patent system. Under these circumstances, we have elected not to introduce new medicines there”.

Other pharmaceutical companies have also refused to reduce the prices of their medicines or issue ‘voluntary’ licenses to ensure affordability. Sanofi-Aventis, for example, offered its medicine Clopidogrel, an anti-platelet agent used in the treatment of cardiovascular disease, at a price 60 times more expensive than the generic equivalent and 250 times more expensive than the first-line counterpart, aspirin. The price of the medicine meant that most patients requiring it could not get treatment through the public sector. Thailand announced its intention to issue a government license to produce a generic version. Sanofi-Aventis responded to Thailand’s announcement by offering a special access programme that would provide up to 3.4 million tablets of the medicine at no additional cost.

Simultaneously however, Sanofi-Aventis exert pressure on Thailand by firstly lobbying the European Commission to urge the Thai Ministry of Health to withdraw the compulsory licenses, and secondly by sending a warning letter to the Indian generic manufacturer, Emcure, which offered to fulfill the Thai government’s tender request.

Companies can become part of the solution to the goal of providing universal access to health. For example, they can invest in Research and Development (R&D) geared towards treatments for poverty-related and neglected diseases and increase efforts to out-license patented products to generics producers in developing countries. They can also apply equitable pricing mechanisms for branded products and make efforts to build sustainable research, manufacturing and distributing capacity in low-income countries. Additionally they can focus drug donation programs in situations where better options are not available.

To their great credit, many MNC pharmaceutical companies have already stepped up to this challenge, as can be seen from the following interview with Stewart Adkins, a respected UK pharma sector consultant, on how are companies changing their strategy in this direction.

INTERVIEW: MR. STEWART ADKINS, STEWART ADKINS ADVISORS, UK

Stewart Adkins set up Stewart Adkins Advisors Limited in 2006. Prior to that, he spent over 20 years as a Pharmaceutical Analyst for investment banks, researching the industry, writing on individual companies, therapeutic categories and strategic themes. He has also served as a working group member for PharmaFutures, a consortium of investors, pharmaceutical executives and other stakeholders which analyzed the opportunities for the pharmaceutical industry in emerging markets. For more information about him and his work, please visit www.saadvisors.net

RR: What are the challenges today and how are the pharma companies changing their strategies to cope?

SA: There are two main issues. Firstly a big chunk of sales of many companies are going off-patent in the next 5 years, around 30% of 2008 sales. Many are unlikely to be able to cope with that whilst maintaining earnings growth. The other problem is the low productivity of R&D. The latter is partly because the FDA is reluctant to approve any drugs, especially primary care products, with even a hint of safety risk.
RR: Why do pharma companies seem to be focusing more and more on specialty rather than primary healthcare products?

SA: AstraZeneca and Bayer each had to spend around US$2bn on clinical development of specific cardiovascular drugs simply to get sufficient data for FDA filing, a sum that few other drugs companies can afford, especially with no guarantees of clinical success. In the case of specialty care products there may be more regulatory flexibility because of the serious nature of these diseases and the lack of alternatives. Specialty care products also require smaller budgets for sales and marketing.

RR: What are the long term issues associated with ignoring the continued development of primary health products?

SA: In ten years’ time, we may find that entities paying for the drugs to treat basic diseases, namely the government, NGOs and insurance companies realize that pharma companies have been ignoring the primary healthcare market, which is, by definition, where most of the prevention and early treatment should be taking place. Civil societies and governments may then allege that the industry has reneged on its social contract. The current model is not sustainable over the long-term anyway, as specialty products tend to be expensive and only affordable by wealthy nations. The developed economies are not where the future of the pharma industry lies.

RR: What have the pharma companies done to change strategies now they realize the existing model is unsustainable?

SA: Some companies have been diversifying into vaccines, generics and OTC medicines whilst also pushing into the growing emerging markets. Many of these products can be sold at affordable prices while still allowing companies to develop a sustainable business model.

RR: Is this diversification the solution then?

SA: It is partly the solution but does not tell the whole story. Much of their product portfolio may be biological or high-priced specialty drugs which do not fit the high-volume/low-price model. Specialty drugs have a higher level of diagnosis and more intense treatment options so require more sophisticated healthcare infrastructure. This is normally only available in larger cities in developing countries. Pharma companies have, understandably, been reluctant to move into infrastructure development.

Even if satisfactory diagnosis and treatment infrastructure were widely available the industry would be reluctant to lower prices because of ‘reference pricing’. If prices are lowered in one country others will demand the same low price, despite their better ability to pay. Companies are trying to get around this issue by capping total treatment costs whilst keeping headline prices high. Others are distributing through controlled channels so that products get to those who need it without intermediaries being able to buy it cheap and ship it to another country.

These are the complex issues surrounding market access, even if the companies are motivated to help. There must be a coordinated effort by industry, government and others stakeholders if these issues are to be resolved.

We encourage companies to look at Aravind Eye-Care which delivers high quality eye-care to millions of people each year, many of them for free, and yet still manages to make sufficient surplus to expand their facilities.

RR: How is the generics sector developing and will we see MNC collaboration with local providers?

SA: There will, eventually, be collaboration because the MNCs struggle to provide low-cost manufacturing capability or adequate distribution.

RR: Does this lead to a conflicted model whereby MNCs can now sell cheaper drugs to developing countries but the generics manufacturers lose their incentive to challenge patents because of contractual obligations?

SA: Generics companies are probably taking the view that, with the MNCs help and financial muscle, they will be long term beneficiaries. There are, however, still many generics manufacturers, especially in India and it continues to be a competitive marketplace. Price levels are unlikely to creep up. It does mean that MNCs will be able to make a wider range of affordable medicines more available beyond the ‘innovator drugs’ they offer. They will still be able to say that they are providing more medicines to more people at lower prices. Generics companies may also be able to manufacturer new drugs, at lower costs than the MNC that discovered it.

RR: Do you see a trend of MNCs entering the generics space?

SA: I suspect so because with middle-income markets like much of Latin American, branded generics are already the majority share of medicines sold. People do not trust the unbranded generics for reasons of poor quality and counterfeit but pure branded generics are already the majority share of medicines sold. People do not.

RR: Do you see ATM becoming a core strategy of pharma companies? Are they thinking about licensing in a big way or are they coming out with multi-tiered pricing?

SA: I think they are changing and this change is being led by GSK and, in particular Andrew Witty, a member of the PharmaFutures project. Sanofi-Aventis and Novartis also think about this very much and it’s part of their core strategy. AstraZeneca did an about-turn on this issue with the arrival of David Brenna as CEO and do seem to be making ATM a core part of strategy. The US companies are not yet on the same wavelength, but their opinions are changing.

RR: As an ex-Lehman’s analyst how do you see improved sustainability reflecting on companies financial performance?

SA: Shares have performed poorly over the last ten years for a number of reasons, including slowing earnings growth, poorly visible development pipelines and reputational blunders. Shareholders are beginning to appreciate that, whilst CSR may not be at the top of the agenda, the provision of a quality portfolio of medicines to more people at affordable prices makes good business sense.

Also, emerging markets are where the growth opportunities lie. As a group, emerging markets contribute margins in the range of 40% before R&D and corporate overheads. This is not far off developed world margins. Investors will still equate emerging markets with growth rather than social responsibility, however. Developing business in the emerging markets is not the only strategy being pursued by the pharmaceutical industry but it is perhaps the most common strategy. Getting it right, therefore, is very important for the industry and its shareholders. Building a business that is sustainable must be preferable to a crash and burn approach. In this respect, access and affordability of medicines must be seen to be key elements to sustainability.
In 2007, the UN Special Rapporteur on the right to the highest attainable standard of health, proposed draft guidelines for pharmaceutical companies in relation to Access to Medicine. Current industry approaches, however, still do not address the problems sufficiently. Major shortcomings include:

**Pricing** - Failure to implement systematic and transparent tiered-pricing mechanisms for medicines of therapeutic value to poor people in developing countries.

**R&D** - Lack of R&D to address the dearth of dedicated products for diseases that predominantly affect poor people in developing countries.

**IP** - Rigidity in intellectual property protection and, in some cases, active lobbying for stricter patent rules and legal challenges to governments’ use of Trade Related Aspects of Intellectual Property Rights (TRIPS) public-health safeguards, thereby preventing poor people from accessing inexpensive generic versions of essential medicines.

Globally, the ATM theme can be broadly broken down into the three issues above, namely pricing, IP protection and lack of R&D into diseases of the developing world. The Index (ATMI), which tracks the performance of world’s top 20 pharma companies, uses eight criteria to determine the rankings and these three criteria above carry the maximum weights, alongside ATM management (see below). In the context of Asian companies, with most of them being generics companies, the selection of criteria requires slight modification.

With MNCs, the ATM report highlights eight criteria for determining ATM policy, namely management, public policy influence, R&D, patents & licensing, capability development, pricing, donations and philanthropy. The definitions of these criteria, along with the methodology used by ATMI, are described in the following sections and in the box below. With generics companies, however, criteria such as public policy influence and advocacy, patents and licensing are either not important or need to be suitably modified. Similarly, R&D and pricing have different implications than for MNCs.

### ACCESS TO MEDICINES MANAGEMENT

The premise for this is that drug companies need to improve global ATM through solid policies implemented by a committed and empowered top management and clearly demonstrated strategy. Some of the best practices from companies differ significantly to board level oversight of ATM policies and guidelines for investment into R&D for new treatments for neglected diseases.

**CASE STUDY: ATM MANAGEMENT BEST PRACTICES**

Sanofi-Aventis’ separate their ATM entity: the French group has created an ATM division within the Corporate Affairs department that is separate from the other philanthropic activities and drug donation programs, currently part of Public Affairs and Communication. The VP of ATM reports to the SVP of Corporate Affairs who reports directly to the CEO. Such an approach indicates that the company considers ATM as a strategic issue.

Ranbaxy’s ATM policy: even though Ranbaxy’s reporting is less sophisticated than leading originator companies, the Indian generic company has developed an approach backed by the board in which it discloses the business rationale for its policies. It talks of the need to uphold company reputation and maintain their license to operate in developing countries. It also recognizes the need for new treatments for neglected diseases and the opportunities India has to offer in terms of low cost and high scientific skills for R&D investments.

### R&D INTO GLOBAL BURDEN OF DISEASE AND NEGLECTED DISEASES

The research has been ongoing now for 20 years and the results of the most recent full survey, 2004, are shown below, for emerging economies.

<table>
<thead>
<tr>
<th>Low-income countries</th>
<th>Deaths in millions</th>
<th>% of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower respiratory infections</td>
<td>2.54</td>
<td>11.4</td>
</tr>
<tr>
<td>Common heart diseases</td>
<td>2.97</td>
<td>13.4</td>
</tr>
<tr>
<td>Diarrhoeal diseases</td>
<td>1.81</td>
<td>6.9</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>1.51</td>
<td>5.7</td>
</tr>
<tr>
<td>Stroke and other cerebrovascular diseases</td>
<td>1.48</td>
<td>5.6</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>0.94</td>
<td>3.9</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>0.94</td>
<td>3.5</td>
</tr>
<tr>
<td>Malaria</td>
<td>0.88</td>
<td>3.4</td>
</tr>
<tr>
<td>Neonatal infections</td>
<td>0.6</td>
<td>2.6</td>
</tr>
<tr>
<td>Maternal</td>
<td>0.46</td>
<td>1.8</td>
</tr>
<tr>
<td>Perinatal and low birth weight</td>
<td>0.84</td>
<td>3.2</td>
</tr>
</tbody>
</table>

R & D is a key component of a sound ATM approach, as it is most likely result in the discovery of new and more effective medicines against neglected diseases and the GBD. In the Asian pharma context, generics companies have limited R&D capability, as their core activities are drug manufacturing and distribution. However, they can still contribute by, for example, developing packaged fixed-dose combinations that can be extremely helpful in reducing the cost burden for poor patients.

Some of the best practices which companies can adopt are to have stated policies and guidelines for investment into R&D for new treatments for neglected diseases and new formulations for the GBD. Evidence of robust partnerships with research institutes and existence of several research programs on suitability for the developing world and for children would also be desirable. The latter is especially significant as it involves developing fixed-dose combinations, developing formulations that do not need to be taken with food, and working on heat-stable formulations and mechanisms to prevent formulations from getting spoiled before reaching their destination. Some companies are also working on reducing the length of treatments, for TB for example, and on improving dosing intervals. Lastly, lessons are being drawn from partnerships between companies and research institutes.

Cipla, the Indian generics company, has demonstrated sound practices with regard to heat-stable and paediatric formulations of HIV and malaria drugs. In August 2007, the US Food and Drug Administration (FDA) approved its drug Triomune, the first fixed-dose, triple-combination HIV/AIDS tablet approved for children under the age of 12 years. Cipla is also working with DNDi on a fixed-dose combination for treatment of malaria.

Globally, there is also a growing interest in quantifying global ‘food borne disease burdens’ those from micro-organisms (e.g. salmonella, E. Coli, listeria, and cholera), parasites, chemical agents and bio-toxins (e.g. toxins found in natural fungi spores), metals which accumulate in food (e.g. lead, mercury, cadmium) and persistent organic pollutants which accumulate in the environment and in human tissues. Added to this list, currently being monitored by WHO are other so called ‘unconventional agents’ such as the agent that caused bovine spongiform encephalopathy - also known as ‘mad cow disease’.
The issue of a lack of flexibility on patents and being forced to enter into licensing agreements with generics companies does not apply to most of the listed pharma companies in Asia as they themselves. Several of these successful Asian generics companies are now, however, also conducting original R&D and filing for their own patents. Hence, as these companies climb the R&D ladder, they will also come under the same scrutiny by NGOs and civil society for their patents and licensing policies.

We spoke to Rohit Malpani a healthcare specialist at Oxfam America, and learnt that generics companies can be just as inflexible with their patents as MNCs. See box below for this interview. In addition, the damage to Novartis reputation in India due to its rigidity over its Glivec patent presents an interesting case study to understand these patent risks. See box below for details.

Gilead Sciences, Inc. is a US research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of ‘unmet need’. Their primary focus is HIV/AIDS, liver disease and serious cardiovascular and respiratory conditions. This company has entered into more than ten licensing agreements with local generic companies. Some in India, and with the International Partnership for Microbicides. Licenses are non-exclusive and allow for sale in a wide range of countries. However, in India Gilead receives a 5% royalty on any sales.

**INTERVIEW: ROHIT MALPANI, HEALTHCARE SPECIALIST AT OXFAM:**

**ATM AND IP IN THE PHARMA INDUSTRY**

Mr. Malpani specializes in business and human rights at Oxfam America. He has had a specific focus on ATM, looking not just at company IP and pricing policies and R&D practices but also at countries’ trade policies. He engages key governments and institutions, such as the United States, EU and the WHO on pharmaceutical policy and its intersection with ATM.

**RR:** What is Oxfam’s role in the Access to Medicines arena.

**RM:** Oxfam has worked on ATM for almost a decade now, since the onset of the HIV/AIDS crisis and the widespread concerns over industry pricing of anti-retroviral medicines. These started out at around US$10,000 per patient per year. Oxfam analyzed and engaged with the 12 largest MNC pharma companies and now continues a constructive dialogue with five major companies on their IP and pricing policies. Beyond our conversations with the pharmaceutical industry and the shareholders who engage with pharmaceutical companies on the business case to promote ATM, Oxfam engages key multi-lateral financing vehicles that promote ATM and advises governments in structuring their own ATM policies.

**RR:** What are the ATM issues in Asia? Is it all about IP protection and pricing? Given that several big drugs are going off-patent, how big an issue is this?

**RM:** Firstly one should look at the trade policies that a country employs to manage intellectual property at the national level. The protection of IP is ultimately a policy that must balance the promotion of the public interest (and innovation) on behalf of governments and the people they represent, whilst also ensuring that private companies can recover the cost of funding innovation. The WTO established a balance between these objectives with the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. We feel this balance has not been respected due to the efforts of many private actors, especially the pharmaceutical industry, to create additional IP-based protections. Yet this extended IP protection upsets the careful balance with respect to medicine that can dissuade innovation and delay generic competition, the one sustainable method proven to reduce medicine prices to the poor.

The Asian markets are of great interest to MNC pharma. In order to serve the low income but fast growing populations there, NGOs continue to advocate strongly for generic competition. Even though pharmaceutical companies claim they can meet the needs of the poor through low-cost or not-for-profit pricing, most NGOs and government health services insist that this is insufficient to meet the price points needed to deliver affordable medicines for the poorest.

Finally, it is true that some important medicines are going off-patent in the next few years. Yet at the same time, many critical cures will not go off-patent for another decade. Even if some medicines are close to going off-patent, they are not necessarily the best option to provide good therapeutic outcomes to patients. Recent off-patent medicines normally offer improved outcomes but other medicines, which are still under patent protection, may provide critical advantages or, in the case of people with HIV and AIDS, for example, may be the only medicines for which patients have not developed drug resistance and, thus, could be life-savers. We should not accept a situation in which the rich countries get access to new medicines as soon as they are approved, while poor countries have to wait many years to get access to those same medicines, even when they are already tested and available.

We need to think about IP not only in terms of the long term social consequences of high prices, but also as to whether or not IP protection is serving its main mandate, which is to stimulate innovation. In recent years, the use of IP legislation has been distorted from simply promoting innovation to effectively generating greater returns for companies without the desired innovation. The practice of ever greening is common. This is where pharmaceutical companies file a series of frivolous patents to extend the patent term beyond what is mandated under global or national trade rules.

**RR:** So, in Asia, if Pfizer partners with Aurobindo will Pfizer grow more like Aurobindo or vice versa?

**RM:** It depends. Pfizer will look at Aurobindo’s capability in low-cost manufacture of drugs and emerging market distribution of medicines. This will enable Pfizer to move more of its products through Aurobindo – and in this way Aurobindo will maintain its core function and purpose. Yet some critical attributes of generics companies may disappear. Those companies that were previously independent may no longer aggressively seek to bring their own generic versions of patented medicines onto markets in both poor and rich countries. These patent challenges not only ensured that low price medicines reached the poor quickly, but also ensured that the IP system was not clogged by ever greening.

Thus, the crucial service which generics companies provide by making medicines available at much lower prices than MNCs all over the world would be lost because they would become more like the arms of MNCs in Asia, Africa and Latin America.

Aurobindo’s geographic scope to sell medicines could also change if they get access to Pfizer’s medicines for distribution in Asia. They may, however, have to sign fairly restrictive agreements to not sell medicines in other parts of the world, or even commit to charging higher prices there.

**RR:** GSK say they have already slashed prices of several important medicines in developing countries. What are the implications of such moves for generics companies and on the overall ATM issue?
RM: Yes, in some emerging countries, GSK is providing medicines at a quarter of the price they are offered in developed markets. This sounds promising but is still much higher than the prices that could be offered by competitive generics companies. We believe that generic competition is the only way to stimulate lower prices. Furthermore, although we see GSK lowering prices in sub-Saharan Africa, there are not lowering prices (and sometimes are actually increasing prices) elsewhere in the world – and especially in countries such as India, Thailand, and the Philippines. Our other concern is that, even as GSK is offering lower prices in the poorest countries, it is ‘tightening the noose’ when it comes to IP protection in middle income countries, which will curtail the production of generic medicines there. This may actually lead to higher overall prices for medicines sold by generics companies in sub-Saharan Africa since generic companies will now have to rely on large ‘economies of scale’ to reduce prices even further. The pricing offered by generics companies in the future may not be low enough to meet the needs of governments and charities in poor countries.

What is noteworthy of the GSK announcement is not these price reductions per se, but that they committed to cutting prices across their portfolio of medicines. We think this is significant since one of the chief concerns of civil society groups has been that companies do not consider their whole portfolio of medicines relevant to public health needs in developing countries (and have traditionally focused solely on HIV and AIDS, TB and malaria). Yet with the rapid growth in non-communicable diseases across the developing world (80% of all deaths from non-communicable diseases occur in developing countries), the need to find lower prices for all medicines is increasingly important.

RR: Are you indicating that MNCs are setting some prices even too low and preventing the generics companies to enter that drug profitably to serve emerging markets?

RM: Well, nobody is saying that MNCs should not reduce the prices to assist in development. What is disturbing is that they are trying to forestall competition in markets that are commercially important to generics companies. Companies are seeking goodwill benefits (and perhaps a small market) in sub-Saharan Africa, but at the same time they are seeking limit generic competition there from companies in Asia and Latin America that could produce generics cheap enough to supply African demand.

RR: Do you see a trend for innovator companies to enter the generics business?

RM: It makes sense for MNCs to try to lower their costs and, especially with upcoming patent expirations. The concern is, however, that they may be trying to choke off the generics companies from fair competition. MNCs are creating new businesses in both patented and generic medicines, selling at high prices to the wealthy and offering some off-patent generic medicines to the poor, but not meeting their specific needs in terms of pricing or the types of drugs required. This expansion into generics may reflect that MNCs are not really finding new ways to innovate, which is a real concern for the future. Commercial returns for the industry have been significant over the last two decades, yet innovation remains a major disappointment.

RR: What are the emerging trends in Asian generics companies?

RM: Firstly that generics companies will be increasingly protective of their own IP, though perhaps not to the extent of the MNCs. We do think, however, that generics companies will be as aggressive as MNCs in filing for patents for new products and technologies. Secondly, generics companies will invest increasingly in R&D into products for emerging markets. This should provide strong revenue, goodwill and social benefits. R&D into neglected diseases can also provide generics companies with access to technology from MNCs and also from public research institutions. For example, the Serum Institute of India developed a vaccine for meningitis A in collaboration with public and private partners. By the end of 2010 they will launch this vaccine at a cost of approximately US$0.40 per dose, which will generate enormous public health benefits across sub-Saharan Africa. It will also provide the Serum Institute with crucial technology for future vaccine conjugation and know-how to develop new vaccines in the future.

Finally, there have been worrying instances of generics companies lobbying governments to fix prices of scale to reduce prices even further. If competition ensures that prices come down, lobbying to establish price floors for medicines prevents these low prices being reached. Generics companies have also sometimes been responsible, in collusion with MNCs, in keeping the prices of medicines artificially high.

RR: Many thanks, Rohit.

CASE STUDY: NOVARTIS SUFFERS REPUTATIONAL RISK OVER ACCESS TO AN IMPORTANT CANCER DRUG IN INDIA

In May 2006, Novartis filed a case in India that sought to have section 3(d) of the Indian patent law removed. This section states that intellectual property claims related to modified versions of known substances are only permissible if it can be proved that the variation has significantly enhanced efficacy. If the clause were removed, it would mean that slight modifications of existing drugs would be grounds for a patent, thus halting the production of cheaper generic drugs. This effort to ratchet up patent protection in India by eliminating legitimate public health provisions in the country’s patent law, centres on a patent on the Novartis cancer drug, Glivec.

In August 2008 Médecins Sans Frontières (MSF) handed over a petition with 420,000 signatures, requesting Novartis to refrain from further steps to alter the patent law in India and especially not to employ the World Trade Organisation (WTO) on its behalf. MSF welcomed the recent decision of an Indian court to reject Novartis’ claim for a change in the law, and it seems that Novartis will not appeal this decision. According to NGOs, the court’s rejection of Novartis’ claim essentially secures the production of cheaper drugs in India while helping to ensure access to affordable drugs by the poor.

Dan Rosan from the US-based Interfaith Center on Corporate Responsibility (ICCR), an association of 275 faith-based institutional investors with US$110 billion in collective assets, said: “Novartis has substantially invested in neglected disease research, policy development, and stakeholder engagement, differentiating itself from the rest of the pharmaceutical industry. Now, their actions in this case are undermining that record. Novartis’ legal tactics in this case have raised the stakes higher than the several thousand Indian patients relying on Glivec, to involve the millions of people kept alive today by generic AIDS drugs from India.”

Alex van der Velden from FairPensions, a British-based campaign for responsible investment, said “Novartis is threatening its own future profits as well as access to medicines, putting at risk its reputation in key emerging markets and undermining public acceptance of the intellectual property regime on which pharmaceutical profits depend.”
Drug pricing is a very complex issue due to the variety of players involved, different social and political contexts, the duality of markets within countries, the risk of smuggling, competition and the many different types of medicines. Pricing issues seen through the lens of the ATM argument deliver further complexities to multinational pharma companies and generics companies. Generics companies developing similar drugs can cause existing drug prices to plunge 80% or more upon market entry. Even though generic companies have poor disclosure on pricing mechanisms, prices are normally more affordable and predictable than prices established by originator companies. They often also allow patients to purchase smaller quantities at a time.

Generics companies in Asia are increasingly extending their own R&D capabilities and creating their own drugs. Oxfam has described already how generics firms have, occasionally, lobbied governments to keep baseline drug prices higher and this is a trend to be watched as counter productive for ATM.

We should also note that there are other reasons why medicines are unaffordable to the poorest people in developing countries. A recent survey found that medicines – both branded versions as well as generics – can have a very high tax burden, add-on costs from the supply chain, and excessive mark-ups by pharmacists and dispensing doctors. Furthermore, some public-health authorities still dispense expensive originator brands, even though inexpensive generics are available, and charge far above the international reference price for these medicines. This only happens where levels of transparency and consumer awareness are low and often indicates a high level of endemic corruption.

**BEST PRACTICES IN PRICING:**

**Merck: tiered pricing policy**

Merck has developed an innovative approach for determining country eligibility for three tiers of pricing discounts for its HIV drugs. It is based on the UN Human Development Index (HDI) and adult HIV/AIDS prevalence rates as reported by UNAIDS. Based on these guidelines, Merck makes no profit on the sale of its current HIV/AIDS medicines in emerging markets and those countries hardest hit by the pandemic. For medium HDI countries with an adult HIV prevalence of less than 1%, HIV/AIDS medicines are available at significantly reduced prices. For high HDI countries, Merck makes its ARVs available at market-based prices that take into account local purchasing power and competitive products. The offer extends to the governments of developing countries as well as to international donor agencies, NGOs, charitable organizations and private-sector employers.

**Cipla and Ranbaxy: willingness to reduce ARV price**

While generic companies traditionally offer low prices, they are still sometimes in a position to offer discounts to people at the bottom of the food chain. At the end of 2006, a group of Indian generic companies agreed to the Clinton Foundation requests to significantly reduce the price of ARVs, in particular the price of paediatric formulations.

---

**Pricing of Drugs**

Oxfam says that this Novartis case threatens access to affordable medicines for millions of poor people in developing countries. They believe Novartis cannot pursue the case while continuing to tout its ‘charitable’ and CSR credentials. Responsible investors are questioning Novartis’s policy on this case and the risk it is taking with its reputation.

“Novartis wants ‘good news’ headlines about its sales figures or its drugs pipeline or its philanthropy. But the real headline is about the company attacking how some of the poorest people in the world are getting affordable medicines,” said Celine Charveriat, head of Oxfam’s Make Trade Fair campaign.

“Novartis should do the right thing and drop its case today.”

An Economic Times of India report from April 2010 gives an update on the status of this case. It seems that several leading Indian drugs makers, through an organization called the Indian Pharmaceutical Alliance, have now decided to collectively challenge frivolous patent applications filed by MNCs in India. A study by the IPA shows that 86 patents granted by India for pharmaceutical products since 2005 were not breakthrough drug inventions, but only a minor variation of existing products or ‘ever-greening’. The problem with this is that once a patent is granted, it is a very costly process to challenge the patents through the courts.

Indian pharma has already launched some successful challenges with MNCs over patents; for example Cipla challenged Bayer’s kidney cancer drug, Nexavar and won.

**Using Manufacturing and Distribution Expertise to Improve ATM**

Drug companies can use their manufacturing, distribution and quality control expertise to improve access to their medicines in low-income markets. Best practices are shown by disclosure of policies on quality, robust mechanisms to fight counterfeiting and product diversion.

**Case Study: Ranbaxy Improves Global Distribution of Generic Drugs**

Ranbaxy, endeavors to make Anti-Retro Virals (ARVs) accessible to patients globally, It’s products are already marketed in over 125 countries and the company has operating staff in 46 countries providing pre- and post-sales support to institutions, NGOs, and Ministries of Health in order to make cheaper Ranbaxy ARVs available in their respective treatment programs. Several humanitarian and government programs have sourced ARVs from Ranbaxy, for example the Ministry of Health of Nigeria, MSF and the governments of Cambodia and Kenya. In Zambia, the Ministry of Health has lauded Ranbaxy’s initiative in making available quality ARVs at reasonable prices and the drugs have now been registered in Brazil, Peru, Venezuela and Guatemala, among others. In Southeast Asia, their ARVs are being marketed in Vietnam, Cambodia and Myanmar and filings have been made in several other countries.

Encouraged by the positive response to its efforts to manufacture world class anti-HIV generics, Ranbaxy is committed to this business line and continues to seek partnerships in other developing countries to improve access to these medicines.
Donations and Philanthropy

Most, but not all, companies have an active drug donation programme. They often rely on these to support disaster relief assistance programmes or for initiatives on disease eradication. Best practice is where management integrates its philanthropic activities into the company's long-term plans, implementation through a consistent and well-managed program with clear targets, mechanisms to measure effectiveness, and close collaboration with local NGOs and governments. In the context of the Asian pharma companies, this aspect is important for their 'license to operate' because some governments rely on donations during natural disasters and pandemics.

Case Study: Philanthropic Drug Donation, Yuhan, Korea

Yuhan Corporation is one of South Korea’s foremost pharma companies, founded by Dr. Ilhan New. Dr. New was a pioneer who was the first to practice his philosophy of returning business profits to the society which supported it. He was concerned about the availability of educational opportunities in Korea, as well as its poor social welfare. In 1963, Dr. New donated 17,000 shares of Yuhan stock to Yonsei University to encourage the development of medical science. He also helped establish the ‘Health Fellowship Foundation' with the donation of additional Yuhan shares. In 1965, the ‘Yuhan Administration Committee for the Education Trust Fund’ was established with Dr. New’s donation of 56,000 Yuhan shares, and various educational programmes, including scholarships, were expanded further. Six months before he passed away, Dr. New left all his property to a ‘Trust Fund for the Social & Educational Assistance of Korea'. After that in 1991, Jaerah New, the daughter of Dr. New, also returned all her property to the society by donating it to the Yuhan foundation.

Pharma companies which do not comply with international standards on environment management face serious risks to their financial performance through enforcement of regulatory provisions as well as political and social mechanisms. Affected communities getting are starting to protest violently against irresponsible companies and politicians are feeling the pressure to take action.

Companies employees are typically resident in local communities and are also affected by the damage to their drinking water sources or air pollution. Lowered staff health and morale is known to have negative impacts on productivity. In the following paragraphs, we discuss Asian cases where companies have fallen foul of environmental non-compliance.

Emergent Killer Diseases

Tuberculosis

India is currently the country with the most tuberculosis infections globally. One thousand people in India die of the disease each day, the equivalent of two people every three minutes. China, with an estimated 4.5 million people living with active TB, continues to rank second. It is worth noting that the incidence of HIV/AIDS and TB in these countries are interrelated, as patients with weakened immune systems are more susceptible to both diseases. Elsewhere, the Philippines and Indonesia also suffer from extremely high prevalence of TB and the Philippines has a staggering death rate from the disease of 52 per 100,000 as against 23 and 12 for India and China, respectively.

Pharmaceutical companies can contribute to the fight against TB in developing countries through various means. Public Private Partnerships (PPPs) are considered to be the most powerful means of comprehensively combating the disease. One such initiative is the ‘India Business Alliance to Stop TB’. More information appears in the box below.

AstraZeneca has responded by opening a purpose-built TB research centre in Bangalore to develop local solutions and to meet specific local disease requirements. The company hopes to recoup its investment in R&D by selling the drugs developed in richer countries at high prices. This investment has been partially funded by the Bill and Melinda Gates Foundation.

Source: www.astrazeneca.com

Figure 5: Hospital waste in Asia, with scavenger, bottom right
In extremely high compared to India at 0.3% and Malaysia at 0.5%. Also has one of the largest HIV-infected populations in the world at 2.4 million. In 2005, an estimated 650,000 people in China were already living with HIV. India The AIDS epidemic continues to spread through Asian populations, and China some of the poorest people in the world. From 1975 to 1999, not only safe and effective, but also affordable to people in India, Africa and elsewhere where the disease is endemic.

HIV/AIDS

The AIDS epidemic continues to spread through Asian populations, and China is expected to have the world’s highest growth in HIV infections. By the end of 2005, an estimated 540,000 people in China were already living with HIV. India also has one of the largest HIV-infected populations in the world at 2.4 million. Thailand has the highest per capita rate in the region of 1.4% in its population, extremely high compared to India at 0.3% and Malaysia at 0.5%.

Some of the most notable initiatives to combat the epidemic in Asia are, again, arising from partnerships between NGOs and the private sector, such as those set up by the Bill and Melinda Gates Foundation. This organisation has already committed around US$200m to India and US$50m in China. See box below for their initiative in India.

Malaria

Malaria affects nearly ten million people in India and 2.5 million people in Indonesia. Currently anti-malarial drugs have a huge potential market but it is one with market with limited spending power and organisation. This, along with the challenges of drug resistance, poor health systems and the lack of affordable, safe and convenient treatment options, means decent low-cost malaria treatment represents one of the world’s largest unmet medical needs.

Returns on the R&D investment are difficult to predict, as the target audience for treatment includes some of the poorest people in the world. From 1975 to 1999, only four of the almost 1,400 new drugs developed worldwide were anti-malarial, and all four were, at least in part, products of publicly funded research.

GSK is a pioneer in anti-malarial vaccines. It is now conducting Phase 3 trials in seven African countries. (See box below). Ranbaxy has also been working on an anti-malaria research project since 2003. The company is developing a synthetic peroxide anti-malarial which has commenced Phase-III clinical trials in India, Bangladesh and Thailand. Ranbaxy is committed to developing a drug that is not only safe and effective, but also affordable to people in India, Africa and elsewhere where the disease is endemic.
CASE STUDY: GSK’S ADVANCED ANTI-MALARIA VACCINE GOES ON TRIAL

An efficacy trial of ‘RTS,S’, potentially the world’s most clinically advanced malaria vaccine, is now underway in Africa. The trial, which is expected to involve up to 16,000 children, is on schedule, with more than 5,000 children already enrolled.

Developing a vaccine against malaria, which has posed a scientific challenge for decades, is critical to eradicating the disease. A vaccine would complement existing interventions, such as bed nets and effective drug therapies. GlaxoSmithKline Biologicals (GSK Bio)’s ‘RTS,S’ is the first malaria vaccine candidate to demonstrate significant enough efficacy during early development to warrant Phase III testing. It is the leading vaccine candidate in the global effort by the PATH Malaria Vaccine Initiative (MVI) to develop a malaria vaccine.

Source: Malaria Vaccine Initiative

Hepatitis B

Hepatitis B is a potentially life-threatening viral liver infection. It is a major global health problem and the most serious type of viral hepatitis. It can cause chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer.

Hepatitis B is endemic in China and other parts of Asia. Most people in the region become infected with HBV during childhood. In some regions, 8-10% of the adult population is chronically infected. Liver cancer caused by hepatitis B virus (HBV) is in the top three causes of death from cancer in men, and a major cause of cancer in women. In the Indian sub-continent, an estimated 2-5% of the general population is chronically infected.

A vaccine against hepatitis B has been available since 1982. The vaccine is 95% effective in preventing HBV infection and its chronic consequences, and is the first vaccine to provide protection against a major human cancer. Chronic hepatitis B can be treated with drugs, including interferon and anti-viral agents, which can help control the spread of the disease.

Treatment with these drugs can cost thousands of dollars per year and is out of the reach of most patients in developing countries. Liver cancer is almost always fatal in these countries, and often develops in people at an age when they are most productive and have family responsibilities. In developing countries, most people with liver cancer die within a few months of diagnosis.

Diabetes

India currently has the largest number of people with diabetes in the world, with over 40 million sufferers. It is a chronic disease that occurs either when the pancreas does not produce enough insulin, a hormone that regulates blood sugar, or when the body cannot effectively use the insulin it produces. Hyperglycaemia, or raised blood sugar, is a common symptom of uncontrolled diabetes and over time leads to serious damage to many of the body’s systems, especially the nerves and blood vessels. Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production and requires daily administration of insulin. Type 2 diabetes (formerly called non-insulin-dependent or adult-onset) results from the body’s ineffective use of insulin. Type 2 diabetes accounts for 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity. Until recently, this type of diabetes was mostly seen in adults in the West but it is now also occurring in children and is increasing rapidly in Asia.

The sharp rise in the prevalence of diabetes is seen mainly in type 2 diabetes, as the prevalence of type 1 diabetes is still only between 1 and 2%. However, ‘malnutrition-related’ diabetes constitutes a significant proportion of people diagnosed with diabetes before the age of thirty. This increase amongst the young is compounded by the recent increase of type 2 diabetes associated with obesity in the same age group. This rise is mostly evident in urban areas where rapid economic development has led to sedentary lifestyles and people are consuming more refined foods and carbonated sugary drinks, leading to greater weight gain. In developing Asia rural communities are also experiencing an increase in the numbers of people with diabetes as new cheap processed foods make up greater proportions of the diet.

China has a diabetes prevalence rate of 4.2% but the higher rates among Chinese populations in the more urbanized and affluent cities of Hong Kong and Singapore indicate that, as China rapidly urbanizes and expands economically, levels seem set to rise. The WHO estimates that from 2006-2015, China will lose US$558 billion in foregone national income due to heart disease, stroke and diabetes alone.

Already, studies indicate that almost one in five children under seven in China, the so-called ‘Little Emperors’, are overweight and more than 7% are obese, according to a study of the Chinese National Task Force on Childhood Obesity. These numbers are higher than in European countries, while the gross domestic product per capita in China is much lower. Social and economic transformation, adoption of western lifestyles and the ‘one child’ policy implemented over the past 30 years have complicated the issue in a country which generally still considers being fat as a sign of good health and prosperity.

Source: Malaria Vaccine Initiative

The International Labour Organization (ILO) defines decent work as that “which sums up the aspirations of people in their working lives – their aspirations for opportunity and income; rights, voice and recognition; family stability and personal development; and fairness and gender equality”.

There are four key objectives of the ILO in regards to ‘decent work’:
- fundamental principles and rights and international labour standards
- employment and income opportunities
- social protection and social security
- social dialogue and tri-partism

In Asia the area of most concern in terms of social risk is where the principles are breached in relation to employees’ freedom of association, the right to negotiate collectively, the eradication of forced and child labour and the ban on discrimination in respect of employment and occupation.

The Global Reporting Initiative (GRI) has laid down clear guidelines on how to report on labour practices. It discusses capacity utilization, labour-management relations, occupational health and safety, continuing education and training, diversity and equal opportunity.

In the context of pharmaceuticals, occupational health and safety (OHS) can be critical. Pharmaceutical factories are essentially chemical factories and safety risks due to exposure to chemicals, heat, noise and vibration are serious. Oversights can lead to fatalities. In March 2006, at GSK’s chemical plant in Irvine, Scotland, for example, two workers suffered serious burns after an explosion. Accidents like these can pose serious risk of damage to reputation and to employee morale.

In most Asian countries, safety is considered a peripheral obligation of the employer and workers rights to a hazard free workplace are less well established. In China, and elsewhere, there have been many instances of lapses in industrial safety and cover-ups to avoid harsh legal actions.

In Shanghai, in September 2006, liquid herbicide was allegedly allowed to leak from a factory that was a subsidiary of the Shanghai Huashi Pharmaceutical Company, making two women sick and causing hundreds of people to call the police and some to flee their homes. An investigation determined that the leak was caused by faulty equipment, lack of proper safety management and ‘unprofessional’ operations. The general manager of the factory’s parent company was reprimanded, as well as the Shanghai Pharma Group.

Continuing education and training assumes an important role in the pharma industry in Asia because of the lack of specific high-quality pharmacological education facilities. Companies have to undertake targeted, in-house skills upgrading for research staff. In this regard, Dr. Reddy’s is a leader on transparency. It publishes the number of employees sent for pharmaceutical science education. In 2009 alone it sent 70 employees to pursue a Masters degree in pharmaceuticals.

Responsible Research also monitors diversity and inclusion, as indicators of sustainability. This includes non-discrimination on the basis of race, ethnicity, gender, thinking styles, religion and belief, sexual orientation, age, differential ability, education and nationality. Corporate equality of this nature tends not to be viewed as critical in Asia. The overall awareness and expectations on these issues, even at MNC subsidiaries, is still very low. Based on past adoption of western management styles and ILO standards, however, we believe awareness or equality issues will only increase in Asia and violations will have the potential to cause severe damage to a company’s reputation.

Many Asian companies have stated non-discrimination policies against gender, religion and race but tend not to have public disclosure on their stance on discrimination on sexual orientation, HIV/AIDS and nationality. For instance, there are still several Asian companies that have mandatory HIV/AIDS testing before granting employment.

Most pharma companies are aware of the fallout from negative publicity surrounding diversity issues; Novartis, for example, suffered damage to its reputation due to class action lawsuits on discrimination against women in the United States. In 2007, several women employees complained that the company discriminated against them in pay, promotions and personnel evaluations, sometimes because they were pregnant or had recently given birth.
**HUMAN RIGHTS**

The UN Universal Declaration of Human Rights (UDHR) and the core labour standards set out by the ILO define the global standards for human rights. Governments have a responsibility to define and enforce a local legal framework for human rights in accordance with international laws and agreements. Businesses have a responsibility to uphold human rights within their sphere of influence, which includes employees, suppliers, communities and society.

In the context of pharma, issues concerning human rights revolve around ATM, unintended effects of medicines due to poor quality, conducting ethical and safe clinical trials, and the use of child or forced labour.

Unintended effects of medicines due to poor quality control, counterfeiting and unanticipated side effects pose severe risks to earnings for a pharma company. Not only can they lead to massive unanticipated expenses due to product recall and compensation, they can also damage a company’s reputation and impact future earnings and brand equity. In one recent example, reported in April 2009, the US FDA disclosed that Qingdao Jiulong Biopharmaceuticals and Shanghai No. 1 Biochemical & Pharmaceutical, two Chinese pharma companies, produced and shipped contaminated heparin, a blood thinner, to the United States in 2007 and 2008. The product was linked to allergic reactions leading to deaths in the US. The latter company was also accused of having given false information to the FDA upon inspection of their facilities. The FDA warned Chinese suppliers that they will refuse to grant new drug applications or allow shipments to unload should safety standards not be upheld.

**Ethical Clinical Trials**

Clinical trials in emerging markets, and the ethical issues surrounding them, have dogged the pharma industry ever since they began. Reports often insinuate that pharma companies pressurize or lure underprivileged people to undergo these trials as a form of scientific imperialism. The concern is that poor people in developing countries are possibly being exploited for the benefit of patients in the developed world where recruitment for random trials for treatment for life-threatening illness would be difficult.

The counter argument is that, as the participants in these emerging market trials are too poor to benefit from the findings, they should not be used in research. In addition, many commentators feel that drugs companies conducting clinical trials on low-income patients should continue to supply the drugs after the trial ends to the subjects who show benefit and who cannot afford to buy them. The assumption is that, even with adverse side-effects from an unsafe drug, these participants at the bottom of the triangle are unlikely to sue an MNC.

Commercial secrecy means that there are few publically available examples of how poor people in developing countries are possibly being exploited for the benefit of patients in the developed world where recruitment for random trials for treatment for life-threatening illness would be difficult.

Unintended effects of medicines due to poor quality control, counterfeiting and unanticipated side effects pose severe risks to earnings for a pharma company. Not only can they lead to massive unanticipated expenses due to product recall and compensation, they can also damage a company’s reputation and impact future earnings and brand equity. In one recent example, reported in April 2009, the US FDA disclosed that Qingdao Jiulong Biopharmaceuticals and Shanghai No. 1 Biochemical & Pharmaceutical, two Chinese pharma companies, produced and shipped contaminated heparin, a blood thinner, to the United States in 2007 and 2008. The product was linked to allergic reactions leading to deaths in the US. The latter company was also accused of having given false information to the FDA upon inspection of their facilities. The FDA warned Chinese suppliers that they will refuse to grant new drug applications or allow shipments to unload should safety standards not be upheld.

**Ethical Marketing**

The marketing policies of global pharma companies have, in the past, been criticised for not treating developed and developing countries equally. The Medical Lobby for Appropriate Marketing, now renamed Healthy Scepticism, an international lobby group based in Australia, has criticised companies which market drugs in developing countries which have been refused product licences in developed country markets due to lack of efficacy or safety issues.
COMMUNITY INVESTMENT

Community investment is defined differently by the various pharma companies.

GSK: “making a positive contribution to the communities in which we operate, and investing in health and education programmes and partnerships that aim to bring sustainable improvements to under-served people in the developed and developing world”.

AstraZeneca: “sponsorships, charitable donations and other initiatives that help to make a difference.”

Most companies segment their community work into global and local support programs. The global programs are usually centrally steered and often in collaboration with global agencies like the WHO or Red Cross. Local support programs are those where group companies or local subsidiaries and employees show their commitment locally through donations, volunteering and disaster relief efforts.

CASE STUDY: GSK GLOBAL HEALTH PROGRAM ON LYMPHATIC FILARIASIS

GSK has committed to one of the biggest global public health initiatives: the WHO-led effort to rid the world of the disfiguring and disabling tropical disease lymphatic filariasis (LF), a mosquito-transmitted disease which is one of the principal causes of permanent disability globally. More than 120 million people in Asia, Africa and Latin America are currently affected.

GSK has donated over 1 billion treatments of albendazole to stop the transmission of this disease in 48 countries. The aim is to expand this to over 80 countries globally.

The Global Alliance to Eliminate Lymphatic Filariasis (GAELF) was officially formed in 2000. GSK is a founder member of the Alliance that now includes the Ministries of Health of LF-endemic countries and over 40 organizations from public and private sectors, academia, government bodies and NGOs.

CASE STUDY: INDONESIAN PHARMA TO THE RESCUE, APRIL 2009

In March 2009 flash floods from a broken dyke caused over 100 deaths and displacement of around 1000 families in Tangerang to the west of Jakarta. Several teams from Indonesian pharma companies – Entrostop Gesit, Hexapharma and Kalbe Farma- began programmes to provide doctors and drugs to those affected. Donated goods and medicines were given from a Medical Relief Centre and door-to-door visits were made to the temporary dwellings of the victims.

Source: Jakarta Post

RISKS TO FINANCIAL HEALTH

Risks for the pharma industry in the ten Asian countries of interest are varied and are very different from their multinational counterparts. Also within the region, risks to corporate earnings between developing and developed countries are significantly different.

The risks themselves can be classified into two categories based on their causal factors:
- Risk from ATM and CSR issues
- Risks from operational issues

ATM and CSR policies and practices are important strategic elements of pharma companies to earn public goodwill and allow them to continue with their IP and pricing policies. MNCs have suffered damage to their reputation in the past due to lack of sensitivity concerning these policies. A good example here is Novartis’ troubles in India with its cancer drug Glivec (see below). Cases like these can deal severe blows to a company’s performance by denting its social goodwill and license to operate. Damage to its reputation as a responsible citizen may invite wrath from public bodies, the government and judiciary, making operations difficult in the medium to long term. Given that these Asian countries are growing robustly, any loss of goodwill here may mean significant impact to companies’ global bottom-line in the future.

Having said that, we must also acknowledge that this problem affects mostly innovator MNCs because they are more in the public scrutiny for their ATM and CSR policies. Asian pharma companies have not yet gone so high in the innovation value chain as to attract significant attention for their responsibility practices. This will change, however, as they are innovating and filing patents for new drugs themselves. Our discussion with Rohit Malpani, Oxfam America, demonstrates that certain generics companies have been involved in lobbying governments to keep prices higher than in a true competitive environment.

These are not signs of a healthy industry and we need to thoroughly analyzed the issues within the generics companies. To avoid risks in the future, they will also need to include ATM and community investment policies at the core of their strategies. With their growing geographical footprints these policies will come more under scrutiny.

CASE STUDY: PROTECTING PATENTS: NOVARTIS IN INDIA

In 2007, Novartis challenged, and lost, a decision by the Indian Patent Office to reject its application for a patent for a drug, Gilev (used to treat chronic myeloid leukaemia and gastrointestinal stromal tumours). In subsequent press coverage, Novartis CEO Dr. Daniel Vasella was quoted as saying: ‘This ruling is not an invitation to invest in Indian R&D, which we would have done. We will invest more in countries where we have protection...Do you buy a house if you know people will break in and sleep in your bedroom?’ (Financial Times, 22 August 2007, ‘Novartis set to switch India R&D plans after court ruling’)

Considering the absence of a market for Gilev in India and more importantly, the fact that poor people in India are dependent upon generic competition for affordable medicines, Novartis’ decision to legally challenge the ruling seems strategically poor. The public outcry that it attracted – more than 200,000 people expressed their discontent with the company – has cost the company its reputation dearly.

Protestors against Novartis in India

Source: BBC, Feb 2007
CASE STUDY: RANBAXY LOSES 17% ON FDA INVESTIGATION*

Investors panicked in Feb 2009 after the US FDA halted reviews of drug applications from Ranbaxy, alleging falsification of data and test results. The FDA said Wednesday that it was continuing to investigate the matter to ensure safety and efficacy of marketed drugs associated with Ranbaxy’s Paonta Sahib site in Himachal Pradesh. The company’s professional reputation was damaged considerably the previous year, also, when the FDA issued warning letters and instituted an import alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy’s Dewas (Madhya Pradesh), Batamandi (Himachal Pradesh) and Paonta Sahib facilities due to violations of the US Good Manufacturing Practices requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect. At the time Ranbaxy said it would analyze the letter from the FDA informing it about action against the Paonta Sahib facility, placing it under a policy entitled Application Integrity Policy (AIP), and “respond appropriately in a timely manner”.

Local pharma companies are much more susceptible to risks to financial performance from operational factors. Newspapers abound with contaminated drugs and discriminatory employment practices in China and Indonesia and human rights violations in Indian pharma companies. There are also several allegations about dumping of toxic waste and other environmental factors, which will be discussed later.

These risks can have deleterious effects on a company’s performance both in the short and long term. In the short term the risk includes product recalls and compensating consumers for any medical ill-effects. The case of Europharm as in the box below illustrates this risk. The long-term risks pertain to loss of reputation and even a ban on the company’s drugs. Ranbaxy’s case is an example of that risk. In this example, Ranbaxy’s 30 drugs were banned from import from the US, its largest market contributing to a quarter of Ranbaxy’s $1.6-billion revenues for the year ended 2008.14

CASE STUDY: EUROPHARM, HK (unlisted) GIVEN MAXIMUM FINE FOR PRODUCING DRUGS UNFIT FOR HUMAN CONSUMPTION*

Europharm has been fined a maximum HKD $200,000 for four charges of selling drugs unfit for human consumption. The medicine, Purinol, was sold to a hospital whilst contaminated with a fungus, and is believed to have caused six deaths. The offense can also carry up to six months in jail, but the company’s owners have escaped prosecution. The Department of Health gave the company the right to resume production shortly after the fine. Use of all Europharm products have escaped prosecution. The Department of Health gave the company the right to resume production shortly after the fine.

FOCUS: GENERICS COMPANIES IN INDIA

Healthcare expenditure in India has grown rapidly over the last decade and the trend is likely to continue in the near future as well. Most of this growth has been driven by private spending and the key growth drivers have been: change in income demographics, change in disease mix and treatment rates for chronic diseases and rapid scale-up of medical infrastructure driven by private investments. The chart in figure 6 shows the size of healthcare spending and it’s CAGR.

Figure 6: Size and growth of healthcare spending in India

Growth in income, medical infrastructure and insurance coverage and spending are fuelling a rapid growth in the pharmaceuticals industry. The Indian pharma market is poised to become the 10th largest pharma market in the world by 2015. It has, up to now, been primarily a lower end branded generics market and is likely to remain so in future as well. The trend is so dominant that several MNCs have been positioning themselves to capitalise on the Indian branded generics opportunity.

Generic drug manufacturers incur fewer costs in creating drugs, as they do not have to cover the expense of drug discovery, or lengthy safety and efficacy trials. Generics manufacturers reverse-engineer known drug compounds. This means that generic manufacturers are able to maintain profitability while offering drugs at much lower price points.

Before the implementation of TRIPS in 1995, there was no real IP protection in developing countries, including India. This meant that Indian generics companies manufactured focused initially on reverse-engineering as many compounds as possible. With the implementation of TRIPS in 1995, the majority of developing countries were given a ten-year transition period in which to comply. This meant that the local companies in India were able to continue developing generic drugs until 2005, whilst the least developed countries still have until 2016.

In 2001, Indian generic drug manufacturer Cipla announced that it would sell a generic copy of a triple-therapy antiretroviral for US$350 per patient per year. This had an incredible impact as the competition this generated dramatically drove down the price of anti-AIDS drugs for developing countries, thereby increasing the range of affordable options for national treatment programs. India is today the largest supplier of generic ARVs to low and middle-income countries, exporting two thirds of the drugs it manufactures.

FOCUS: GENERICS COMPANIES IN INDIA

Growth in income, medical infrastructure and insurance coverage and spending are fuelling a rapid growth in the pharmaceuticals industry. The Indian pharma market is poised to become the 10th largest pharma market in the world by 2015. It has, up to now, been primarily a lower end branded generics market and is likely to remain so in future as well. The trend is so dominant that several MNCs have been positioning themselves to capitalise on the Indian branded generics opportunity.

Generic drug manufacturers incur fewer costs in creating drugs, as they do not have to cover the expense of drug discovery, or lengthy safety and efficacy trials. Generics manufacturers reverse-engineer known drug compounds. This means that generic manufacturers are able to maintain profitability while offering drugs at much lower price points.

Before the implementation of TRIPS in 1995, there was no real IP protection in developing countries, including India. This meant that Indian generics companies manufactured focused initially on reverse-engineering as many compounds as possible. With the implementation of TRIPS in 1995, the majority of developing countries were given a ten-year transition period in which to comply. This meant that the local companies in India were able to continue developing generic drugs until 2005, whilst the least developed countries still have until 2016.

In 2001, Indian generic drug manufacturer Cipla announced that it would sell a generic copy of a triple-therapy antiretroviral for US$350 per patient per year. This had an incredible impact as the competition this generated dramatically drove down the price of anti-AIDS drugs for developing countries, thereby increasing the range of affordable options for national treatment programs. India is today the largest supplier of generic ARVs to low and middle-income countries, exporting two thirds of the drugs it manufactures.
The graph below illustrates the effect of generic competition on proprietary drug prices for triple combination therapy between 2000 and 2001. The role that the production of generic drugs had on the distribution of treatment for developing countries cannot be underestimated.

Figure 7: Pricing trends of triple combination therapy drugs between 2000 and 2001

Source: Avert, an international AIDS charity

After this moment, the Indian generics companies business model took off. India now has a large number of high quality sources for generics today. It has over 110 FDA approved plants, the highest number outside US and also the highest number of Drug Master Files outside the US. The low-cost manufacturing opportunities it offers has led to several MNCs scouting for sourcing opportunities in India. Daiichi-Sankyo, Japan’s second largest pharmaceutical company, acquired Ranbaxy to source cheaply and to get a foothold in the Indian market. The company now owns almost 64% of Ranbaxy and Malvinder Mohan Singh has stepped down from the positions of Chairman, CEO and Managing Director of Ranbaxy four years ahead of schedule. Since this time Pfizer has also entered into an agreement with Aurobindo Pharma.

Mr Singh and Takashi Shoda, CEO Daiichi, at the time of the take-over in 2008

At the same time, the largest players in India, Ranbaxy, Wockhardt and Dr. Reddy’s Laboratories, have been making targeted acquisitions of their own. Ranbaxy has acquired Terapia, to create the largest Romanian pharma company. Dr Reddy’s also acquired the fourth-largest German generic drug maker, Betapharm Arzneimittel, for euro 480m in 2006. Lastly, Sun Pharma is in the process of acquiring Israel-based Taro Pharmaceuticals, although the transaction seems to be mired in controversy and is being handled by the Israeli courts at present.
CORPORATE GOVERNANCE

Timely disclosures, transparent accounting, rigorous internal control systems and a strong and independent board go a long way to preserving shareholder trust, while maximizing long-term shareholder value. Corporate governance standards vary by country and listing jurisdiction but the key features remain the same. In India, for example, the Securities and Exchange Board of India (SEBI) through Clause 49 of the listing agreement with the Stock Exchange regulates, corporate governance for listed companies.

Pharma industry worldwide faces peculiar challenges in its corporate governance model. The industry must contend with potentially conflicting demands from investors, regulators, governments (both as legislators and customers), physicians and consumers. Companies are under pressure to simultaneously increase sales, open up new markets, maintain high profit margins, discover breakthrough therapies, produce safe products, avoid aggressive marketing practices, improve access to drugs in the developing world and control the rising cost of health care in developed markets.

Moody’s, in its 2007 report, ‘Pressure on Pharmaceutical Industry Creates Long-Term Corporate Governance Challenges’ highlights the following challenges ahead for corporate governance in the pharma industry:

Pay – How should boards set pay incentives to simultaneously drive favorable shareholder returns, improve pipelines, avoid product safety scandals, and limit price erosion over the long term?

Leadership – Can industry veterans adjust to the changing operating environment and provide new vision?

Strategy – Are strategic, as opposed to incremental, tactical adjustments necessary to address long-term challenges to the business model?

Financial Policy – Can boards justify continuing to maintain large cash reserves, low debt and limited share purchases given the broad trend toward returning excess cash to shareholders?

Product safety, compliance and risk management – Can the risks related to product safety and marketing practices be contained over the long term?

Another peculiarity of governance practices in the pharma sector relate to the organization of innovation. Organizational rigidity and inertia may severely hinder the ability to take advantage of new opportunities. There has been a trend for companies, especially biotech ones, to set up separate entities for carrying out research and drug development activities. In pharmaceuticals, some once in this value chain, such as manufacturing, are generic activities with low added value. As research is one of the highly specialized and value-added processes, the fact that most biotechnological research is taking place within small start-up firms rather than large firms is an important change to adapt to.

The vast majority of these SMEs are crucially dependent on large pharmaceutical firms. This is leading to interesting networks of agreements being observed, where the biotech firms supply the ideas, etc., and the larger firms supply the complementary specialized assets such as development, financing, obtaining regulatory approval, and finally marketing, that allow them to appropriate most of the gains from innovation.

In Asia, however, especially in China, India, the Philippines and Indonesia, the legal system is incomplete, law enforcement is weak and business is tightly connected to politics. Hence, the effectiveness of conventional governance mechanisms are greatly compromised.

IMD in Switzerland surveyed 60 economies in the world in 2004 and provided an economy-level corporate governance ranking emphasizing its performance on the following four categories: corporate board, shareholder value, insider trading, and shareholder right. Among 60 economies surveyed China ranks 25th on the corporate board category, 40th on shareholder value, 57th on insider trading, and 44th on shareholder right. Its overall ranking, not surprisingly, appears on the low-end of the sixty economies surveyed.

In a survey by the World Economic Forum in 2003 with 49 economies, China underperforms in corporate governance category. China’s overall ranking is only the 44th, slightly better than Indonesia, but worse than other Asian economies such as Taiwan, Malaysia, Thailand, and India. The protection of shareholder rights is poor, insider trading is rampant, and the listed companies do not take shareholder value maximization as their primary goal, in practice.

In the case of India, a Moody’s report states that negative credit implications could arise from common corporate governance issues such as adaptability, leadership transition, checks and balances and a lack of transparency. The report adds that there are “material residual issues regarding checks and balances, for example, the lack of activist shareholders and a business and cultural environment that does not permit hostile mergers and acquisitions. Furthermore, important governance issues persist in areas not covered by regulation”.

Despite regulations concerning independent board directors, founding families retain significant control over listed companies in India, as does the government in China. As such, the difficulty in ascertaining the true independence of directors is a big corporate governance challenge. The lack of board nomination sub-committees in many companies suggests that succession planning is not well structured and lacks input from independent directors. Within the pharma industry there is often insufficient transparency on ownership/control, related-party transactions and on the group’s overall financial position and risks to earnings.

MOODY’S WARNS OF CORPORATE GOVERNANCE CHALLENGES IN PHARMA INDUSTRY

Moody’s Investors Service has conducted Corporate Governance Assessments (CGAs) of the largest US pharmaceutical companies since 2003. Research found that while the industry’s practices looked reasonably strong for the next 18 to 24 months, pressures on companies and the industry’s shifting business model have created many challenges involving pay, leadership, strategy, and financial policy.

The report found that executive pay in the pharmaceutical industry focused on near-term shareholder interests, and while compliance and risk oversight have grown, challenges and risks still persist.

“Given the challenges facing the sector, selecting new leadership is a sign of board engagement and interest in change... the question (to which the answer is unclear at this point) is whether these new leaders will be able to change enough and do so fast enough to meet long-term challenges.” – Moody’s

On the whole Moody’s found that MNC pharma boards have deep business, financial and scientific experience; and board engagement has improved in the last several years, mostly in succession planning, strategic planning, and compliance oversight, the report found.
BOARD COMPOSITION

Board composition in the pharmaceutical industry varies significantly across companies and countries. In Europe and North America, most large companies have larger boards comprising of varied professionals alongside company executives. Typically, boards have one or two doctors in the board as well. For example, Pfizer’s board has two acclaimed doctors as independent directors. Similarly, GSK’s board has two doctors out of 14 directors.

The picture changes completely when we look at pharmaceutical companies in Asia. Typically, the number of Board directors is much smaller, mostly between 5 and 10 individuals. For instance, two major Chinese pharma companies, Sinovac and China Animal Healthcare both have only 5 directors including independent ones. They both have one doctor on their Board. Indian pharmaceutical companies, on the other hand, rarely have doctors represented on their Board. Neither Sun Pharma nor Dr Reddy’s have any doctors on their board from the 7 and 10 members.

Board independence is also poor within the Asian pharma sector. Most companies have independent directors but their independence is a matter of debate and it is challenging to validate. Most companies do not separate the position of CEO and Chairman, a common indication of poor governance.

BRIBERY, INCENTIVES AND CORRUPTION

Reports of corruption, bribery and kickbacks are common amongst pharma companies worldwide. Such practices include paying ‘fees’ to doctors and health officials for prescribing their medicines. Such kickbacks may be in the form of cash, TVs or lavish junkets to exotic destinations, sometimes in the name of attending ‘medical conferences’, often in resort locations, with their families. See the news analysis from RepRisk® on Johnson & Johnson.

CASE STUDY: JOHNSON & JOHNSON ACCUSED OF PAYING MILLIONS IN KICKBACKS

In January 2010 the US Justice Department filed a complaint in the federal court in Boston alleging that Johnson & Johnson illegally paid millions of dollars in kickbacks to Omnicare, a nursing-home pharmacy company, to buy J&J products, resulting in a tripling in annual purchases of J&J products. In November 2009 Omnicare agreed to pay almost US$100m to settle charges related to the kickback scheme, and IVAX Pharmaceuticals, a subsidiary of Teva Pharmaceutical Industries, also agreed to pay US$14m to settle charges related to the same case. The investigation was prompted by allegations made by former Omnicare employees.

Other such practices include pharma companies promoting their drugs for unapproved uses. For instance, AstraZeneca in 2009 revealed that it paid over US$500 million to settle two federal investigations over illegal marketing of its psychiatric drug Seroquel. The government accused the company of marketing the drug to children and the elderly, uses that were not approved by the FDA. In a Securities and Exchange Commission filing, AstraZeneca said that it received more than 14,000 complaints from users regarding health complications from using the drug.

In Asia, corruption is generally two-fold; the bribing of medical practitioners and the bribing of government officials or other agencies to win supply contracts or to get away with product contamination or environmental degradation allegations.

For example, in 2008, World Bank probe uncovered “serious incidents of fraud and corruption” in US$570m of Indian health care projects funded by the bank. The probe was launched after a 2005 investigation uncovered corruption by two Indian drug firms, Nestor Pharmaceuticals Ltd. and Pure Pharma Ltd. The Bank then banned them from further procurement contracts. Current investigations have not yet concluded whether the corruption involves World Bank staff members, Indian government officials or other parties.

Several pharma companies in China have also recently been accused of corruption in terms of product contamination for short-term profits and of environmental degradation to avoid the costs of setting up treatment plants. In most cases, there is evidence of loose regulatory frameworks and local administrators have very close links with negligent company officials to encourage economic activity and employment.
Government relations are more important in this sector than most because the products directly affect the health and lives of a government’s voter base. Governments issue licences to carry out trials, manufacture and market the drugs. Violations and government bias poses extensive risks to pharma companies throughout their value chain.

Relations generally get difficult when there are allegations of illegal marketing practices, product recalls and unethical clinical trials in developed countries and over contamination, pricing and IP issues in developing countries in Asia. In developing countries, governments frequently bow to political pressure and tend to over-regulate on drug prices and IP. That poses a severe risk to the profitability of pharma companies. For instance, the Maximum Drug Retail Price Executive Order in the Philippines in July 2009 enforced low drug prices for several blockbuster molecules like Atorvastatin, Amlodipine and others.1 The new prices were nearly half that of the prevailing prices.

In South Korea we witnessed many drug licensing issues over H1N1 vaccines at the height of the bird flu crisis. The case illustrates how pharma companies are under the close scrutiny of government bodies and, hence, need to tread very carefully. In our ATM section, above, we also covered the tussle between the Thai government and MNC pharma companies related to IP protection.

In South Korea we witnessed many drug licensing issues over H1N1 vaccines at the height of the bird flu crisis. The case illustrates how pharma companies are under the close scrutiny of government bodies and, hence, need to tread very carefully. In our ATM section, above, we also covered the tussle between the Thai government and MNC pharma companies related to IP protection.

CASE STUDY: SOUTH KOREA INVESTIGATES ROCHE FOR ILLEGAL TAMIFLU SALES IN 2009

Swiss pharmaceutical giant Roche was probed in South Korea for allegedly illegally selling their swine flu treatment. The Korea Food and Drug Administration raided the Seoul office of Tamiflu maker Roche Holdings and seized computer files and other documents. The raid followed an investigation which began in May into local hospitals, drugstores and companies accused of selling or stockpiling Tamiflu illegally. South Korean laws ban large-scale drug purchases by non-medical professionals without doctors’ prescriptions. HSBC was implicated by the FDA who claimed they had bought the drugs illegally for their Korean work force. The drug was also in the news for being used as a pawn in the political game between North and South Korea during the time of the H1N1 epidemic in Asia.

Trucks carrying Tamiflu embark on a journey to North Korea in 2009 as part of a rare example of humanitarian aid from South Korea since their hard-line stance began in 2008.

Source: AP Photo/Ahn Young-joon

In 2001, the largest shareholder of Meierya, a profitable pharma company colluded with other insiders to embezzle overUS$40 million, around 40% of the company’s total equity. In the same year, the largest shareholder of Sanjiu Pharma, once seen as a ‘blue chip’ in China, ‘extracted’ over US$300m, equivalent to almost all of the listed company’s total equity. A study conducted by the Shanghai-based Shenyin and Wanguo Securities surveyed 130 listed firms and found that 29% of those firms’ controlling shareholders, on average, owe the listed entities around US$40m in the form of accounts receivables or outright borrowing. This practice unfortunately still tends to be seen as standard practice.

Qiao Liu, a scholar at The School of Economics and Finance, University of Hong Kong, in 2005 pointed out that more than a third of listed CEOs in China are also Chairman of the Board of Directors, a situation that can prevent the Board from playing an effective monitoring role. The proportion of ‘outside’ directors on Chinese Boards is surprisingly high, normally around 70%. However, the level of true board independence and professionalism is often lacking. Politicians and representatives from SOEs frequently occupy most board seats.

In the same year, the largest shareholder of Sanjiu Pharma, once seen as a ‘blue chip’ in China, ‘extracted’ over US$300m, equivalent to almost all of the listed company’s total equity. A study conducted by the Shanghai-based Shenyin and Wanguo Securities surveyed 130 listed firms and found that 29% of those firms’ controlling shareholders, on average, owe the listed entities around US$40m in the form of accounts receivables or outright borrowing. This practice unfortunately still tends to be seen as standard practice.

Qiao Liu, a scholar at The School of Economics and Finance, University of Hong Kong, in 2005 pointed out that more than a third of listed CEOs in China are also Chairman of the Board of Directors, a situation that can prevent the Board from playing an effective monitoring role. The proportion of ‘outside’ directors on Chinese Boards is surprisingly high, normally around 70%. However, the level of true board independence and professionalism is often lacking. Politicians and representatives from SOEs frequently occupy most board seats.

Top managers typically own very small proportions of their companies’ shares, on average only 0.1%. Incentives are unlikely to be a primary corporate governance mechanism, normally being reserved for sales or profit growth only. Managers normally expect to receive ‘gratuities’ in other ways; for example, excessive perks not reflected in salary and bonus, gains from insider trading, etc. It is hard to understand Chinese senior management’s true income and incentives, unless one includes proxies to captures these ‘grey’ income areas.

Corruption in the sales and marketing of pharma products can manifest itself in several ways. The two most common forms are bribing doctors to prescribe certain brands of medicines and promoting drugs for unapproved medical indications and patient classes. Both practices are prevalent almost everywhere and are tackled once in a while by Asian governments. Several countries, such as India and the Philippines are bringing in new Codes of Conduct for pharma companies and medical practitioners, forbidding them from giving or receiving bribes. If these Codes are strictly enforced sales of several expensive brands, which are currently pushed through these practices, could be severely impacted.

In terms of impacts, there have been few cases in Asia of enforcement and fines but, below, we discuss the case of Pfizer being fined $2.3 bn by US Department of Justice.

CORPORATE GOVERNANCE RISKS IN CHINESE PHARMA COMPANIES

Large corporations around the world are constantly balancing influence and power between the minority shareholders and controlling shareholders, with the independent director supposedly adjudicating. China, where both legal enforcement and corporate governance are weak, delivers particular challenges in this area. Almost 80% of listed companies are part of large conglomerates with opaque accounting practices which means that highly profitable businesses often find their surpluses ‘appropriated’ by more needy companies within the group. As minority shareholders, institutional investors are often unable to ascertain exactly how and when this is happening. There are many examples, from China, of how firms’ controlling shareholders abuse minority shareholder interests and misallocate assets and resources.

Bottom line impacts from governance issues range from a mild loss of face and a dent to the reputation to several billions of dollars in law suits and compensations. Lack of adequate corporate governance checks and balances in pharma companies may lead to minority shareholders interests being compromised. It may also lead to problems between management and owners when the management start to accept bribes and inappropriate perks. Weak and ineffectual boards deliver little strategic supervision of management, which is a clear red flag.

RISKS TO FINANCIAL HEALTH
CASE STUDY: PFIZER FINED A RECORD US$2.3bn BY US DEPARTMENT OF JUSTICE FOR ILLEGAL MARKETING PRACTICES

In September 2009 drugs giant Pfizer was hit with the largest criminal fine ever after being found guilty of mis-selling its treatments and offering kickbacks to U.S. doctors. The sanction is the largest healthcare fraud penalty ever meted out by the U.S. Department of Justice (DOJ), eclipsing an US$67m fine handed to Eli Lilly earlier the same year. Despite the size of the fine, it was still only less than 3 weeks of sales revenues for the company.

The case was of specific interest because six whistleblowers who came to the authorities with evidence of the widespread fraud will share a huge reward of US$112m. The DOJ case exposed many fraudulent practices used by marketing executives at Pfizer, best known for its anti-impotence pill, Viagra.

The case revolved around the company promoting its painkiller treatment, Bextra, as a cure for many other ‘unapproved’ ailments, including pain following surgery. While doctors are allowed to prescribe drugs to treat ‘off-label’ medical conditions, US law prohibits drugs companies from actively marketing their products for ‘unapproved’ uses.

Pfizer was also found to have taken doctors and other medical professionals on lavish trips to holiday resorts in the hope that they would buy other drugs developed by the company, admittedly still a common practice but theoretically illegal. Investigators discovered that marketing executives had made false and misleading claims about the safety and potency of many other treatments.

In 2008 the group also paid out around US$1.1bn to settle a civil case over the allegedly damaging side effects caused by Bextra and fellow pain reliever Celebrex. Bextra was withdrawn in 2005 over links with a rare skin condition. Shareholders also suffered after a case in 2004 where they had to settle around US$470m with the U.S. authorities after illegally promoting an epilepsy drug Neurontin for migraine and bi-polar disorder.

CASE STUDY: KOREA FINES PHARMA FOR FRAUD

In 2007 the South Korean corporate watchdog, The Fair Trade Commission (FTC) fined ten local pharmaceutical companies over US$22m for having engaged in unfair trade practices. The companies, including Dong-A Pharmaceutical, Yalit Corp., and Hanmi Pharmaceutical Co., were found to have offered various kickbacks to both doctors and hospitals for using their products. The kickbacks included rebates, contributions, and the paying of personal travel expenses. It said in some cases money was given to doctors and hospital staff in the form of so-called ‘post-market surveillance’.

FOCUS: CORRUPTION IN CHINESE PHARMA SECTOR

Corruption in China is endemic and structural. According to some commentators, for example Lu Xiaobo, Assistant Professor of Political Science at Barnard College, in the USA, this has, in the past, arisen from the State’s inability to maintain a disciplined and effective administration. State agencies have been granted regulatory power with few institutional constraints, allowing them to tap into new opportunities to seek benefits from rapid growth in businesses and the economy.

Corruption in the pharmaceutical industry in China is affected by the highly regulated nature of the industry and hence, is under the influence of the administrative officials. There are often incestuous relationships between local businesses and governments. Local corporate tax revenues are extremely important to local authorities and many companies invite local officials to become so called ‘silent partners’ in their corporations, in return for political protection. As corporate transparency is so poor, on attendance at board meetings for example, it is often hard for investors to tell which board members are fulfilling these roles.

Corruption, however, is not restricted to the intersection between business and government. It also exists within the business domain in terms of corporate governance, supply contracts to hospitals and marketing practices. In November 2009 PricewaterhouseCoopers analyzed more than 660 Chinese companies’ CSR reports, and demonstrated significant discrepancies between what the companies wrote in their reports and what they actually did.

One of the recent events that summed up several facets of the corruption issue in China was the melamine milk scandal of 2008. This ongoing incident has shown investors how companies commonly evade quality control procedures for short term gain, even if they have policies and procedures in place to protect consumers health. It also demonstrated the extent to which companies will go to cover up serious issues when bad news leaks out. Lack of transparency in the media and weak institutional systems only complicated the issue. Lastly, we can see that the State Food and Drug Administration was seriously shaken by the external focus on its affairs and the resulting penalties were severe.

CASE STUDY: CHINESE INFANT FORMULA SCANDAL EXPOSES THE ROT

The 2008 Chinese milk and infant formula melamine tainting scandal led to regulatory changes, severe criminal penalties and a shake up in the FDA. As of November 2008 there were an estimated 300,000 victims. Six infants were dying from kidney damage and a further 860 babies had been hospitalized. It appears that melamine was routinely added to milk in order to cause it to appear to have higher protein content. The scandal broke after mothers of 16 infants in Gansu Province, who had been fed on milk powder produced by the Sanlu Group, were diagnosed with kidney stones.

Fronterra, a New Zealand firm which owned 43% of Sanlu, waited one month after hearing about the tainting scandal, before informing its own government and had to emphatically deny that they had any knowledge of revelations that Sanlu lied for eight months to hide complaints about its melamine-contaminated baby formula. Access Asia, a Shanghai-based consumer consultancy, said Fonterra was a classic example of western executives operating in China who believe the advice that they must avoid making their local partners ‘lose face’ at all costs.

Sanlu is now bankrupt, Fonterra took a impairment charge of $139 million and its assets are being sold off. In April the 3000 head herd, which it jointly owned with Fonterra, was not sold at an auction and negotiations are underway for Fronterra to buy the entire stake back in order to pay off Sanlu’s debts.

According to the Chinese State channels, Sanlu began receiving complaints about sick infants as far back as December 2007, but did no additional testing until June 2008. Officials in Shijiazhuang city failed to report the contamination to provincial and state authorities until Sept 2008, in violation of rules on reporting major incidents involving product safety. According to People’s Daily, Sanlu wrote a letter to Shijiazhuang city government in August 2008, asking for help to “increase control and coordination of the media, to create a good environment for the recall of the company’s problem products….to avoid whipping up the issue and creating a negative influence in society.”
According to accounts confirmed by media reports and health officials, the company compounded its crimes by trying to buy off critics and cover up the contamination. In a memo from August, Beijing-based public relations agency Teller International, advised Sanlu to seek cooperation with major search engines to censor negative information. This agency apparently contacted key account staff at Baidu and proposed a US$440,000 budget to ‘screen’ all negative news.

Helen Clark, New Zealand’s Prime Minister, said of the local Chinese government actions: “I think the first inclination was to try and put a towel over it and deal with it without an official recall.” Western media speculated that Chinese desire for a perfect summer Olympic Games contributed to the delayed recall of the infant formula, citing a guideline allegedly issued to Chinese media that reporting food safety issues, such as cancer-causing water toxicity, was “off-limits”, although Central government strongly denies this.

In late July Southern Weekend, a local newspaper in China, wrote an investigative report for publication about infants who had fallen ill after consuming milk powder from Sanlu. Six weeks later, senior editor Fu Jianfeng revealed on his personal blog that the report had been suppressed by authorities. While this was happening, Sanlu was honoured in a national award campaign called “30 Years: Brands that Have Changed the Lives of Chinese.” The press release on the award, written by a senior PR manager at Sanlu, was distributed as news content on People’s Daily and other media.

CASE STUDY: DISGRACED SFDA CHIEF SENTENCED TO DEATH77

As China struggled to root out corruption within its pharmaceutical sector, the former head of the State Food and Drug Agency (SFDA), Zheng Xiaoyu, was sentenced to death after being found guilty of taking bribes. Experts are, however, still calling for a more systematic approach to cleaning up China’s drug business in order for it to develop healthily.

In May 2007, Beijing First People’s Intermediary Court ruled that Zheng, 62, should be executed for taking bribes of around US$ 850,000 from eight pharmaceutical and medical equipment firms and illegally approving their products. The court explained in its ruling that Zheng’s behaviour had over-ridden the normal drug regulatory procedure, threatened people’s lives and health, and had a negative impact on society. Zheng had ruled China’s SFDA for eight years, since the agency’s establishment in 1998 until he retired in 2005. He was the only senior central government official to be sentenced to death after being found guilty of taking bribes. Experts are, however, still calling for a more systematic approach to cleaning up China’s drug business in order for it to develop healthily.

Zheng had led China’s SFDA for eight years, since the agency’s establishment in 1998 until he retired in 2005. He was the only senior central government official to be sentenced to death on bribery and corruption charges in the past five years, although other officials have been convicted in recent years of taking bribes greater than Zheng, they were sentenced to life imprisonment or shorter penalties. Qian Liyong, a criminal defense lawyer based in Beijing said at the time that officials taking bribes of more than US$12,000 could legally qualify for a death sentence.

This case came after a series of medical scandals which claimed dozens of lives in China and shook confidence on the country’s fast-developing pharmaceutical industry. In 2006, 11 people died after being injected with drugs produced by a company in Heilongjiang province. Separately, six people died and 80 fell ill after taking an antibiotic produced in Anhui province in the same year. Hopefully, now, SFDA officials will be more disciplined in processing new drug applications. Already the Regulation on Medicine Registration, for approving new drugs, has become more rigorous, ruling out changes in dosage or branding as sufficient criteria for a new drug application. The new draft also stipulates public hearing process for key issues in pharmaceutical regulation.

It is not likely that the introduction of harsh discipline and tightening drug regulation on their own will be enough to encourage Chinese pharmaceutical firms to pursue genuine innovation. There still needs to be greater pricing transparency, wider medical insurance coverage and research funding at academic institutions.

According to accounts confirmed by media reports and health officials, the company compounded its crimes by trying to buy off critics and cover up the contamination. In a memo from August, Beijing-based public relations agency Teller International, advised Sanlu to seek cooperation with major search engines to censor negative information. This agency apparently contacted key account staff at Baidu and proposed a US$440,000 budget to ‘screen’ all negative news.

Helen Clark, New Zealand’s Prime Minister, said of the local Chinese government actions: “I think the first inclination was to try and put a towel over it and deal with it without an official recall.” Western media speculated that Chinese desire for a perfect summer Olympic Games contributed to the delayed recall of the infant formula, citing a guideline allegedly issued to Chinese media that reporting food safety issues, such as cancer-causing water toxicity, was “off-limits”, although Central government strongly denies this.

In late July Southern Weekend, a local newspaper in China, wrote an investigative report for publication about infants who had fallen ill after consuming milk powder from Sanlu. Six weeks later, senior editor Fu Jianfeng revealed on his personal blog that the report had been suppressed by authorities. While this was happening, Sanlu was honoured in a national award campaign called “30 Years: Brands that Have Changed the Lives of Chinese.” The press release on the award, written by a senior PR manager at Sanlu, was distributed as news content on People’s Daily and other media.

CASE STUDY: DISGRACED SFDA CHIEF SENTENCED TO DEATH77

As China struggled to root out corruption within its pharmaceutical sector, the former head of the State Food and Drug Agency (SFDA), Zheng Xiaoyu, was sentenced to death after being found guilty of taking bribes. Experts are, however, still calling for a more systematic approach to cleaning up China’s drug business in order for it to develop healthily.

In May 2007, Beijing First People’s Intermediary Court ruled that Zheng, 62, should be executed for taking bribes of around US$ 850,000 from eight pharmaceutical and medical equipment firms and illegally approving their products. The court explained in its ruling that Zheng’s behaviour had over-ridden the normal drug regulatory procedure, threatened people’s lives and health, and had a negative impact on society. Zheng had ruled China’s SFDA for eight years, since the agency’s establishment in 1998 until he retired in 2005. He was the only senior central government official to be sentenced to death on bribery and corruption charges in the past five years, although other officials have been convicted in recent years of taking bribes greater than Zheng, they were sentenced to life imprisonment or shorter penalties. Qian Liyong, a criminal defense lawyer based in Beijing said at the time that officials taking bribes of more than US$12,000 could legally qualify for a death sentence.

This case came after a series of medical scandals which claimed dozens of lives in China and shook confidence on the country’s fast-developing pharmaceutical industry. In 2006, 11 people died after being injected with drugs produced by a company in Heilongjiang province. Separately, six people died and 80 fell ill after taking an antibiotic produced in Anhui province in the same year. Hopefully, now, SFDA officials will be more disciplined in processing new drug applications. Already the Regulation on Medicine Registration, for approving new drugs, has become more rigorous, ruling out changes in dosage or branding as sufficient criteria for a new drug application. The new draft also stipulates public hearing process for key issues in pharmaceutical regulation.

It is not likely that the introduction of harsh discipline and tightening drug regulation on their own will be enough to encourage Chinese pharmaceutical firms to pursue genuine innovation. There still needs to be greater pricing transparency, wider medical insurance coverage and research funding at academic institutions.

There are also suggestions that companies have tried to maintain higher price floors for drugs, in collusion with other manufacturers and the government. A major concern is that, with intensifying competition and TRIPS provisions firmly in place, companies might resort to these tactics to maintain future profitability.

Another concern pertains to IP protection by the generics companies who also carry out their own research. The government of India is providing financial and fiscal incentives to encourage this R&D. It remains to be seen how aggressive the Indian pharma companies will be in protecting their IP, for example, against Chinese manufacturers.

On the issue of produce safety, Indian companies need to become much more alert in ensuring quality compliance. There have been several complaints in the past regarding human rights as well in the pharma supply chain. Hence, companies need to ensure strict compliance to human rights norms, screening for child or forced labor and discrimination within their supply chain as well.

There are also suggestions that companies have tried to maintain higher price floors for drugs, in collusion with other manufacturers and the government. A major concern is that, with intensifying competition and TRIPS provisions firmly in place, companies might resort to these tactics to maintain future profitability.

Another concern pertains to IP protection by the generics companies who also carry out their own research. The government of India is providing financial and fiscal incentives to encourage this R&D. It remains to be seen how aggressive the Indian pharma companies will be in protecting their IP, for example, against Chinese manufacturers.

On the issue of produce safety, Indian companies need to become much more alert in ensuring quality compliance. There have been several complaints in the past regarding human rights as well in the pharma supply chain. Hence, companies need to ensure strict compliance to human rights norms, screening for child or forced labor and discrimination within their supply chain as well.

Figure 8: Price increases by major drug companies in India since 2002

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>Phenyltoin</td>
<td>Epstain</td>
<td>72%</td>
<td>66</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>Ilugrotin</td>
<td>Brunen</td>
<td>49%</td>
<td>82</td>
<td>91</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupin</td>
<td>Ramipril</td>
<td>Ramistar</td>
<td>99%</td>
<td>5</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Pfizer</td>
<td>Amiodarone</td>
<td>Amilogard</td>
<td>88%</td>
<td>5</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>Fenofibrate</td>
<td>Stanpl</td>
<td>19%</td>
<td>6</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>USV</td>
<td>Plogitazone</td>
<td>Ploz</td>
<td>34%</td>
<td>17</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Zyius-Cadila</td>
<td>Amiodril</td>
<td>59%</td>
<td>38</td>
<td>48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omaprazdia</td>
<td>Cuid</td>
<td>39%</td>
<td>15</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

So far Indian generics manufacturers have been lauded for their role in making cheap, high-quality medicines available to the developing and least-developed countries. They are chiefly responsible for developing fixed-dose combinations for several diseases and also for new formulations such as heat-stable and paediatric treatments for deadly diseases such as HIV/AIDS. They have also been carrying out research into neglected diseases.
THE HEALTHCARE SECTOR IN ASIA
**ENERGY EFFICIENCY**

Hospitals are very high users of electrical energy for lighting, air-conditioning, heating, water supply, running medical devices and other equipment, much of which is operating 24/7. Achieving high energy efficiency not only reduces climate change impacts but can significantly reduce energy bills, thus improving bottom lines.

In the United States grants are awarded to hospitals, from the recent fiscal stimulus packages, to carry out energy efficiency projects to create jobs and stimulate innovation and the local economy. For example, the Rafitan Bay Medical Center, in New Jersey, has received over US$3m from the Public Service Electric and Gas Company (PSE&G), under its ‘Hospital Efficiency Program’, to implement energy-efficiency improvements.48

We also highlight the case of the respected New York-Presbyterian Hospital, which significantly reduced its energy consumption through sustained organizational commitment, effective communications and regular audits of projects.

### CASE STUDY: ENERGY STAR SUCCESS STORY: NEW YORK-PRESBYTERIAN HOSPITAL49

New York-Presbyterian Hospital (NYPH), a leading academic medical center affiliated with two of the nation’s leading medical colleges Columbia University College of Physicians and Surgeons and Weill Cornell Medical College, delivers comprehensive medical services to residents of New York City and its surrounding boroughs. NYPH established, and has successfully met, rigorous energy savings targets since embarking on energy management initiatives in 2003.

NYPH is among the top 5% of energy consumers in New York City. The hospital was facing rising energy costs, combined with a period of aggressive expansion. In the interest of curtailting these costs, senior management decided to commit to energy management with a full-time Energy Programs Manager position dedicated to maximizing the hospital’s energy savings. They also adopted an energy policy, and created the Office of Energy Management as well as becoming an ENERGY STAR Partner. A group of stakeholders from Real Estate, IT, Facilities Development, Strategic Sourcing, and Human Resources have since set aggressive goals to improve performance. Numerous energy efficiency projects have now paid off. In 2004 the hospital was recognized as an ENERGY STAR Leader becoming the first, and only, healthcare system to attain this recognition.

Energy savings contributed US$900,000 to the bottom line in 2004, equivalent to generating US$18 million in new revenues and preventing the emissions equivalent of a fleet of 700 cars.

By 2005 the team achieved an 11% energy efficiency improvement across its entire building portfolio and by 2006 several energy audits had determined the best opportunities for improving efficiency. In response to the audit recommendations, HVAC upgrades were performed, with estimated paybacks of less than five years, and lighting and central plant was upgraded, with paybacks estimated in just over eight years.

A long-term study at Weill Cornell Medical Center determined that an on-site energy efficient Combined Heat and Power (CHP) plant would dramatically lower energy costs, improve power quality, increase reliability, and be economically feasible. In 2005, they received a US$1m grant from New York State to begin construction on the CHP plant. It will provide Weill Cornell Medical Center with 100% of its base electricity requirements and two-thirds of its peak electric requirements. It should lower NYPH’s annual energy bill by approximately US$5m. In addition, the Heart Hospital is expected to be the first Silver-certified healthcare building in the U.S. Green Building Council’s Leadership in Energy and Environmental Design (LEED) program.

**EMISSIONS**

Green House Gas (GHG) emissions from the healthcare industry can be massive. For instance, the US healthcare sector accounts for 8% of the country’s carbon dioxide emissions.49 Emissions are critically linked to energy efficiency upgrades made by hospitals, since most emissions occur from generators and boilers. Technology upgrades can have significant impacts on overall reduction in emissions.

Emission controls are essential components of ‘green hospital’ designs. Green certified buildings with a focus on emissions, energy efficiency and other criteria are becoming almost standard in the west. In Asia, however, ‘green buildings’ are still viewed as a ‘nice to have’, even though upfront costs are reducing all the time and benefits are manifold. The indirect benefits are also important – increased productivity, employee health benefits and waste reduction are some of the benefits of going ‘green’.

We highlight below the cases of Asia’s first green hospital.

### CASE STUDY: ASIA’S FIRST LEED PLATINUM RATED GREEN HOSPITAL IN MUMBAI50

Asia’s first and the world’s second LEED Platinum rated hospital under the LEED Green Building Rating System, Kohinoor Hospital, is a world class, multi-speciality hospital. As a ‘Green Building’, the hospital is resource efficient (energy, water, materials and land) and has more natural light and better air quality. It should contribute to improved employee and public health, comfort and productivity. Innovations include CO2 sensors that automatically trigger injections of fresh air into the hospital premises when CO2 exceeds a certain level, to ensure that patients and visitors have a clean, healthy environment.

...
Hospitals discard tons of waste each year. The waste can generally be classified as risky (10-25%) and non-risky (75-90%). Risky waste types are shown on the chart, below. Medical waste generation levels can be quite high, ranging from 0.36 Kg/bed/day in Sri Lanka to 2.27 Kg/bed/day in Vietnam, according to a study by the Asian Institute of Technology in 2006.

Medical wastes in Asia is often not segregated but is disposed of together with municipal solid waste (MSW). This lack of segregation creates a hazardous waste management chain. There are frequently no regulated disposal sites for medical wastes and there is often open burning by clinics, dispensaries and hospitals. In many countries incineration, in old and poorly managed facilities, is the common method of treatment and a lack of close monitoring & inadequate maintenance can create threats to general public.

To mitigate this problem, governments should encourage the installation of individual incinerators should be discouraged, health and healthcare units should treat their waste in common biomedical waste treatment facilities. New non-burn technologies like autoclaving and microwave disinfection should be used.

CASE STUDY: HOSPITAL INCINERATORS THE BIGGEST POLLUTERS

In 2004 a report Toxic Link, an environmental NGO, suggested that hospital incinerators were the biggest polluters in Delhi, with government hospitals especially, guilty of burning most of their medical waste.

Burning of this waste causes the emission of Persistent Organic Pollutants (POPs) like dioxins and furans. Dioxin exposure is linked to a variety of health problems such as impairment of the nervous system, the endocrine system, and the reproductive system.

The Central Pollution Control Board issued guidelines on Common Bio-Medical Waste Treatment Facility and on the Design and Construction of Bio-Medical Waste Incinerators, which discourage on-site incinerators. The guidelines limit the categories of waste that require incineration as a treatment option.

New Delhi had around 59 medical waste incinerators in 2000 but, because of the complexities in meeting emission standards, most private hospitals decided to shut them down. At the time of the report, in 2004, most incinerators in New Delhi still did not have pollution control equipment. Millions of single-use syringes are disposed of during immunization programs in the country and these are mostly still incinerated.
WATER USAGE
Healthcare facilities are often one of the highest water consumers in their communities. Within hospitals the major water intensive processes are sanitation, house-keeping, air-conditioning, medical processes, food and laundry services. Typical water use per capita is split in the following way and ranges from 40 to 350 gallons per day.71

Source: Massachusetts Water Resources Authority, based on hospitals in the Boston area.

The intensity of water at a facility varies depending on the services provided, in-patient vs. out-patient visits, staff attendance, equipment used, age of the facility, and periodic maintenance practices, followed. Hospitals also need to minimize waste water discharge and should ensure that the discharged effluents do not carry any toxic, pathological or chemical wastes which may seep into local water bodies and impact the health and well-being of local communities.

CASE STUDY: APOLLO HOSPITAL IN GOA GETS A STATE POLLUTION CONTROL BOARD WARNING

The Goan State Pollution Control Board, in July 2009, gave a warning to Apollo Victor Hospital to immediately stop the release of untreated wastewater into the River Sal and submit a compliance report within 15 days.

Apollo had earlier been held responsible for pollution in this area and was warned that failure to comply with the directions would lead them to be charged under the Water (Prevention and Control of Pollution) Act, 1974.

Discharge from a chamber of Apollo Victor Hospital was seen flowing into a nullah (small canal) leading to the river. Analysis of a collected sample of this discharge indicates that the values for BOD (biochemical oxygen demand) and COD (chemical oxygen demand) exceed the permissible limits for discharge into water bodies. Garbage was also seen dumped in the nullah.

The hospital initially denied the charges and said that all 150 kg of garbage generated daily is disposed of properly. It has assured to repair and restore its malfunctioning sewage treatment plant within fifteen days.

A few weeks later it admitted some liability:

“We submit that our sewage treatment plant has been malfunctioning for some days in view of the choking up of the system that probably has resulted in some of the waste water flowing into the nullah. We have already taken measures to rectify the problem existing in our modern STP plant and will ensure that the same is in perfect working condition within fifteen days,” the letter signed by V M Albuquerque of Apollo Hospital says.

FOCUS: HEALTHCARE WASTE IN THAILAND

The Thai healthcare system has traditionally been characterised by under-funding, inadequate patient coverage and widespread inequality of access. Among the most fundamental problems is the limited reach of the country’s employment-based social security schemes, which cover only 20% of the population. Efforts to provide adequate healthcare for the remainder, including many patients living below the poverty line, have dominated government policy for the best part of 30 years.

The latest approach, initiated at the beginning of this decade, is the ‘30 Baht’ scheme, named in recognition of the nominal payments required at the point of delivery – though even these are now being scrapped. The long-term goal of the healthcare policy is to merge the 30 Baht initiative with proper social security schemes to create a universal public health insurance programme, but this is unlikely to be achieved within the next five years, especially with the deep political issues taking place. In the meantime, funding the 30 Baht scheme, which, like previous attempts to provide universal coverage, has run into financial difficulties – will remain a key issue.

The 30 Baht initiative has increased substantially the load on Thailand’s public hospital network, which is the main source of healthcare for the vast majority of patients. Many facilities have been brought to the verge of financial collapse, while long hours and low pay for those employed in public sector have prompted a stream of doctors and other healthcare professionals to decamp into the private sector. The quality of care available in government facilities has suffered as a result.

Faced with long queues and declining standards in the public sector, many patients who can afford to do so have begun to seek treatment in private hospitals and clinics. This is not an option for most, however, and the majority of patients continue to rely on basic provision in public hospitals. For some, drugstores represent the only source of primary care, since a broad range of pharmaceuticals can easily be accessed through pharmacies without prescription.

Meanwhile, low pay, long hours and poor working conditions have taken their toll, with more than 2000 doctors resigning from their posts in state hospitals during the past few years. Most have pursued work in the private sector overseas, where both pay and conditions are better. Chronic staff shortages have added to the problems faced by those who remain in the public sector.

Against this background, the government’s enthusiastic approach to the development of Thailand as a hub for the private treatment of foreign patients has come in for growing criticism. Opponents of the policy say it is at odds with efforts to improve levels of care for the country’s own patient population, since it is contributing to the drift of medical expertise away from the public sector into private practice.

Hospitals catering to tourists have mushroomed in recent years, leading to additional environmental issues, especially the disposal of medical waste. By far the most common method of disposal is incineration. The Bangkok Metropolitan Administration (BMA) operates incinerators for the disposal of medical wastes in the Bangkok area. Technical matters of hospital waste management are dealt with by the Pollution Control Department (PCD), Department of Health (DoH) and the Bangkok Metropolitan Administration (BMA). Due to differences in the definitions of hospital wastes, there is some confusion as to the legality of incineration of different products. However, waste generation seems to be somewhere between 0.11 and 0.65 Kg/bed/day equivalent to around 10,000 SUVs a year at the top end.72

Incineration as a means of disposing medical waste is not a recommended practice. Medical waste incinerators have been identified as one of the largest sources of dioxin specifically polychlorinated di-benzodioxins (PCDDs), in air pollution. The hazards of dioxin were exposed in 1994 when the United States Environmental Protection Agency (EPA) issued a critical report on the substances.73 The EPA makes no bones about the chemical’s potency, saying that dioxin, a known...
carcinogen, is the most deadly substance known to humankind, a probable carcinogen, with great risks also from non-cancer effects, on the reproductive and immune system. Dioxin was the active ingredient in Agent Orange, the defoliant widely sprayed over Vietnam during the war. To this day, Vietnam veterans exposed to Agent Orange face an increased risk of many cancers and other endocrine and immune disorders.

Alternative treatment methods to medical waste incineration exist. They include autoclaving, microwaving, electrothermal-deactivation, gasification or thermal treatment. Each treatment method should be carefully evaluated to assure that it is appropriate and meets the health and safety needs of the workers and the community.

The hospital industry in Thailand still uses mostly chlorinated plastic products. Safer alternatives exist for almost all uses of PVC plastic. For example, IV containers made of non-chlorinated plastics such as polyethylene or other polyolefins are now available. These plastics do not produce dioxin when burned or manufactured. Also, rigid PVC products often have alternatives made of metal or non-chlorinated plastic such as polypropylene and polycarbonate.
BASIC HEALTH CARE COVERAGE

It is important to examine the obligations of the State to provide healthcare. Although not expressly stated as a “right” within the United Nations Universal Declaration of Human Rights (1948), the UN Economic and Social Council states that “health is a fundamental human right indispensable for the exercise of other human rights”. The WHO has had substantial involvement in the promotion of health as a human right, in 1978 further defining ‘health’ as “a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity”. This declaration expressly states that health is a human right, requiring the engagement of a range of other social and economic areas in order to realise maximum levels of health.

Healthcare in Asia is in stark contrast between developing and the developed countries. While countries like South Korea and Singapore can boast the finest healthcare systems and indicators in the world, India, Indonesia and China are at the other end of the scale. Singapore has one of the lowest rates of infant mortality in the world at 3 per 1000 births vs India’s 57. Life expectancy in Singapore and Hong Kong is now over 80 years whereas India is still only 63. Maternal mortality figures also vary tremendously.

We observe the same wide range of extremes in the prevalence rates of major diseases. Thailand, for example, has the highest prevalence rate of HIV in the region, nearly 1140 per 100,000 population whereas Korea has a reported prevalence rate of below 100. TB shows similar trends with the Philippines showing a prevalence rate of 430 per 100,000 people vs 25 in Singapore. It is likely that prevalence of certain diseases, especially HIV, are under-reported in some countries. Diversity appears within as well as between countries. In India, for example, 37.5% of rural births are attended by skilled health personnel whereas the same figure for urban India stands at 72.5%.
India has the notorious distinction of having the worst healthcare figures on most criteria amongst its Asian peers. Diseases such as diabetes and cancer are on the rise as people live longer and levels of affluence increase. Some communicable diseases such as dengue fever, once thought to be under control, have resurfaced. The country already has a strong public health infrastructure but public hospitals and clinics are understaffed by an estimated 15-20% on average and the situation is much worse in rural areas. Low pay, poor working conditions and a lack of prestige limit the appeal of the public health service as a career path for medical talent. Many public health doctors devote a large percentage of their time to private practice, viewing their public duties as secondary and supplemental. What makes the situation worse is the prevailing ignorance of basic medical requirements in society and understaffed public hospitals. This has led to conditions ripe for unqualified doctors, ‘quacks’, to run successful businesses.

In a country where 70% of the population lives in rural areas and the poor rely on the public system for preventive and inpatient care, the shortage of qualified medical staff poses significant challenges: public institutions handle 93% of immunizations, 74% of prenatal care, 66% of inpatient bed days and 63% of delivery-related inpatient bed days. There is an urgent social need for private health institutions to contribute in a significant way to the provision of access to health to poor people, especially in rural and sub-urban areas.

**CASE STUDY: FALLING BETWEEN THE QUACKS**

Barefoot labourers, skinny housewives, and half-naked, snuffling toddlers wait outside a corrugated iron and plywood shack in a New Delhi slum to see ‘the Bengali doctor’. Noor Muhammed, the nattily dressed 30-something inside, is indeed Bengali, but, as he cheerfully admits, not a doctor. Yet as he makes quick temperature and blood-pressure checks and hands out tablets, many of them antibiotics, his patients nod respectfully, and pay.

India has more fake than genuine doctors, according to K.K. Kohli, who chairs the anti-quackery committee of the Delhi Medical Council. In Delhi alone there are around 40,000. “They take acute patients and make them chronic”, says Dr Kohli, citing quacks who misdiagnose, prescribe steroids as pick-me-ups, mix traditional and modern remedies, and buy cheap, out-of-date antibiotics. Their most common error is prescribing and selling antibiotics unnecessarily. Sandeep Guleria, a professor at the All India Institute of Medical Sciences (AIIMS) in Delhi, says quacks have helped cause the high levels of drug resistance in India.

Ten years ago New Delhi’s state government drew up an ‘Anti-Quackery Bill’ of which nothing more was heard. But the real problem is less the quacks themselves than the health-care vacuum in which they flourish. The public health system remains skeletal. In slums, sick poor people go to quacks because government-run clinics are too far away and the queues too long. In many rural areas, there are no clinics. ‘Some quacks, of course, may be perfectly responsible. Mr Noor, for example, swears that he refers all “serious cases” to government hospitals. How he diagnoses them is not clear.’

The Indian Medical Association (IMA) is now putting pressure on the government to address the problem by pushing for an anti-quackery bill. While quacks currently get up to one year’s imprisonment, and a fine of Rs 1,000, doctors are demanding more stringent punishment for these ‘criminals who give the medical profession a bad name’. ‘Quacks are now arrested under the Drugs and Magical Remedies Act, and sometimes, the Goondas Act. We have requested the government to float a separate law against quackery, with a punishment of Rs 1 lakh, and a prison term of 10 years,’ says Dr R Guttasekar, state president of IMA.

**CASE STUDY: FALLING BETWEEN THE QUACKS**

Barefoot labourers, skinny housewives, and half-naked, snuffling toddlers wait outside a corrugated iron and plywood shack in a New Delhi slum to see ‘the Bengali doctor’. Noor Muhammed, the nattily dressed 30-something inside, is indeed Bengali, but, as he cheerfully admits, not a doctor. Yet as he makes quick temperature and blood-pressure checks and hands out tablets, many of them antibiotics, his patients nod respectfully, and pay.

India has more fake than genuine doctors, according to K.K. Kohli, who chairs the anti-quackery committee of the Delhi Medical Council. In Delhi alone there are around 40,000. “They take acute patients and make them chronic”, says Dr Kohli, citing quacks who misdiagnose, prescribe steroids as pick-me-ups, mix traditional and modern remedies, and buy cheap, out-of-date antibiotics. Their most common error is prescribing and selling antibiotics unnecessarily. Sandeep Guleria, a professor at the All India Institute of Medical Sciences (AIIMS) in Delhi, says quacks have helped cause the high levels of drug resistance in India.

Ten years ago New Delhi’s state government drew up an ‘Anti-Quackery Bill’ of which nothing more was heard. But the real problem is less the quacks themselves than the health-care vacuum in which they flourish. The public health system remains skeletal. In slums, sick poor people go to quacks because government-run clinics are too far away and the queues too long. In many rural areas, there are no clinics. ‘Some quacks, of course, may be perfectly responsible. Mr Noor, for example, swears that he refers all “serious cases” to government hospitals. How he diagnoses them is not clear.’

The Indian Medical Association (IMA) is now putting pressure on the government to address the problem by pushing for an anti-quackery bill. While quacks currently get up to one year’s imprisonment, and a fine of Rs 1,000, doctors are demanding more stringent punishment for these ‘criminals who give the medical profession a bad name’. ‘Quacks are now arrested under the Drugs and Magical Remedies Act, and sometimes, the Goondas Act. We have requested the government to float a separate law against quackery, with a punishment of Rs 1 lakh, and a prison term of 10 years,’ says Dr R Guttasekar, state president of IMA.

**CASE STUDY: ‘Illegal medical practice’ case being heard in Beijing courts**

The High Court in Beijing has turned down appeals and upheld a ruling made by a lower court over a controversial “illegal medical treatment” case. The Court heard that Xiong Zhuowei, a member of the Beijing University faculty, died of pulmonary failure after undergoing spinal surgery at the age of 49 in January, 2006. A plaintiff, Wang Ji, husband of the victim, filed a lawsuit at Beijing No.1 Intermediate People’s Court in September 2007 against the prestigious Beijing University First Hospital where Xiong was treated, claiming his wife died during “illegal medical treatment” by the hospital that involved uncertified medical staff. The plaintiff demanded a sum of more than US$800,000 in compensation for his wife’s death. The High Court said it had reviewed the litigation documents concerning the death of Xiong and found the lower court’s handling of the case was correct and that it’s ruling was appropriate.

**Source:** China Daily, April 2009

**CASE STUDY: Untreated mental disorders a major health issue in China**

Mental disorders are becoming a major public health problem in China, with a national survey suggesting about 17.5% of Chinese adults suffer from a form of mental disorder. The survey was conducted by the Beijing Suicide Research and Prevention Center at Beijing Huilongguan Hospital. The survey found rural residents suffer a higher prevalence of mental disorders than urban residents. Those over 40 years old have higher rates than the younger groups, according to the survey. Female adults suffered higher rates of mood disorder and anxiety disorder than men. Alcoholism is a very male issue, with the rate among men at 38 times that of women, the survey showed.

According to the survey, mental disorders vary by region due to local customs. It also showed that fewer than 11% of people with mental disorders in Shandong have received treatment, and the rate is even lower in Qinghai, where only 3% have been to hospital for treatment.

**Source:** China Daily, April 2009
CASE STUDY: ‘ROBIN HOOD’ MODEL AT THE ARAVIND EYE HOSPITAL

Aravind’s innovative approach to healthcare for the bottom of the pyramid

Source: Changemakers.net

Aravind Eye Hospital has been pioneering approaches to affordable healthcare for over 30 years. Today, it is the largest provider of eye care in the world. It comprises patient care, manufacturing (Aurolab), research, training and capacity building. It has a network of five eye hospitals with 3,600 beds, performs over 260,000 surgeries and handles over two million outpatient visits annually. By 2007, Aravind had performed more than three million surgeries, a tremendous achievement. Approximately 12 million people are thought to be needlessly clinically blind in India.

Aravind is unique among healthcare organizations. First, it has a social mission to eradicate unnecessary blindness in India. Second, the company has proven the ‘Robin Hood’ business model to be financially viable. That means it is able to provide high-end surgical services to wealthy customers, to subsidise mass surgeries for poor patients. The model proven to be highly effective and scalable.

The basic premise of this model is that the cost structure has to be dramatically lower than other, more mainstream medical service providers. In order to achieve this, Aravind has designed an ‘assembly line’ surgery model, with multiple beds in each room and an average patient stay of only half a day. All staff members at Aravind clinics have mobile personal digital assistants (PDAs), which ensures that the preparation of facilities is done in a timely way, and all prescription information is transmitted digitally.

Patients self-assign to different income groups, on an honour-based system. The wealthier patients get a higher standard of ancillary service (private rooms, higher nursing ratios and air conditioning), and their fee helps to subsidise the cost of surgery for the poorer patients who, in turn, get a more basic ‘patient experience’. All patients receive the same level of quality medical services. Currently, the breakdown of the patient base is 45% paying, 55% free. This split not only covers Aravind’s operational costs but also funds continuous growth.

CASE STUDY: APOLLO HOSPITAL MOVES TO EXTEND HEALTHCARE REACH IN INDIA

Apollo Reach Hospitals was launched in September 2008 at Chennai. Their aim is to make world-class healthcare accessible to people even in remote areas. Apollo Reach Hospitals would be 100-150 bed multi-specialty facilities in tier 2 and 3 cities across India. Over the next two to three years over 200 such Apollo Reach Hospitals are to be set up all over India.

Apollo also runs a Telemedicine Networking Foundation (ATNF). There are two key projects. Aragonda is a remote village in the Chittoor district of Andhra Pradesh with minimal healthcare facilities. It now benefits from the addition of a 50 bed secondary care center with state of the art equipment and a Telemedicine Center with facilities such as a CT Scan, Ultrasound, X-ray. The hospital is staffed by qualified and dedicated healthcare professionals but supported by doctors from across the Apollo Hospital Group via telemedicine communications.

The telemedicine facility connects the district hospitals/health centers with super specialty hospitals for providing expert consultation to the under-served population. The mobile telemedicine unit is an effective solution for saving lives by providing initial medical care and shifting the patient to specialty centre or treating the patient on site by super specialists using telemedicine.

Source: Business Today, 2008

China, like India, has made rapid strides in healthcare delivery over the last half-century but there still several gaps to fill. Commercialisation has led to a decline of the less-profitable preventative health care in China and immunisation coverage has dropped by half in the five years following health care reforms. Prevalence rates of TB, measles and polio are now rising and could cost the economy millions in lost productivity and unnecessary treatment over the next few years. Another major issue is the fact that a third of drugs dispensed by private vendors are counterfeit and vendors are earning huge mark ups. Profit motives can drive irrational or over-prescribing of medicines, leading to potential drug-resistance for deadly diseases including HIV, TB, and malaria. Gaps in health care, due to privatisation of hospitals, has been cited as an important reason for growing anger towards the government in some rural districts. This has led to increasingly frequent local riots and disturbances.

In another example, market reforms of the public health systems in Viet Nam has led to a substantial increase in rural people reporting illness but not using health services. High costs mean that those unable to pay are increasingly excluded: self-medication is the cheapest and now most common form of health care among the poorest in Vietnam.
CASE STUDY: PRIVATIZING HEALTH CARE IN CHINA: A FAILED EXPERIMENT

From 1952 to 1982 the Chinese government-owned, funded, and operated health-care system achieved enormous improvements in domestic health care. Infant mortality fell from 200 to 34 per 1,000 live births, and life expectancy almost doubled. Since the 1980s, however, cuts in government health spending and wide-scale privatization have had devastatingly inequitable consequences. Services that were once free are now charged for by for-profit hospitals. Insurance to cover costs has been introduced but 80% of the rural poor are not covered. The numbers and quality of health-care facilities and personnel in rural areas are inadequate which has resulted in huge disparities in health outcomes. Infant mortality is now three times higher in rural than in urban areas.

Following the 2003 SARS outbreak, the government realized that the highly fragmented and inequitable profit-driven health-care system was unable to respond to the nation’s health needs. Market-based reform has led to a decline in both the fairness of medical services and the efficiency of investment in the health sector. More recently, high out-of-pocket payments for basic health have been blamed for low levels of domestic spending in China. This issue is now receiving urgent attention as the government attempts to boost domestic demand in order to safeguard its economy from the international financial crisis. Reforms to reverse the market-driven policies of the last two decades and allow a much stronger role for government in health care have been announced.

Elsewhere in the region other healthcare issues gain prominence. ARV treatment coverage for patients with advanced HIV infection is quite poor in most Asian developing countries. Only 10% of the patients in India in advanced stages of HIV infection receive ARV treatment. The charts below also show the wide gap between the developing and developed countries in terms of physician density, hospital beds per person and births attended by skilled health personnel.


Figure 14: Antiretroviral therapy coverage among people with advanced HIV infections (%)

Figure 15: Hospital beds (per 10,000 population)

Figure 16: Physician density (per 10,000 population)

The three essential priorities - increasing the availability of care, access to affordable care and awareness of healthy and preventive behaviour - can be adequately addressed only if governments, civil society and the healthcare sectors work together. Too often organizations have worked in opposing directions, leading to failures of various healthcare initiatives.

Health and safety in hospitals is critically important because it involves hospital employees, patients and their relatives whilst in the hospital premises. Safety concerns in hospitals revolve around fire hazards, electrical fittings and man and material flow layouts such as proper entrance and exit infrastructure.

Case Study: Hyderabad - Hospitals or Deathtraps?

The Times of India in February 2010 reports that the management of Park Healthcare Hospital in Hyderabad has flouted regulations by constructing an illegal additional floor, as have many other hospitals in the city. Few of the 1,100 private hospitals and nursing homes in the city have even minimum fire-fighting equipment. Several requests from for-profit hospitals for ‘No Objection Certificate (NOC)’ for constructing additional floors are pending with the fire services department.

“There is no proper entrance and exit facility at most hospitals and no open space around the buildings. None of the hospitals has enough stretchers, evacuation chairs, ramps, etc, to handle emergencies,” said a fire official. The fire department is, apparently, turning a blind eye to violations. Although the National Building Code and state government regulations state that all hospitals, irrespective of height, should have fire-fighting equipment, it seems that under 10% are in compliance.

Even government hospitals can lack simple safety standards. The premier hospital in the city, Nizam’s Institute of Medical Sciences, added three floors to its Millennium Block, despite objections from Fire Services. Most hospitals, including Osmania General Hospital, Fever Hospital, Niloufer, Chest Hospital and other district and area hospitals in the city have just a few fire extinguers in place. Many have already had fire incidents which have caused disruptions in the past.

The new Gandhi Hospital building has some equipment that seem to have become mere ‘ornaments’ as none of them is in working condition. “We have reminded the hospital authorities several times to carry out maintenance but there is no response,” said the official. National Building Code specifies hospitals should have mandatory fire extinguishers, hose reels, manually operated electric alarm systems, wet raiser and automatic detection and alarm systems, a 50,000 litre underground water tank and a terrace tank with a capacity of 5,000 litres. Enforcement on these regulations is sadly lacking.

Diversity and Inclusion

The Asian healthcare industry does not have the same awareness levels of non-discrimination and diversity as in North America and Europe. Hospitals there, being in the business of delivering care to people from all backgrounds, tend to have staff from all backgrounds, ethnicities and races to offer individual service to their customers. This trend is catching up rapidly in Asia, not least because of the growing importance of medical tourists from the west, especially Russia, seeking treatments here.

The results of the 2010 Medical Tourism Climate Survey released in May 2010 suggested that the leading medical tourism destinations in Asia are India, Thailand and Malaysia. The Russian Federation is seen as one of the leading source of patients here as they relate to the healthcare industry.
HUMAN RIGHTS

The UN Universal Declaration of Human Rights and the ILO core labour standards define global standards for human rights. Businesses have a responsibility to report on and uphold human rights within their sphere of influence, which includes employees, suppliers and communities. In Asian healthcare, issues concerning human rights revolve around access to primary healthcare, unintended effects of treatments and child and forced labour.

Below we discuss a Chinese case where a prestigious hospital suffered damage to its reputation because of fake medicines supplied by pharma companies. The case highlights how quality control on incoming medicines for hospitals can be a matter of life and death, quite literally.

CASE STUDY: CHINESE HOSPITAL SUED FOR FATAL INJECTIONS

In May 2007, several families of Chinese patients killed by a fake medicine have sued the southern Chinese hospital that gave toxic injections. There were ten plaintiffs, all families of patients of the Zhongshan University Number Three Hospital in southern Guangzhou city who were allegedly killed by tainted medicine, according to Guangzhou local press. They are demanding around US$2.6 million total compensation after the hospital gave injections of fake Armillaris A, made by the QiQihar No. 2 Pharmaceutical Co. Ltd., based in the country’s northeast, a lawyer for the hospital said. This QiQihar company used a fake syrup, supplied by a manufacturer in the eastern province of Jiangsu, the same supplier whose toxic ingredients killed at least 100 people and possibly many more in Panama, according to the New York Times.

This case underscores how Chinese citizens are also exposed to the dangers of poor supply chain management, even in prestigious hospitals. This incident exposes serious problems in the production and distribution of medicines in China. A lawyer for the hospital said the institution should not bear the blame for the toxic injections. Doctors had checked the documentation for the injection serum, as regulations require. If all the affected parties sued the Zhongshan Number Three Hospital, the amount claimed could be well over US$14.6m, apparently.

MEDICAL TOURISM

Asia has become the most popular destination for medical tourists in the world with high quality, world-class, standard medical treatment at only 20% of the equivalent treatment in the United Stated and the United Kingdom. The quality of procedures in some locations is on a par with the western world with many of the doctors holding western qualifications. Medical tourism is rapidly growing rapidly with the number of medical tourists to Asian countries increasing by about 20-30% each year. It is estimated that industry in Asia will be worth US$4 billion by 2012.

In India medical tourism is growing at a rate of 30% per year and it is estimated that earnings will reach US$2.2 billion a year through medical tourism by 2012. Singapore, another important centre for medical tourism in Asia, aims to receive one million foreign patients every year. It is estimated that medical tourism in Singapore could earn US$1.6 billion annually. Malaysia, also, expects to earn up to US$500 million. Altogether, medical tourism in Asia could be a US$4.4 billion business by 2012. Currently, the number of medical tourists to Asia is estimated to be around 1.32 million annually. Medical tourists come mostly from United States and Europe, but it is estimated that most of the medical tourists to the medical tourism centres of Asia come from within Asia, for example from Indonesia to Singapore.

Whilst not commonly known outside Thailand, the modern Thai medical system has its origins in the United States when Prince Mahidol of Songkla, the King’s father, earned his Medical degree from Harvard Medical School in the early 20th century. Prince Mahidol convinced the Rockefeller Foundation to pay for an American medical education for a group of Thai men and women who became the first educators for the modern Thai medical system. Today many Thai physicians hold US professional certification.

It is claimed that more than one million tourists a year receive healthcare in Thailand, mostly for day surgery at facilities such as Bumrungrad International Hospital, which offers a full spectrum of services from executive health tests to cardiac packages, cancer therapy, eye surgery, liposuction and other cosmetic options. Bumrungrad has more than 700 internationally-trained and board-certified doctors, and a complete range of healthcare services and facilities. Singapore, also, makes headlines for performing complex neurological procedures and delivering cutting-edge medical treatment conducted by the region’s leading health specialists. The Republic’s reputation for high quality medical facilities and well-trained doctors pulled in more than 370,000 visitors last year.

India promotes its private healthcare sector as a tourist attraction, providing first-class service at a third-world price. The Escorts Heart Institute and Research Centre in New Delhi boasts a death rate for coronary bypass patients of 0.8%, compared to 2.35% for the same procedure in New York, says Escorts’ cardiovascular surgeon.

Short waiting periods and low prices are attracting many medical tourists to India. For instance, a heart valve replacement that would cost $200,000 in the United States can be performed for around $10,000 in India, including the round trip flights and a relaxing post-op vacation. The medical care provided is extremely modern and technologically on par with the developed countries. India is a new entrant to the field of medical tourism, but the number of foreign patients is already well over 500,000 a year and growing at the rate of 30% every year.

The cost of procedures like liver transplant, heart surgery, orthopedic surgery, cataract surgery, bone marrow transplant, dental implants, metal free bridge, porcelain metal bridge and rhinoplasty (nose jobs) are approximately 25% of the costs of the same procedures in the United States.

Indraprastha Apollo Hospital, a 700 bed hospital, provides some of the most modern medical treatment available including a complete range of latest diagnostic, surgical, and medical facilities for patients. For international arrivals, the hospital arranges airport pick up and drop, travel arrangements, translators, and post-op accommodation for patients and attendants.
As can be expected, medical tourism raises several social and ethical issues. For example, some argue that a policy of medical tourism for the Western upper classes and a lack of basic health care for the masses will lead to a deepening of the inequities already embedded in the health care system. Given the already inadequate health infrastructure for the rural poor, profitable medical tourism incentivizes companies to invest in more expensive and luxurious infrastructure, catering to the rich. In Thailand, it is often said that “doctors are so busy caring for foreigners that Thai patients have trouble getting seen”.

The deployment of skilled medical personnel to medical tourism deprives the poor and the needy from getting medical services at affordable prices. Supporters, however, counter by saying that, without medical tourism, talented professionals would have probably gone to work in the west anyway.

Another major social issue to address is the illegal purchase of organs and tissues for transplantation in countries such as India and China. Also, ‘Surrogacy Tourism’ is becoming more common in India for childless parents overseas. Many couples are now travelling to India to ‘commission’ a baby. There are some concerns about this trend. The first is the potential misuse of technology, causing serious problems such as a declining sex ratio, as well as rising numbers of risky caesarean sections and over-diagnosis, leading to unnecessary medical procedures.

When combined with new reproductive technologies the results can be disturbing. There are reports of young women being used to harvest oocytes or ova without their informed consent on the risks and consequences of this procedure, of clinics promoting IVF without the necessary technical resources and human power, and of specialists organising surrogacy contracts for foreign clients without ensuring the security and rights of the surrogate mother or baby.103

This industry has been very profitable and, so far, the limitations of this technology are not publicised. Assisted Reproductive Technologies (ARTs) have relatively low success rates. They also pose risks to the gestational mother, the baby and the ovum donor. Among the complications are hyper-ovulation syndrome, multiple pregnancies and the risks of techniques such as foetal reduction. Babies from ARTs are more often of low birth weight and have a higher rate of birth abnormalities than babies born the conceived naturally. These facts are generally known in the profession but donors and their customers are rarely made aware of them.104

The other main issue in India is the commoditization of body parts, such as the clandestine trade in kidneys, placentas and aborted foetuses for medical research and organ transplant purposes.

VANITY SURGERY

The issue of ‘vanity’ or aesthetic surgery contributing to the development of unjust social norms and superficial definitions of beauty raises many ethical issues. Vanity surgery is costly and the implication then is that the rich can ‘buy’ beauty promoting further inequity in society and making the economically deprived insecure. In developed countries there has been an increase in the number of young females seeking surgery to chase physical perfection, with rhinoplasty being performed on girls as young as 14. In Asia a similar phenomenon is seen with double eyelid surgery for the Chinese race and skin whitening for the darker ethnicities.

Social and ethical issues aside, vanity surgery also delivers medical risks, illustrated by the following case of a Singaporean liposuction procedure which resulted in death, below. Singaporean General Practitioners are allowed to practice certain liposuction procedures (reputedly up to 1kg of fat) and these surgeries are more profitable than general consulting, leading unscrupulous doctors to promote them needlessly.

CASE STUDY: DEATH FORM LIPOSUCTION104

The death, in January 2010, of a 44-year-old man who underwent liposuction treatment at a general practitioner’s clinic, seems to be Singapore’s first such case. Franklin Heng, who was the CEO of property firm, YTL Pacific Star died following the fat-reduction treatment. The Singapore Medical Association said in a statement that, since July 2008, it had received three complaints related to aesthetics treatment, but that none were related to liposuction.

Generally, plastic surgeons say, liposuction has a 90% success rate and complications include fat embolism, where fats enter the circulatory system during surgery or electrolyte imbalance, where a lack of salts cause seizures in a body. Experts say surgical inexperience can also result in the tubes used for withdrawing fats instead puncturing vital organs, resulting in internal bleeding.
COMMUNITY INVESTMENT

In the west, CSR is becoming an integral part of the business models of healthcare companies. Community investment, in the form of not-for-profit medical care, disaster and calamity relief programs and disease treatment 'camps' are examples of strategic investing in community initiatives. In South and South East Asia, where natural calamities are becoming far too regular, in part due to climate change, privately run hospitals are frequently expected to provide pro bono medical and financial aid in times of disaster. Governments may also pressure private hospitals to act on behalf of the community at times of pandemics such as the SARS (2002) and H1N1 (2009) breakouts and the Tsunami in 2004.

Community investment is an important way for private hospitals in the region to earn social and political good will. Most do not offer healthcare services to the poor directly so this is an important strategic direction for them.

CASE STUDY: APOLLO’S STRATEGIC COMMUNITY DISASTER RELIEF\(^\text{25}\)

The Apollo Hospitals Group offers ‘timely and efficient assistance’ whenever disasters affect the community. It has provided manpower and materials for relief and rehabilitation of victims in multiple locations.

Cyclone relief (Andhra Pradesh), May 1990
A cyclone relief camp was set up at Madipattinam, Guntur, Andhra Pradesh that covered surrounding islands and villages for nearly 10 days.

Earthquake relief (Maharashtra) May 1994
Relief work was done at Latur, Maharashtra to help the victims affected by the earthquake.

Cyclone relief (Andhra Pradesh) November 1996
A cyclone disaster relief team was sent to the Godavari districts in Andhra Pradesh. About 3500 patients were provided relief.

Earthquake relief (Gujarat) January 2001
A multi-specialty medical team of 30 personnel and support staff with OT equipment and medication were deployed in Gujarat in response to the massive earthquake in January, 2001. Flying medical squads were set up performing over 40 plastic and orthopedic surgeries. Medical teams went from village to village treating patients.

Tsunami relief at Chennai – December 2004
Apollo hospitals played a substantial role in providing medical care to the victims of the Tsunami in December 2004.
- Over 12,000 patients were treated at the special Tsunami relief medical centres set up in Chennai, Nagapattinam, Pondicherry, Cuddalore and Colombo.
- Medical services, food, clothing and medical teams to affected areas were dispatched through the hospital network.
- Over 200 medical professionals were positioned at key locations.
- Medical supplies worth over Rs.2 million were sent out.
- Rs.10 million was made to a relief fund in Tamil Nadu.
- An additional contribution of Rs.3 million was made towards the relief in Andhra Pradesh and Sri Lanka.
- A dedicated Helpline number was created to enable members of the public and concerned corporate donors to extend their support.

Disaster Relief Floods in Chennai - November 2005
A medical relief camp was arranged at Chennai for victims affected by flood and treatment was provided to over 2000 people.

FOCUS: WORLD CLASS HEALTHCARE IN ASIA

Singapore\(^\text{26}\)

Singapore has one of the highest levels of medical care across Asia earning the title of Asia’s regional centre of medical excellence. The well-established healthcare system is composed of 13 private hospitals and a number of specialist clinics, each one catering to the needs of specialised patients at varying costs. What is remarkable is that Singapore spends only 4% of its GDP on healthcare compared to 14% in the United States and 10% in France, while achieving comparable life expectancy figures.\(^\text{10}\)

Life expectancy is not the only indicator of the quality of healthcare. Singapore also performs well on other indicators, including low infant mortality rates and acceptable waiting times for most forms of healthcare treatment (particularly noticeable in public health care facilities).

Patients are free to choose their healthcare providers, both within the public and the private healthcare system. Medical practitioners are generally well-trained and qualified. Furthermore, pharmaceuticals are widely available from pharmacies, department stores, supermarkets, shopping centres and hotels.

Both the private and public hospitals in Singapore are equipped with state of the art medical equipment in order to maintain the highest standards of medical services. Certain training hospitals also deliver world beating healthcare services such as Singapore General Hospital, Tan Tock Seng Hospital and National University Hospital as well as the private hospitals, Gineagles and Mount Elizabeth Hospital, which charge more for care.

The key to Singapore’s efficient health care system is the emphasis on the individual to assume responsibility for their own health and, importantly, their own health expenditure. The result is a system that is predominantly funded by private coverage and out of pocket expenditure. For example, in 2002, private expenditure on healthcare made up 70% of total health expenditure in Singapore (that is, financed by individuals or employers on behalf of individuals) amounted to almost 67% of total health expenditure with the remaining 33% financed by the government from the national tax revenue. In most developed countries these proportions would be reversed with the bulk of the services being provided for by tax revenue. Singapore’s low public health expenditure means that individual income tax rates can remain very low, (2-28% for individuals and 17% headline tax for companies) compared to other countries that need to draw higher taxation revenue to fund their public health expenditure.

The Singapore health system is based on a workable combination of government subsidies (funded through taxation) and individual responsibility. In order to assist individuals to meet their personal medical expenses, the Government has established the ‘3M’ framework of Medisave, Medishield and Medifund which provides a safety net to support the health needs of low-income Singaporeans. The Government has also recently introduced Eldershield, a private insurance scheme designed to help fund future medical expenses incurred in the event of severe disability, especially at advanced age.

In addition to individuals self-financing through Medisave, Medishield and Eldershield, a significant portion of workers and their dependents are covered by private health insurance. This is often funded by employers on behalf of employees and covers a diverse range of medical expenses that are not typically reimbursed under the 3M system.

Invariably, individuals will still need to pay some of their medical expenses directly (deductibles and co-payments), even after receiving reimbursements from Medisave, Medishield or private health insurance. Over The Counter prescription drugs are also not covered by private health insurance.

The use of compulsory savings (that is, the Medisave account) has been very successful as the main source of private funding for hospital expenses.
The government has been successful so far in ensuring that overall health expenditure does not fall victim to inflationary pressures evident throughout the rest of the world. This has been achieved by micro managing the supply and prices of healthcare services in the country.

**Hong Kong**

Hong Kong’s healthcare system is well respected and standards are comparable to some major European cities. Both private and public facilities are available. The decision on where to seek treatment normally depends upon what is covered in a particular health plan and where the specialists are located (some specialists only practice in public teaching hospitals).

Hong Kong has the lowest infant mortality rate in the world and the second highest life expectancy rates and, at 5.2% of GDP, its health care spending is about half of the OECD average. All medical students are trained to use and rely on electronic medical records.

Hong Kong government supports 55% of the total healthcare expenditure. 12% comes from health insurance and 33% comes from out-of-pocket contributions.

Since the Hong Kong Hospital Authority took over the management of public hospitals over a decade ago, tremendous strides have been made to improve the quality of healthcare. The levels of service, both in terms of availability of newer technologies and access to quality care can now be considered at par with highly developed countries.

Medical practitioners are now trained in "good practice". Good practice means that they are required to have active participation in continuing education, clinical audits, attendance of clinical management meetings, community care participations, and contributions to clinical research, teaching, and data.

In Hong Kong people enjoy public health care for nominal fees, but have potentially lengthy waits for non-essential surgery. For example, the average wait to see a specialist is more than seven months. The average wait is 2-3 years for Lasik surgery and 4-5 years for plastic surgery.

**Comparison between the Singapore and Hong Kong healthcare systems**

Both Singapore and Hong Kong have world-class healthcare facilities and indicators. Life expectancies and infant and maternal mortality indicators compare well with those in advanced western countries. Remarkably too, these governments spend significantly less of their GDP on healthcare, 4% for Singapore and 5% for Hong Kong, compared to other developed countries.

There are certain differences between the Singapore and Hong Kong healthcare systems. In terms of quality of care, Singaporean patients seem to have lower waiting times in their public hospitals compared to their counterparts in Hong Kong and Hong Kong patients seem to suffer from a general problem of over-prescription which does not seem to be apparent in Singapore. There are also minor differences in terms of government subsidies. In Singapore, the government contributes to around 33% of health expenditure whilst in Hong Kong that figure is around 55%. 
HOSPITAL BOARDS

An ideal hospital board should demonstrate a degree of independence in the same manner as companies from other industries. The board should comprise of independent directors and individuals from diverse professional backgrounds who practice processes that meet minimum acceptable levels of corporate compliance. Disclosure levels should be adequate enough for outsiders to understand most parts of the business. The corporate governance report should disclose attendance and results of meetings for all committees.

A critical part of the board’s strength and independence comes from the separation of the office of CEO and chairman. The board should also have independent directors in the true sense of word, at least as many as the local legal requirement. Apollo Hospitals in India, for example, has a board comprised of 15 members of which nine are independent, well above SEBI’s minimum requirement. Board audit, remuneration and nomination committees should exist and should have independent directors as well. The same individuals should not sit on all three boards.

Bumrungrad Hospital’s board is supported by these three committees alongside an investment committee. The Governing Board consists of three directors, two management, six physicians and one member by invitation. In 2008, the Governing Board held six meetings.

CORRUPTION

Hospitals and healthcare facilities are witness to corruption at several levels and the degree of corruption tends to reflect the overall country transparency level. For instance, Indonesia, Philippines, India and China have generally higher endemic corruption levels than the other countries.

Hospital corruption includes doctors accepting bribes from pharma companies to prescribe their medicines, hospitals purchasing teams accepting bribes from healthcare equipment companies and patients having to pay additional ‘rents’ to get decent medical services in hospitals. Doctors also often conduct private practice alongside their public jobs and often accord more preference to the private practice.

According to a 2005 New York Times article, “the bribes vary from place to place and in the services affected, but stretch from cradle to grave... People pay to give birth, and to collect their loved ones’ bodies from mortuaries, and for everything in between: garbage collection, clean water, medicines.” A survey at a birthing centre found that nine of ten families whose relatives gave birth in the hospitals reported paying a bribe, usually to see the baby. The average amount paid was around $7. In 2003 eight in ten women reported paying bribes- to have their baby delivered, to see the child after birth, to get their newborn immunized or to obtain medicines that were supposed to be free.

It is common practice for maternity nurses in Bangalore to ask for payment to bring babies to their mothers after birth.

Source: New York Times 2005
GOVERNMENT RELATIONS

Hospitals are always in the public eye and, as a means to deliver on political promises to the electorate, they are often misused by those in power. Use of facilities come under government scrutiny due to access to healthcare issues, community investment and during natural calamities.

Government relations become a matter of concern in states with high levels of corruption. Public hospitals have large capital outlays for procuring equipments and upgrading infrastructure. Authorities may often force the hospitals to procure sub-standard equipment to serve their own interests. This case study of a former health minister of Indonesia embroiled in graft charges illustrates this.

CASE STUDY: FORMER HEALTH MINISTER FACES JAIL FOR GRAFT

In April 2010 former Indonesian health minister, Achmad Sujudji, was sentenced to five years in jail for corruption that caused state losses of over US$11 million. The Prosecutor said Sujudji was responsible for directly appointing PT Kimia Farma Trade and Distribution as the ministry partner in the procurement of health devices distributed to 32 hospitals in East Indonesia in 2003-4 without a state procurement tender process and of marking up prices. The prosecutor has suggested that total kickbacks to ministry officials came to over Rs. 8bn. Achmad was also indicted for abuse of power in order to enrich himself, other people and corporations, and causing significant losses to the state.

Another defendant from the Health Ministry indicted the same day, former Planning and Budgetary division head Madiono, was allegedly involved in a corruption case in relation to the ministry’s x-ray procurement arrangements for remote areas. He was facing up to 20 years jail for appointing the winner of a public auction without due process. KPK found indications of possible state losses of almost Rp10 billion as a result of markups.

FOCUS: POOR HEALTHCARE IN THE PHILIPPINES

The Philippines health system is a highly fragmented mixture of public and private healthcare providers, with most private facilities located in the metropolitan area. Although the public sector has a relatively well-developed infrastructure and the National Health Insurance Programme (NHIP) is expanding its coverage, the population relies on private out-of-pocket spending for much of healthcare provision and most pharmaceutical purchases.

Around 60% of overall healthcare is funded by the private sector and there are more private than public hospitals. Decentralisation of public healthcare has led to a deterioration of public healthcare and further contributed to inequality in healthcare provision. High population growth and continued migration of people from rural areas to the major cities, will place a great strain on the inadequate public health services over the next five years.

A combination of a lack of resources, volatile economic performance, regional disparities and poverty has prevented significant healthcare reform in the Philippines, although attempts at improvements continue to be made. Many Filipinos, particularly in the more remote regions of the country, have no access to healthcare in any form. Moreover, access to pharmaceutical services is confined to a comparatively small segment of the population, estimated to be just 10-20% of the total.

The health system also continues to suffer from a severe exodus of qualified doctors, nurses, staff and pharmacists, who like many educated Filipinos, are leaving to work in more developed countries. Remittance money remains an important contributor to the Philippine economy. The Alliance of Health Workers (AHW) claimed in 2006 that less than half the country’s private hospitals were fully operational due to the shortage of nurses and doctors, and that many qualified doctors leaving the Philippines were working as nurses, particularly in the United States. Unequal distribution of healthcare workers remains another problem, with most doctors concentrated in the urban areas.

Although health indicators have improved, the health status of Filipinos still reflects the paucity of spending on healthcare, as well as continued lack of disease prevention and investment in basic public health measures, such as clean drinking water. The major causes of death are infections, including diarrhoeal infections, bronchitis, pneumonia, influenza, tuberculosis, malaria, measles and chickenpox. In addition, cardiovascular disease, malignancies and pulmonary disorders are moving up the list of leading causes of mortality and morbidity.

Life expectancy at birth is still relatively low, averaging 68 years for the total population. Infant and maternal mortality rates are a particular cause of concern. Child mortality (under five years of age) was 24 per 1000 live births.

The combination of the recent turbulent political environment, corruption, the distant possibility of a debt crisis, terrorism and kidnapping incidents of recent years will conspire to hamper more concerted efforts to boost investment in the healthcare sector. The new political regime led by Liberal Party leader Benigno “Noynoy” S. Aquino III aims to achieve a “holistic and comprehensive” public healthcare system. Speaking at the Philippine Academy of Family Physicians (PAFP) Universal Health Care Forum before 3,000 doctors, Noynoy promised to ensure that all Filipinos have access to Philippine Health Insurance Corporation (PhilHealth) cards and its services. He noted that the National Health Insurance Law that created PhilHealth had called for health insurance for all Filipinos by 2010. However, according to the National Demographic and Health Survey of 2008, health insurance still covers only 38% of the Philippine population. Aquino said he will work with local government and private health professionals to make sure that the services are available in hospitals and clinics everywhere. His administration has promised to build 22,000 more barangay (local) health stations, 3,000 more outpatient rural health units, and at least 150 more district hospitals as well as increasing the health budget to 5%.

Universal healthcare cannot be achieved in the Philippines, however, without eliminating graft and corruption. According to estimates, in 2009 alone, 280
billion pesos from the national budget was lost to corruption, much of it in the health care system. This amount could have built 560,000 health clinics around the country.

Presently, the country boasts around 1,708 Department of Health (DOH) licensed hospitals, more than 1,100 of which are privately operated, while the remaining 640 are operated by either the DOH or by local governments. The administration of the health sector is currently highly decentralised, with much of the work being undertaken by local government officials, which can make planning difficult and inefficient. Also, with power devolved to local institutions, there are far greater opportunities for corruption, with some industry observers claiming that this is the primary reason for a substantial rise in such activities over the past decade.

Despite some encouraging signs, a recent study by Transparency International claims there to be substantial malfeasance in the Filipino health sector. In its 2006 report, the organisation ranked the Philippines 126th out of 163 countries for corruption. The UN Development Programme estimates that, in 2004, 13% of the government’s annual budget – approximately US$1.8bn – was lost to ‘official’ theft. Industry sources say that these practices are severely damaging a health system that is already underfunded. In one example, millions of pesos were lost through the illegal sale of vaccines and medicines in a single government hospital.

The problem has escalated in the past decade, primarily because many civic functions have been devolved from central government to local institutions. It is alleged that local officials often hoard medicines and then distribute them during election campaigns in order to win votes. In addition, there is a thriving trade in faked pharmaceutical diplomas to untrained personnel wishing to open a pharmacy. Pharmaceutical companies have also been accused of bribing local officials to pay inflated prices for medicine purchases with kickbacks reaching their pockets.

Counterfeit drugs remain a serious threat as pharmaceuticals remain largely unaffordable. Currently, around 5% of the population consumes more than 66% of the drug market in value terms. Despite the recent introduction of tougher penalties, including the possibility of life imprisonment for convicted counterfeiters, fake drugs remain a serious problem, especially in urban areas such as the capital city, Manila, where fakes account for 10% of the drug market. Recent data suggest that only US$23mn of counterfeit goods (across all industries) were seized by the authorities in 2005, a minimal amount considering the size of this trade, driven by high drug prices and estimated to be worth around US$140m per year. Most counterfeits enter the country from Thailand, India and China. The most commonly counterfeited drugs are leading branded cancer and HIV/AIDS treatments. These drugs are targeted by counterfeiters because of their cost, with a month’s supply of ARVs costing up to US$600.
The development and regulation of the biotech industry has triggered ‘ethical’ discussions from different academic fields including economics, law, politics and even history. Specifically, however, the genetic engineering of living cells, plants, animals and human beings has brought ethical concerns and issues to the forefront. The media has made much of the ethical arguments against the creation of genetically engineered food products, the cloning of the sheep “Dolly”, the deciphering of the human genome, stem cell harvesting and research on “cloning” human embryos. Diverging views have been expressed, as representations of our “natural” world are constantly challenged.

There are certain products and processes which are raising particular concern: genetically modified organisms (GMO) biofuels, natural and genetic resources derived from bio-prospecting, transgenic and cloned animals, private genetic information systems and stem cell banks.

The biotechnology community in Asia has seen significant growth in recent years. By establishing in several key niche markets, the Asian biotech and pharma industries have thrived. The high standards of life science education in Singapore and India have increased the level of growth and the quality of workforces and broadened its reach within the world. With a dedication to innovation and research, Asia has established itself as a leader in biotechnology.

China and India, with their low-cost base and huge scientific talent pool, are likely to emerge as the highest potential biotech research and manufacturing outsourcing destinations in the future. Singapore already has a thriving biotechnology industry focusing on high-end value-added research. Asia is expected to become the major destination for stem cell research and biogenetic manufacturing.

In Asia there are not the same levels of low public support for genetically modified food as one finds in Europe. Here there are generally positive attitudes to science, technology and biotechnological progress, particularly where feeding rapidly growing populations is concerned. Genetically Modified (GM) food is often seen as morally unacceptable and a risk for society due to its implications on biodiversity. It remains unclear if technical progress could inspire more positive opinions. NGOs adverse positions, stemming from ethical concerns on health and environmental safety issues, have been influential and resulted in the 1999 EU moratorium on GM food and crops.

Populous less-developed Asian countries as India and China, however, are hugely interested in GM, which is seen as a ‘sustainable’ or ‘humanitarian’ means to ‘feed the hungry’ and reducing deforestation in order to plant more agricultural crops. Support hence depends on the GM industry’s ability to address the long term concerns about environmental, health and biodiversity impacts of using mass monoculture GM products. There is still quite a bit of political resistance to introducing GM foods. The Indian government, for example, has rejected the development of GMO Brinjal production due to health concerns.

In most cases public and government support for genetic testing and mapping technology in Asia remain strong. The morality and uses of deciphering of the human genome has been debated for many years and non-medical use of genetic information still inspire debates and adverse positions from NGOs, particularly in the United States. Additionally, the future development of pharmacogenetics, the study of how genetic variation and differences in metabolic pathways give rise to differing responses to drugs, will be closely monitored.

In all countries, medical professionals and facilities will have a more important influence on the general regulation and storage of genetic information. In Asia, genetic testing in most countries is still only in concept stages and awareness levels are low.

Public attitudes on adult and embryonic stem (ES) cell research in the region are also generally positive and it is seen as an exciting technology which has the likelihood to deliver new treatments and therapies to existing diseases and save lives. Many single disease associations support ES research already.

Human reproductive cloning, on the other hand, is generally seen viewed negatively. Debates on the production of embryos through nuclear transfer techniques (“therapeutic cloning”) are very intense in countries with highly influential religious groups, such as the Roman Catholic Church in the Philippines. In India and China, ES cell research and “therapeutic cloning” do not seem to have become of religious or ethical concern.

In our upcoming food report (Feeding Asia: Issues for Responsible Investors) we highlight two recent cases concerning the global use of biotechnology. The first looks at opposition to GM beets in the United States. The Interfaith Center for Corporate Responsibility (ICCR) has been led a campaign on behalf of its investor partners, mostly faith-based investors opposed to GMO. The other case pertains to genetically engineered rice contaminating organic rice, causing a furore in Europe and beyond. These risks could increasingly threaten companies involved with genetic engineering operations in Asia as well.
## THE FRONTIER MARKETS: PAKISTAN, VIETNAM, CAMBODIA

<table>
<thead>
<tr>
<th>Healthcare Indicator</th>
<th>Cambodia</th>
<th>Pakistan</th>
<th>Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult HIV/AIDS Prevalence Rate (%)</td>
<td>0.80%</td>
<td>0.10%</td>
<td>0.50%</td>
</tr>
<tr>
<td>ARV Coverage Rate (%)</td>
<td>67%</td>
<td>3%</td>
<td>26%</td>
</tr>
<tr>
<td>TB Prevalence Rate (Rate per 100,000)</td>
<td>680</td>
<td>314</td>
<td>281</td>
</tr>
<tr>
<td>Malaria Cases (#)</td>
<td>261,956</td>
<td>1,498,882</td>
<td>70,324</td>
</tr>
<tr>
<td>Percent With Water (%)</td>
<td>65%</td>
<td>90%</td>
<td>92%</td>
</tr>
<tr>
<td>Access to Sanitation (%)</td>
<td>28%</td>
<td>58%</td>
<td>65%</td>
</tr>
<tr>
<td>Population Undernourished (%)</td>
<td>26%</td>
<td>23%</td>
<td>14%</td>
</tr>
<tr>
<td>Child Malnutrition (%)</td>
<td>28.40%</td>
<td>31.30%</td>
<td>20.20%</td>
</tr>
<tr>
<td>Health Expenditure Per Capita ($)</td>
<td>$96</td>
<td>$47</td>
<td>$151</td>
</tr>
<tr>
<td>Total Expenditure on Health (%)</td>
<td>5.90%</td>
<td>2.00%</td>
<td>6.60%</td>
</tr>
<tr>
<td>Out-of-Pocket as a % of total health expenditure (%)</td>
<td>62.68%</td>
<td>81.84%</td>
<td>61.07%</td>
</tr>
<tr>
<td>Physicians (Rate per 10,000)</td>
<td>2</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Nurses and Midwives (Rate per 10,000)</td>
<td>9</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Births Attended by Skilled Health Personnel (%)</td>
<td>44%</td>
<td>39%</td>
<td>88%</td>
</tr>
<tr>
<td>Hospital Beds (Rate per 10,000)</td>
<td>NA</td>
<td>10</td>
<td>27</td>
</tr>
<tr>
<td>Infant Mortality Rate (Rate per 1,000)</td>
<td>54.79</td>
<td>65.14</td>
<td>22.88</td>
</tr>
<tr>
<td>Maternal Mortality Ratio (Rate per 100,000)</td>
<td>540</td>
<td>320</td>
<td>150</td>
</tr>
<tr>
<td>Life Expectancy - Female (#)</td>
<td>64</td>
<td>64</td>
<td>75</td>
</tr>
<tr>
<td>Life Expectancy - Male (#)</td>
<td>58</td>
<td>63</td>
<td>70</td>
</tr>
<tr>
<td>GDP Per Capita ($)</td>
<td>$2,000</td>
<td>$2,600</td>
<td>$2,800</td>
</tr>
</tbody>
</table>

Source: [http://www.globalhealthfacts.org](http://www.globalhealthfacts.org)
Ayurveda, the traditional Indian integrated healthcare system and Traditional Chinese Medicine (TCM) remain the most ancient yet living traditions in medicine. Increased side effects of Western medicines, lack of available curative treatments for several chronic diseases, high cost of new drugs, microbial resistance and emerging diseases are some reasons for renewed public interest in complementary and alternative medicines (CAM).

TCM includes several components including acupuncture, acupressure, herbal remedies, diet, massage, and lifestyle. Today, acupuncture describes a family of procedures involving stimulation of anatomic points on the body by a variety of techniques. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by hand or by electrical stimulation. Variants of needle therapy include stimulation of acupuncture points by vigorous massage (shiatsu, a Japanese technique), heat (moxibustion), lasers, magnets, gentle massage, pressure, or electrical currents (similar to kinesiology).

Developed by Samuel Hahnemann in 1790, homeopathy is another alternative health therapy which is based on the theory that 'like cures like', meaning that small, highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses could actually cause those symptoms. Unlike classic pharmacology, homeopathy follows the theory that the greater the dilution, the greater the potency of the product due to the bodies ability to protect itself.

In India the value of the ‘botanicals’ trade is about US$10 billion per annum with annual exports of around US$ 1.1 billion while China’s annual herbal drug production is worth US$4.8 billion with export of US$3.6 billion. Presently, the United States is the largest market for Indian botanical products accounting for about 50% of the total exports. Japan, Hong Kong, Korea and Singapore are the major importer of TCM products taking 66% share of China’s botanical drugs export.122

Basic Principles of TCM and Ayurveda

Ayurveda and TCM have many commonalities. The focus of both the systems is on the patient rather than disease. Almost half of the botanical sources used as medicines have similarities; moreover, the systems have similar philosophies geared towards enabling classification of individuals, materials, and diseases.

TCM considers the human to be at the centre of the universe as an antenna between celestial and earthly elements. Water, earth, metal, wood and fire are the five elements in the material world. The world is a single unit and its movement gives rise to yin and yang, the two main anthetic aspects which can be viewed as ‘opposites’, such as the positive and the negative. However, Chinese believe that yin and yang are not absolute but relative elements. Consistent with the modern view of homeostasis, yin and yang are interchanged to meet the view that ‘yang declines and yin rises’ or ‘yang is raised to produce a decline of yin’. There are four bodily humours - qi (or chi) blood, moisture and ‘essence’ - and the internal organ systems (zang fu) play an important role in balancing yin and yang in human body. When the two energies ‘fall out of harmony’ disease is thought to be allowed to develop. and illnesses are caused by factors related to climate changes, a person’s emotional changes and his or her personal habits. The physician takes into account this concept while treating patients. Drugs or herbs are used to correct this imbalance of yin–yang in the human body.

Ayurveda considers that the universe is made up of combinations of the five elements (tattvas) and five ‘doshas’ or ‘fluids’ that are akasha (ether), vayu (air), teja (fire), aap (water) and prithvi (earth). The five elements can be seen to exist in the universe at all scales of life and in both organic and inorganic things. In the human system elements are grouped into three forces, which govern life processes. These three forces (kapha, pitta and vata) are known as the three ‘doshas’ or simply the tridoshas. Each of the doshas is composed of one or two elements. Vata is composed of space and air, Pitta of fire, and kapha of water and earth. The tridoshas are thought to regulate all physiological and psychological processes in living organisms. The interplay among them determines the qualities and conditions of the individual. A harmonious state of the three doshas creates balance and health; an imbalance, which might be an excess (vriiddhi) or deficiency (kshaya), manifests as a sign or symptom of disease.

OVERVIEW

The best-known chain of TCM stores in Asia is Eu Yan Sang, founded in 1879 with the mission of “Caring for Mankind”. It has been listed on the Singapore Exchange since 2000. EYS manufactures and retails traditional Chinese medicine and herbs in Hong Kong, Macau, China, Malaysia and Singapore and operates clinic services in Singapore, Hong Kong and Malaysia.

It is a well-managed company with a strong stated governance policy which can be found on its website. It’s Board obviously thinks carefully about the bio-ethics and is developing sophisticated fingerprinting technology using analytical chemical techniques including High Performance Liquid Chromatography, Thin Layer Chromatography, Gas or Liquid Chromatography/Mass Spectroscopy (LC/ MS), Gas and Infrared (IR) and Ultraviolet (UV) Spectroscopy, to establish a ‘chemical barcode’ for each product which will help define the source, toxicity and harvest date of ingredients. This scientific and systematic approach of fingerprinting will enable precise quantification of ingredients and properties of Chinese Medicine and ensure the stability and consistency of quality between products of different batches.
Presently, the Indian systems of medicine uses over 1,100 medicinal plants of which most are collected from the wild. More than 60 species are in great demand. The tribal belt of India is rich in these plants and the tribes mainly depend on this trade for their livelihood. There are ample opportunities for adulteration and contamination in the process. Similar to China, India needs to follow Good Agricultural Practices (GAP) to ensure the use of correct raw materials and cover the entire life cycle including the harvesting, processing, transportation and storage. The Chinese government has developed more than 100 research units and encouraged private enterprises to build over 600 standard planting bases for herbs in great demand.\textsuperscript{124} Selection of the correct germplasm using modern DNA fingerprinting and chemoprofiling techniques is a priority for this industry.

Controlled clinical trials are important to develop evidence for safety and efficacy of alternative therapies. Analysis of most frequently used plant based therapies in Ayurvedic system revealed that 43\% of them have been tested on humans while 62\% have been the subject of one or more animal studies.\textsuperscript{125} The Ayurvedic Pharmacopoeia of India gives monographs for 258 different Ayurvedic drugs. The standards mentioned are currently inadequate to understand the quality and likelihood of contraindications of the botanical materials.

Consistency in composition and biological activity are essential requirements for the safe and effective use of therapeutic agents. Quality is the critical determinant of safety and efficacy of botanical medicines. However, botanical preparations rarely meet pharma industry quality standards, which refer to procedures and markers for assessing and verifying the strength of botanical raw materials or extracts or formulations thereof.\textsuperscript{124} Chromatographic techniques and chemical marker assisted characterization of the botanicals is not thought to assure consistent biological activity or stability. Therefore, production of quality botanical medicines has become a challenge to regulatory authorities, scientific organizations and manufacturers.

WHO, US FDA and the European Scientific Cooperative on Phytotherapy (ESCOP) have published standard sets of guidelines to address these safety concerns. Some of the progressive manufacturers follow them to provide standardized botanical medicine. In India, about 9,000 licensed units manufacture traditional medicines with or without proper standardization.\textsuperscript{127} Indian manufacturers generally follow WHO guidelines for quality control.

Adulteration of product remains a major problem in domestic and export markets for Indian herbal products. Examples of chemical analysis of some Ayurvedic anti-arthritic medicines has led to a finding that synthetic anti-inflammatory drugs like phenylbutazone, indomethacin and/or corticosteroids have been added. Contamination with heavy metals such as mercury, arsenic and lead contamination has also become a critical problem in some cases.\textsuperscript{128} Market botanicals are often stored under undesirable conditions over the years and product can be contaminated or adulterated by other materials, thereby adversely affecting the efficacy and sometimes even adding to toxicity. Availability of the desired genotype of plant in the required quantity, free from toxic contaminants and with desired therapeutic activity has become critical for the industry.

Many TCM quacks operate in the region, professing to have training in TCM or Ayurveda. Several have no medical certification or training of any kind. The quality of alternative therapy education in colleges is also under suspicion. In a recent case the Sri Lanka Ayurveda Medical Council reported that there are around 5,000 bogus doctors practicing under the guise of Ayurveda physicians in the country. The government has established an Ayurveda Medical Council to ensure standards among the doctors practicing traditional medicine. There are currently about 17,500 Ayurveda medical practitioners registered under the Ayurveda Medical Council. However, the Registrar of the Council, Danister Perera said the Council has so far only approved 8,000 of them.\textsuperscript{144}
## HEALTHCARE IN ASIA: A COUNTRY SUMMARY

<table>
<thead>
<tr>
<th>Healthcare Indicator</th>
<th>China</th>
<th>India</th>
<th>Indonesia</th>
<th>Malaysia</th>
<th>Philippines</th>
<th>South Korea</th>
<th>Singapore</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult HIV/AIDS Prevalence Rate (%)</td>
<td>0.1%</td>
<td>0.3%</td>
<td>0.2%</td>
<td>0.5%</td>
<td>&lt;0.1%</td>
<td>&lt;0.1%</td>
<td>0.2%</td>
<td>1.4%</td>
</tr>
<tr>
<td>ARV Coverage Rate (%)</td>
<td>19%</td>
<td>NA</td>
<td>15%</td>
<td>35%</td>
<td>31%</td>
<td>NA</td>
<td>NA</td>
<td>61%</td>
</tr>
<tr>
<td>TB Prevalence Rate (Rate per 100,000)</td>
<td>88</td>
<td>185</td>
<td>213</td>
<td>121</td>
<td>418</td>
<td>126</td>
<td>27</td>
<td>163</td>
</tr>
<tr>
<td>Malaria Cases (#)</td>
<td>99,938</td>
<td>10,649,554</td>
<td>2,518,046</td>
<td>14,600</td>
<td>124,152</td>
<td>6,474</td>
<td>NE</td>
<td>257,020</td>
</tr>
<tr>
<td>Percent With Water (%)</td>
<td>88%</td>
<td>89%</td>
<td>80%</td>
<td>99%</td>
<td>93%</td>
<td>NA</td>
<td>NA</td>
<td>98%</td>
</tr>
<tr>
<td>Access to Sanitation (%)</td>
<td>65%</td>
<td>28%</td>
<td>52%</td>
<td>94%</td>
<td>78%</td>
<td>NA</td>
<td>NA</td>
<td>96%</td>
</tr>
<tr>
<td>Population Undernourished (%)</td>
<td>9%</td>
<td>21%</td>
<td>17%</td>
<td>&lt;5%</td>
<td>16%</td>
<td>&lt;5%</td>
<td>NA</td>
<td>17%</td>
</tr>
<tr>
<td>Child Malnutrition (%)</td>
<td>7%</td>
<td>44%</td>
<td>20%</td>
<td>NA</td>
<td>21%</td>
<td>NA</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Health Expenditure Per Capita ($)</td>
<td>216</td>
<td>86</td>
<td>82</td>
<td>544</td>
<td>120</td>
<td>1,467</td>
<td>1,536</td>
<td>264</td>
</tr>
<tr>
<td>Total Expenditure on Health (%)</td>
<td>5%</td>
<td>4%</td>
<td>3%</td>
<td>4%</td>
<td>4%</td>
<td>6%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Government Health Expenditure as Percent of Total Health (%)</td>
<td>41%</td>
<td>25%</td>
<td>51%</td>
<td>45%</td>
<td>33%</td>
<td>56%</td>
<td>33%</td>
<td>65%</td>
</tr>
<tr>
<td>Private Expenditure on Health (%)</td>
<td>59%</td>
<td>75%</td>
<td>50%</td>
<td>55%</td>
<td>67%</td>
<td>44%</td>
<td>67%</td>
<td>36%</td>
</tr>
</tbody>
</table>

| Social Security Expenditure on Health (%) | 57% | 5% | 17% | 1% | 26% | 77% | 18% | 12% |
| Out-of-Pocket Expenditure on Health (%) | 83% | 91% | 70% | 73% | 84% | 81% | 94% | 77% |
| Out-of-Pocket as a % of total health expenditure (%) | 49% | 69% | 35% | 41% | 56% | 36% | 63% | 27% |
| Physicians (Rate per 10,000) | 14 | 6 | 1 | 7 | 12 | 16 | 15 | 4 |
| Nurses and Midwives (Rate per 10,000) | 10 | 13 | 8 | 18 | 61 | 19 | 45 | 28 |
| Births Attended by Skilled Health Personnel (%) | 98 | 47 | 66 | 100 | 60 | 100 | 100 | 97 |
| Hospital Beds (Rate per 10,000) | 22 | NA | NA | 19 | 13 | 86 | 32 | NA |
| Infant Mortality Rate (Rate per 1,000) | 20.25 | 30.15 | 29.97 | 15.87 | 20.56 | 4.26 | 2.31 | 17.63 |
| Maternal Mortality Ratio (Rate per 100,000) | 45 | 450 | 420 | 62 | 230 | 14 | 14 | 110 |
| Life Expectancy - Female (#) | 75 | 65 | 70 | 75 | 74 | 82 | 83 | 74 |
| Life Expectancy - Male (#) | 72 | 63 | 67 | 70 | 67 | 76 | 78 | 66 |
| GDP Per Capita ($) | 6,000 | 2,800 | 3,900 | 15,300 | 3,300 | 26,000 | 52,000 | 8,500 |

Source: http://www.globalhealthfacts.org
Regulatory trends in Asia vary tremendously between developing and developed countries. While developed countries like Singapore and South Korea have advanced regulatory standards, this is not the case with most of the other countries in the region. We have summarized some of the key regulatory trends below.

**China**

In January 2009, the SFDA issued a new regulation, Requirements on Special Approval for New Drug Registration, setting up expedited approval for certain types of drugs. In theory, these drugs are supposed to receive significantly faster technical approval, promoting research and development. The categories affected are as follows:

- Active ingredients or their formulations extracted from plant, animal, or mineral resources that have never been marketed in China
- Chemical raw drug materials, their formulations, or biological products, which have never been marketed anywhere in the world
- New drugs with demonstrated therapeutic advantages in treating AIDS, cancer, or rare diseases
- New drugs to treat diseases for which no effective therapy currently exists

The details of this system, however, have not yet been made concrete. For example, there is no definition so far as to what constitutes a ‘rare’ disease for the purposes of receiving special approval status (The US FDA definition is a disease with under 200,000 patients). It remains to be seen how easy and accessible the system will actually be to the drug industry.

In 2008, the SFDA issued a set of technical guidelines concerning changes to previously-approved chemical drugs. These guidelines laid out in detail the issues and responsibilities for post-market approval changes. Drug manufacturers must inform the SFDA of any changes that require additional testing. If a single change requires testing, the SFDA must conduct the review. If the change involves multiple changes, then the SFDA can do a review. However, in 2008, the SFDA passed a proposal that may allow for the use of third parties in the future.

In 2008, a third-party testing entity was used on a trial basis to verify product samples of several TCMs that were submitted with their registration application. The SFDA is now making plans to incorporate such outsourced testing into the Chinese drug registration system. Eventually, this could greatly speed up the back-up registration process. The initiative could pose concerns on IP protection. However, the SFDA has said it will only provide third-party organizations with limited sections from the registration applications to protect IP.

**India**

Most of India's pharmaceutical product policy is governed by the Drugs and Cosmetics Act (DCA). The DCA was first enacted in 1940 and has been amended numerous times since then. It is administered by both National and State level authorities. The principal national drug authority in New Delhi is the Central Drug Standards Control Organization (CDSCO). CDSCO is often referred to as the DCGI, which stands for Drug Controller General India, the title of its head official. There are also state-level Food and Drug Administrations, one for each of 35 India’s states and territories. The DCGI registers all imported drugs, new drugs, and drugs in certain categories. It also has responsibility for clinical trials and quality standards. The state-level FDBs register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections. The Indian cabinet has now approved a plan that would bring all drugs regulation under a new central drugs authority, modelled on the US FDA.

The DCGI has a shortage of reviewers, often relying on outside experts to provide opinion. To pursue regulatory approvals effectively, a company must use a regulatory professional based in New Delhi with significant experience in applications for foreign companies.

Drugs count as ‘new drugs’ in India if they fall into one of the following categories:

1. Drugs never marketed in India
2. Drugs with new therapeutic purposes or dosages that have not been marketed in India
3. New fixed-dose combinations of two or more drugs
4. Any drug which was first approved in India less than 4 years ago, unless it is included in the Indian Pharmacopoeia
5. Also, all vaccines are treated as new drugs, unless notified otherwise by the DCGI

All submissions require basic dosage and indication information, test specifications of active and inactive ingredients, listing of any applicable patents, and the raw material manufacturer.

New fixed-dose combinations, new dosages and indications, new bulk drugs, and new formulations require additional testing. The DCGI can and does conduct the review of products that do not qualify for Path I or Path II evaluation processes. However, the guidelines mandate that, if the manufacturing location of an imported drug changes, GMP certification for the new site must be submitted. The process of registering drugs for marketing in China can be slow and tedious. Drug registration is only conducted by the SFDA, without technical assistance from third-party organizations (the ‘Notified Bodies’). However, in 2008, the SFDA passed a proposal that may allow for the use of third parties in the future.

In 2008, a third-party testing entity was used on a trial basis to verify product samples of several TCMs that were submitted with their registration application. The SFDA is now making plans to incorporate such outsourced testing into the Chinese drug registration system. Eventually, this could greatly speed up the back-up registration process. The initiative could pose concerns on IP protection. However, the SFDA has said it will only provide third-party organizations with limited sections from the registration applications to protect IP.

**Indonesia**

The drug registration process is divided into two categories:

1. New drug applications (a new active ingredient, a new derivative or combination, or a new dosage form, strength or indication)
2. Drug variation applications (drugs which have already been granted a marketing authorization license, but have undergone a modification of some kind)

The drug registration process consists of two stages:

1. Pre-registration and
2. Submission of the registration dossier.

The pre-registration process is conducted to determine the application review and evaluation pathway. The National Drug Evaluation Center (NA-DFC) reviews drug applications via one of three pathways, Path I, II or III. Path I includes drug applications for products used to treat serious or life-threatening diseases, or for essential generic drugs for public health programs. New drugs already approved in certain designated countries may qualify for the Path II registration process. Any drug applications for products that do not qualify for Path I or Path II evaluation processes will be reviewed via the Path III process.
Generally, applications are reviewed within the following timeframes:

Path I: 100 working days
Path II: 150 working days
Path III: 300 working days for new drugs; for all other drugs, 80 working days

Marketing authorization licenses are valid for five years in Indonesia. The regulations and accompanying forms and accompanying documents can be obtained in Bahasa Indonesian or English. Drugs produced for export-only are not required to have labels in Bahasa Indonesian and only English labels are required.

The following lists some of the documents and information required for the dossier:

- Good Manufacturing Practice (GMP) certificate
- Specifications and method of analysis
- Pharmacodynamic, pharmacokinetic and toxicity data
- Clinical trial report
- Labeling and packaging materials, including materials for the label, box, outer packaging, blister strip and catch cover
- Product insert/leaflet
- Product sample

The head of the NA-DFC is responsible for issuing the marketing authorization approval/non-approval decision. In some cases, the NA-DFC may request additional data in order to determine the product approval/non-approval. In this situation, the applicant will have 120 days to submit the requested information. If the applicant is unable to provide data within the given timeframe, the application will be rejected. However, the applicant has the option of resubmitting the dossier as a new registration application.

Singapore

The Center for Drug Administration (CDA) regulates pharmaceuticals in Singapore under the following five regulatory guidelines: Medicines Act, Poisons Act, Sale of Drugs Act, Medicines (Advertisement and Sale) Act and the Misuse of Drugs Regulations. The CDA's responsibilities include, but are not limited to, inspection and licensing of pharmaceutical manufacturers/importers/wholesalers, ensuring GMP and Good Distribution Practice (GDP) standards, and post-marketing surveillance.

Medicines Act

Under the Medicines Act, a medicinal product refers to a substance that is used in one of the following ways:

1. Administered to humans for a medicinal purpose or
2. Used as an ingredient in the preparation of a substance to be administered to humans for a medicinal purpose.

A pharmaceutical product may only be imported into Singapore if a product license has been granted by the Health Sciences Authority. In Singapore, product licenses are specific to the product name, formula, indication, use, manufacturing process, dosage form, and applicant. If any of these factors are changed, a new product license application or variation application will be required. Variation applications are acceptable for already-approved products which have a new indication, dosage recommendation, etc.

New and variation product license applications are evaluated via one of the three possible routes, depending on the type of product change. Pharmaceutical products which have not been approved by any regulatory agency will receive a full evaluation, which according to the CDA, takes approximately nine months to complete. If a product has already been approved by another country's regulatory authority, an abridged evaluation process will be required, taking around six months to complete. Finally, if the product has already been approved by one of the principle regulatory agencies (US FDA, UK MHRA, Australia TGA, EU EMEA or Health Canada), only a verification evaluation will be necessary. This third evaluation process takes about six weeks to complete.

Thailand

The Thai FDA regulates pharmaceuticals through the Drug Act which requires a company to obtain a license in order to import, sell or manufacture drugs in Thailand. Specifically, licenses are required for the following activities:

- Importing, manufacturing or selling modern medicines
- Acting as a wholesaler of modern medicines
- Selling modern medicines in sealed packages that are not classified as dangerous or specially-controlled medicines
- Importing, manufacturing or selling traditional medicines
- Selling veterinary medicines in sealed packages

Thailand's product registration process has been set up to ensure the safety, quality and efficacy of pharmaceutical products in Thailand.

According to the Drug Act, for product registration purposes, pharmaceuticals are divided into three categories:

1. New medicines (products with new chemicals, chemical combinations, indications, delivery systems or dosage forms)
2. Generics and
3. New generics (medicines with the same active ingredients, doses and dosage forms as those of new compounds registered after 1992)

Product registration licenses are valid for five years.

New medicines will require a complete dossier for registration, while generics will require dossiers containing only product details, manufacturing and quality control information. New generic drug applications will need to include bioequivalence studies in addition to the requirements for a generic drug application. The Drug Control Division of the Ministry of Public Health, or a provincial public health office, is responsible for reviewing and issuing registration licenses. Prior to granting a license, the health authority may conduct an inspection of the manufacturing site to ensure GMP compliance.

Malaysia

The National Pharmaceutical Control Bureau, through the Drug Control Authority, oversees pharmaceutical regulations in Malaysia. It was created to ensure the safety, quality and efficacy of pharmaceuticals in Malaysia and its responsibilities include:

- Registration of pharmaceutical products and cosmetics
- Licensing of drug importers, manufacturers and wholesalers
- Adverse Drug Reaction Monitoring

The registration process usually takes 12-18 months. Only locally-incorporated companies can apply for product registration. Foreign companies can use a Market Authorization Holder as their local company.

Some of the required documents for registration are:

- Letter from product owner stating that the local Market Authorization Holder is authorized to submit the application on behalf of the product
- Free Sale Certificate from country where product is made and GMP certificate
- Samples of finished product for testing with Certificate of Analysis

Philippines

Registration times for the large number of new generics entering the market lengthened further in 2008, but the situation is likely to improve once the Bureau for Food And Drugs (BFAD) is up and running. On-line registration is also in development.
In terms of improving Access to Medicine, the implementation guidelines of the Cheaper Medicines Act has clarified the Intellectual Property Code in respect of medical patents. The amendments cover regulations to do the following:
- Prevent originator companies blocking the introduction of new generics
- Exclude ‘frivolous’ patents
- Impose limitations on patent rights
- Introduce a ‘Bolar’ type early working provision where the patent owner cannot prevent testing, using, manufacture or selling of the invention and
- Introduce data protection from unfair commercial use

The code of marketing ethics in Philippines is also likely to improve with industry bodies voicing concerns about present abuses, particularly in the area of promotion to doctors. MNCs continue to adhere to strict international codes of marketing practice, such as those provided by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). However, local companies have been slower to adopt equivalent constraints, if only because doctors and retailers expect inducements to supply cheaper generic brands. Foreign trips and games of golf are still routinely offered.

Thailand

Further improvements in the efficiency of the drug approval process are anticipated, including acceptance of electronic submissions. Average registration times will continue to decline as a result, but full market access for new drugs is lengthened because of Safety Monitoring Periods (SMP), which precludes drugs in the monitoring period from listing on the National List of Essential Drugs (NLED) and sale through retail channels.

Adherence to tighter GNP and bioequivalence standards will be required as a result of Thailand’s commitments to the ASEAN harmonisation programme. This will result in the closure of some small, low-quality domestic producers. Recent surveys of drugs being prescribed to patients under the 30 Baht scheme have highlighted worrying problems with the quality of some locally manufactured products. Inadequate active ingredient concentrations and poor absorption rates were among the main deficiencies uncovered in a sampling programme undertaken by regulators, the results of which prompted the establishment of a new quality surveillance project designed to restore public confidence in pharmaceuticals.

Compulsory licensing has become a thorny issue in Thailand between the state and multinational pharma companies. Thailand issued their first ‘compulsory license’ in November 2006 and discussions about compulsory licensing intensified in January 2007, when the military government, without prior consultation with the industry, announced its decision to issue two further compulsory licenses. The government has not ruled out issuing further compulsory licenses for other patented, high-volume products.

Efforts will be made to clamp down on counterfeiting, with tougher penalties for those convicted of illegal trade to be introduced under the new Medicines Act. Tracking down imported and locally manufactured counterfeits will be difficult, however, and will only be effective if the Thai FDA receives adequate support from other regulatory organisations.
Private healthcare will continue to grow rapidly

The healthcare industry in Asia is expected to grow at about two and a half times the growth rate in the West, and the overall quality of care is gradually improving. With increased wealth, Asians are living longer, and diseases of the poor are being replaced by the diseases of the West (i.e. diabetes, heart disease). Many people in Asia want better healthcare and are happy to pay for it.

Although most Asians currently rely on state-subsidized care, more than 130 million Asians (not including Japanese) pay for some type of private healthcare. Private healthcare is expected to grow dramatically in the next ten years to over 60% of the overall healthcare sector. In Taiwan, private care is growing about 30% per year.

More Asians will benefit from health insurance

More and more of Asian populations will also be covered under their National Medical Insurance scheme. For example, in India, 20 million people are already covered under the NREGS Rashtriya Swasthya Bima Yojana and many more will come under the cover in the next two years. China is massively investing into expanding its own public health insurance scheme called the New Rural Co-operative Medical Care System (NRCMCS). Similar projects are planned in the developing countries in the region also.

Globalization will continue full speed

Global companies will need to source parts, manufacture, service and perform R&D throughout Asia in order to maximize economies of scale and get closer to their future customers. For example, researchers in China and India can be used to help expand R&D for US companies. Medical tourism from the west into Asia and also within Asia will continue to grow.

Generics companies in India and the rest of Asia will continue to aggressively increase their global product offerings at affordable prices. With more and more patented drugs coming off-patent within the next few years, the trend is unlikely to abate. We believe multinational pharma companies will continue to collaborate with generics companies either for low-cost manufacturing capabilities or for increasing distribution reach in Asia.

Medical alliances between medical institutions in the West and Asia will become more and more commonplace such as Singapore’s Enterprise Development Board (EDB) tying up with Stanford University’s School of Medicine. Stanford owns a stake in a joint venture in Singapore that is building an advanced medical imaging facility.

Product registration times should improve

Registration times are expected to improve in most of the countries in the region. Standardization of documents and computerization would enable quicker processing of registration in most countries in the region.

Quality standards will be the focus of attention in the region for two main reasons: the ASEAN harmonization program with its set of GMP and the crackdown on poor drug quality by countries such as China. With these two driving forces, governments would force pharma companies to pay more attention to product quality.

Intellectual property will continue to be at risk from compulsory licensing

Compulsory licensing is being adopted by countries like Thailand and Philippines to lower their cost of medicines. This trend is likely to catch on with other developing countries as well. The United States will continue to put pressure on regional governments to refrain from using the provisions of compulsory licensing. Governments are also likely to reject patent extension or new patent applications unless significantly different outcomes are proved.

Mandatory bioequivalence

Bioequivalence is also being mandated as a requirement for drug registration. However, ASEAN harmonization should lead to acceptance of bioequivalence data across countries.

Codes of marketing practice will become more commonplace

Pharma industry bodies are keen to implement marketing practice codes which require prohibiting companies to offer doctors and hospital personnel generous gifts and foreign junkets. In the absence of compliance from doctors and enforcement by governments, however, these codes are likely to have minimal impact. Already, multinationals are bound by their global codes of ethics which often do not apply to local companies.

Parallel imports and counterfeit products on the rise

Parallel imports from India and China are being encouraged by smaller countries like Philippines and Thailand, where drug prices are significantly higher. This trend is likely to continue, much to the dismay of originator companies. Counterfeiting is also on the rise. To control this trend, regulatory agencies will bring in new means of auditing the veracity of drugs such as electronic documentation and tracking.

Improved product labelling

More and more governments are now stressing the printing of certain vital information by generics companies on product packaging. This is to raise awareness about safety and dosages.
RISKS TO ASIAN CORPORATE EARNINGS FOR POOR HEALTHCARE
In many parts of Asia, a lack of clean water adversely affects human health and development. Using 1990 as a baseline, Goal 7 of the MDGs seeks to reduce by half the proportion of people without sustainable access to safe drinking water by 2015. Figure 15 shows access to clean drinking water as a percentage of national populations in 2004. We see here that Asian countries such as China, Indonesia, Myanmar, Bangladesh, Sri Lanka, Laos and Cambodia are not providing clean drinking water to over 83% of the population. Within countries also, there is great disparity between the urban and rural parts. For instance, in Eastern Asia, while 93% of the urban population had access to clean water in 2004, the figure for rural areas was only 67%.

With the deadline of the MDGs approaching, access to clean water has been expected to improve but, in general we find that pollution and toxicity from agriculture and industry is meaning that access to clean water is, if anything, worsening. Companies will need to be prepared for prevalence of water-borne diseases in their workforce and their families. This will potentially lead to additional financial burdens from higher insurance premiums and lost workdays.

Source: UNEP 2004

Figure 18: Access to clean water
There are three main vaccines included under all international vaccination programs. These are DTP3 (triple dose of diphtheria toxoid, tetanus toxoid and pertussis vaccine), MCV (measles-containing vaccine) and POL3 (polio vaccine). Coverage with three doses of the DTP vaccine is generally used as a proxy for a fully immunized child. DTP coverage is also seen as an indicator of health system performance.

The vaccination coverage rates for various Asian countries covered in this report are shown in Figure 4 below. India still has some of the lowest coverage rates in the world and Indonesia is not too far behind. As a consequence of its comparatively low vaccination rates, India has the largest number of Diphtheria and polio cases in the world. Surprisingly, China has the largest number of measles cases in the world, probably due to low vaccination rates in the past.

Vaccination coverage as such may not have significant financial impact for companies in the region. But in affected countries, like India, several private companies are taking a lead in organizing vaccination camps as part of their social responsibility programs.

Per capita consumption data shows that the consumption of milk, wheat, meat, beef, seafood, animal fat, vegetable oil and beer has increased dramatically over the past few years. One telling statistic is the increase in number of McDonald’s outlets in Asia Pacific in the last twenty years. In China, for instance, the number of outlets has increased from three in 1987 to 1100 today.

Changes in diets towards higher fat and sugar content are expected to result in higher incidence of diet-related non-communicable diseases (NCDs). NCDs take an enormous toll in lives and account for a number of premature deaths due to heart disease, stroke, cancer, diabetes and lung diseases affecting the most productive age-group of the population. Hence, companies operating in Asia may have to consider insuring the health and well-being of their employees against the increasing incidence of these lifestyle diseases. They can also spread more awareness about balanced diets and about keeping an active lifestyle.

Urbanization is also likely to increase the demand for food safety leading to higher labeling and nutrition information disclosure requirements. Hazard Analysis and Critical Control Point (HACCP), ISOs, traceability systems and private quality labels are becoming entry tickets to international markets and increasingly the reference for quality in the domestic markets of developing countries. In developing countries, the informal sector is often a significant producer, processor, distributor and preparer of food and food products (e.g. street foods). Imposing standards on such food producers would be very difficult to achieve. Companies operating in the region in some part of the food supply chain are very likely to come under increasing regulatory pressure to invest in improving their product quality and traceability and also to improve their labelling and nutrition information disclosure capabilities.
HIV/AIDS, HEPATITIS B AND DIABETES

The AIDS epidemic continues to spread through Asian populations. UNAIDS estimates that 700,000 people were living with HIV in China in 2007. This figure is lower than previously published estimates of 840,000 in 2003. This is not because prevalence is falling, but rather due to better data and improved methods of estimation. However, massive under reporting, especially in the rural areas, means that even the revised figures may be inaccurate.

"Exact figures are difficult to arrive at because government at local levels are very reticent to report on actual cases, a situation compounded by individuals who are reluctant to come forward because of discrimination," said Qi Xiaojun, Director of China's Department of Disease Control. UNAIDS and other organisations had previously estimated that by 2010 there could be a generalised epidemic with between ten and twenty million HIV positive Chinese. Although this is no longer anticipated there is still potential for a severe epidemic in China.

India already has one of the largest HIV infected populations in the world at 2.4 million. Thailand has the highest prevalence rate in the region at 1.4% in its population against 0.3% and 0.5% in India and Malaysia, respectively.102

Hepatitis B is endemic in China and other parts of Asia. Most people in the region become infected with hepatitis B virus (HBV) during childhood. In some regions, 8-10% of the adult population is chronically infected. Liver cancer caused by HBV is among the first three causes of death from cancer in men, and a major cause of cancer in women. In the Middle East and Indian sub-continent, an estimated 2-5% of the general population is chronically infected.104

Presently, India has the largest number of people with diabetes in the world, over 40 million.105 Type 2 makes up 90% of diabetes cases around the world, and is largely the result of excess body weight and physical inactivity. Until recently, this type of diabetes was seen only in adults but it is now also occurring in children. The sharp rise in the prevalence of diabetes is seen mainly in Type 2 diabetes, and the prevalence of Type 1 diabetes is still only 1-2%. This rise is mostly evident in urban areas where rapid economic development has made people adopt a sedentary lifestyle and consume more refined foods leading to greater weight gain. However, rural communities are also experiencing an increase in the numbers of people with diabetes due to the commercialization of villages by market forces.

China overall has a current prevalence rate of 4.2% but the high prevalence among Chinese populations in the more urbanized and affluent cities of Hong Kong and Singapore indicate what may develop as China rapidly urbanizes and expands economically. WHO estimates that in the period 2006-2015, China will lose US$558 billion in foregone national income due to heart disease, stroke and diabetes.106

With the rise in numbers of people affected by these diseases rising in Asia, companies would inevitably end up spending more on healthcare of employees. They would also bear the risk of falling productivity due to lost workdays.

MENTAL HEALTH

Mental health refers to a broad array of activities directly or indirectly related to the mental well-being of the WHO’s definition of health: “a state of complete physical, mental and social well-being, and not merely the absence of disease”. It is related to the promotion of well-being, the prevention of mental disorders, and the treatment and rehabilitation of people affected by mental disorders.

Mental disorders comprise a broad range of problems, with many different symptoms. However, they are generally characterized by some combination of abnormal thoughts, emotions, behaviour and relationships with others. Examples are epilepsy, schizophrenia, depression, mental retardation, autism and disorders due to drug or alcohol abuse. Most of these disorders can be successfully treated with therapies and pharmacologically.

Epilepsy affects about 1% of the population of SE Asia, meaning that there are approximately 15 million people suffering in the region.114 It is estimated that India alone has approximately 8–10 million people suffering from epilepsy.115 Unlike many other disorders, instances of death directly due to epilepsy are few. However, serious injury can occur during a seizure, such as falling into a well while drawing water, falling down a mountain, falling into a fire while cooking, automobile accidents while driving or work accidents. Such accidents during seizures can be fatal. Deaths from epilepsy occur in larger numbers in distant and remote areas as compared to urban areas, probably due to lack of care.

Epilepsy has significant economic implications in terms of health care-needs, premature death and lost work productivity. An Indian study calculated that the total cost per epilepsy case was US$344 per year (or 88% of the average income per capita). The total cost for an estimated five million cases in India was equivalent to 0.5% of gross national product.116

Schizophrenia is a mental disorder interfering with a person’s ability to recognize what is real, manage his or her emotions, think clearly, make judgements and communicate. People with schizophrenia usually suffer strange symptoms, such as hearing imaginary voices, and believing that these voices are controlling their thoughts and actions. They may believe that people are plotting to harm them. They become frightened and withdrawn. Their speech and behaviour become disorganized. Population studies of schizophrenia all over the world have shown a rate of occurrence of 0.1 to 0.4 per 1,000 population. However, it appears that the number of new cases of schizophrenia is largely similar across different regions and cultures.117

The WHO has introduced a new concept of measuring suffering of populations based on time lived with disability which has been described as, Disability-Adjusted Life Year (DALY). According to World Health Report 1999, in 1998, an estimated 39% of all DALYs lost in low and middle-income countries, were attributable to non-communicable diseases, of which, 10% of the disease burden was due to neuropsychiatric conditions. A large proportion of the burden of disease resulting from neuropsychiatric conditions is attributable to unipolar major depression, which was the fourth leading cause of overall disease burden in 1990, while in adults aged 15-44 years, it was the leading cause of DALYs lost worldwide. The disease burden resulting from depression is estimated to be increasing both in developing and developed regions.118

Companies in the region will be forced to work towards eliminating discrimination against people with mental disorders such as depression, as these diseases become more common and accepted.
MATUREITY/
PATERNITY LEAVE

Safe maternity and health care for mother and infant survival is at the core of life itself. It is also central to decent work and productivity of women. For working women — whether it is their active participation in labour markets, the vital unpaid work they conduct at home or various forms of atypical or self-employed work — balancing maternity and family responsibilities with work is at the root of their crucial roles.

The full cost of maternity leave, which is mostly borne wholly by employers, gives rise to discrimination against women workers, with the perception that they ‘cost’ more than men. However, a guarantee for pregnant women and new mothers that they will not lose their job — as a result of being pregnant, absent on maternity leave or because they have just had a child — is essential for preventing maternity from becoming a source of discrimination against women in employment.

Upon return from leave, women should be entitled to return to the same position or an equivalent one. Pregnancy and maternity leave should have no adverse effects on women’s employment or on their entitlements under the employment contract, in particular, those linked to seniority (such as paid annual leave) or to length of service (such as retirement benefits). ILO’s convention on maternity protection convention No. 183 entitles women to one or more remunerated daily breaks, or a reduction of hours of work without loss of pay, for breastfeeding.

Paternity leave provides an important opportunity for fathers to nurture their infants and to support new mothers with the many physical and emotional demands related to childbirth and caring for newborns. Paternity leave provisions are becoming more common and reflect evolving views of fatherhood.

Families may be concerned about sacrificing income when paternity leave is unpaid or poorly paid. Even when paid, some men may decline their leave entitlements if they fear they will not be seen as committed to their work. Prevailing stereotypes of masculinity may also clash with caretaking roles and influence their decisions as well.

In Asia, even in developed societies like Japan, the concept of men taking paternity leave is still evolving. According to Japan’s Labour Ministry report, only 0.4% of men with children aged under one took leave in 2003 at companies with 30 employees or more, compared to 73.1% of women in the same situation. This is despite the fact that Japanese law allows both women and men to take a full year off until their children turn one. Attitudes in other developing countries are even worse.

However, conditions are changing fast and both maternity and paternity leave terms are expected to improve in the region. For instance, in 2004, the cabinet of the Rajasthan government in India unanimously approved paternity leave for state government employees. Government employees in Rajasthan can now take 15 days paternity leave while the maternity leave period has been increased from 120 to 135 days.
This report has highlighted the potential risks to earnings for companies within the pharma and healthcare industry due to environmental, social and governance issues. We have focused on the ten countries in the MSCI AC Asia ex-Japan Index namely China, India, Indonesia, Philippines, Thailand, Malaysia, South Korea, Hong Kong, Taiwan and Singapore with a summary table on frontier markets in Pakistan, Vietnam and Cambodia. The focus sections have revealed the potential risks for the industries in those countries. For instance, the section on generics in India unearthed certain aspects that challenge these companies claims to be contributing tirelessly to improving access to medicines. The section on corporate governance in China showed how the industry is struggling against corruption, complex government relations and how minority shareholders’ rights are not protected comprehensively.

Case studies from the industry in the region and from best practices worldwide highlighted environmental, social and governance risks. Our interviews with several key personalities on the Access to Medicines (ATM) and healthcare debate such as from Oxfam International and Boston Common Asset Management have provided interesting insights to the discussion.

From a bird’s eye view, the healthcare industry in Asia is characterized by stark contrasts between developed countries like Singapore and Hong Kong on the one hand and developing ones like India, China and Indonesia on the other. We found startling differences within countries as well which has made regional comparisons more challenging. The industry in Asia is growing much faster than that in the west promising handsome returns. National insurance coverage is expanding fast in most of the countries improving affordability and governments are spending massively to overhaul their healthcare delivery infrastructure. However, the industry is steeped in ESG and ethical issues giving responsible investors a real opportunity to engage with companies.

The company rankings provide insights into how the largest companies in the region are performing along internationally accepted ESG guidelines. We discovered an extreme range of performance from companies in the region. Dr. Reddy’s led the pharma pack with industry-wide best practices in their GRI compliant reporting standards. Similarly Fortis led the companies in the healthcare rankings universe with their comprehensive policies to expand healthcare coverage and to minimize corrupt practices and damage to the environment. On the other hand, companies such as TTY Biopharma and Shanghai Pharma scored very poorly. It should be noted here that the reason for their poor performance can be either that they do not make efforts to mitigate their environmental, social and governance risks or that they don’t report their efforts as comprehensively as the leaders.

From our case studies, benchmarking analyses and interviews on ATM and access to healthcare (ATH) issues, we found that companies in the region need to include ATM and ATH as part of their core strategies rather than just corporate philanthropy. Pharma companies need to overhaul their IP, pricing and R&D policies to facilitate access for the needy millions. Similarly healthcare providers need to devise business models for maintaining their profitability and expanding into semi-urban and rural areas at the same time. We highlighted the example of Aravind eye hospitals in this direction. We also found examples of Indian generics companies reducing prices for antiretrovirals by 90%. Since healthcare financing in Asia is mostly out-of-pocket and given the significant proportion of population living below the poverty line, improving ATM and ATH is going to remain critical for responsible players.

Governments in the region have succumbed to socio-political pressure by imposing compulsory licensing and pricing caps on drugs. We have highlighted these instances in Philippines and Thailand. With the imposition of ASEAN harmonization process, good manufacturing practices will be implemented and product quality is expected to improve. Companies not complying with these practices face serious risks of penalizing actions by regulatory bodies.
Methodology

We selected 37 of the largest companies from the healthcare space listed in the ten countries covered in the report. These companies were selected based on their market capitalization and care was taken to ensure that all of the ten countries were represented in the rankings. 20 of these companies were from the Pharma space and the remaining from the healthcare provider space. These companies are shown below, listed by US$ market cap.

<table>
<thead>
<tr>
<th>Company</th>
<th>US$ million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biogen</td>
<td>9,794.64</td>
</tr>
<tr>
<td>Sanofi-Aventis</td>
<td>7,915.19</td>
</tr>
<tr>
<td>GSK</td>
<td>6,522.13</td>
</tr>
<tr>
<td>Roche</td>
<td>6,024.91</td>
</tr>
<tr>
<td>Janssen</td>
<td>4,608.66</td>
</tr>
<tr>
<td>Amgen</td>
<td>4,491.80</td>
</tr>
<tr>
<td>Pfizer</td>
<td>4,294.64</td>
</tr>
<tr>
<td>Shanghai Huan</td>
<td>3,435.61</td>
</tr>
<tr>
<td>Hikma Pharma</td>
<td>3,226.81</td>
</tr>
<tr>
<td>Halyard Biotech</td>
<td>2,940.85</td>
</tr>
<tr>
<td>Valeant</td>
<td>1,943.81</td>
</tr>
<tr>
<td>China Biopharmaceuticals</td>
<td>1,977.40</td>
</tr>
<tr>
<td>Kyorin</td>
<td>1,667.64</td>
</tr>
<tr>
<td>Meiji Rohto</td>
<td>1,480.75</td>
</tr>
<tr>
<td>Boehringer</td>
<td>1,357.35</td>
</tr>
<tr>
<td>Tilly Biopharmaceuticals</td>
<td>389.06</td>
</tr>
<tr>
<td>Young Shin Pharm</td>
<td>287.81</td>
</tr>
<tr>
<td>SanoPharma</td>
<td>284.03</td>
</tr>
<tr>
<td>Sequoia Stock</td>
<td>275.81</td>
</tr>
<tr>
<td>Apex Biotech</td>
<td>100.11</td>
</tr>
</tbody>
</table>

We then selected a list of 23 criteria for ranking these companies. These criteria were designed to cover the internationally recommended best environmental, social and governance practices. To short-list these criteria, we took help from GRI recommendations, company best practices and also from the Asian Sustainability Rating®, a Responsible Research product. The final list of these questions appears below.

Environmental Indicators – 9 Questions

1. Is there an environment code/policy with comprehensive coverage of all areas (energy, emissions, water, waste)?
2. Does the company provide GHG emissions data clearly and comprehensively?
3. Does the company disclose their GHG emissions reduction initiatives with targets?
4. Does the company provide energy consumption data clearly and comprehensively?
5. Does the company disclose their energy consumption initiatives with targets?
6. Does the company provide water consumption data clearly and comprehensively?
7. Does the company disclose their water consumption initiatives with targets?
8. Does the company provide waste production/reduction data clearly and comprehensively?
9. Does the company disclose their waste production/reduction initiatives with targets?

Social Indicators – 7 Questions

1. Does the company have an access to healthcare policy with initiatives to cover rural and sub-urban areas with hospitals/ facilities
2. Does the company report on access to healthcare initiatives with targets
3. Does the company have a comprehensive labour policy with coverage on employee health and safety, freedom of association, diversity and non-discrimination?
4. Does the company report on its health and safety accidents and initiatives with targets?
5. Does the company report on its diversity statistics, initiatives with targets?
6. Does the company have a human rights policy with coverage on child and forced labour and service levels?
7. Does the company set out a community investment mission with reporting on initiatives and targets?

Governance Indicators – 7 Questions

1. Is there a corporate governance policy which covers all issues comprehensively (structure and function of the committee, role of the board, accountability, role of the CEO and Chairman)?
2. Are independents represented (over 30%) on the Board and is the board independent (over 50%)?
3. Are the roles of CEO and Chairman separate?
4. Is the experience of board members clearly outlined and is the experience broad-based and appropriate?
5. Is there an independent audit committee? (i.e majority of independent members)
6. Is there an independent remuneration committee? (i.e. majority independent members)
7. Is there an anti-corruption and/or anti-bribery policy with coverage on actions to be taken in case of violations?

On each of these 23 questions, companies were marked either 0, 1 or 2 depending upon whether there is any disclosure at all, incomplete disclosure or a comprehensive policy and disclosure of initiatives, data and targets. Totals were calculated for every company to arrive at that company’s overall score. It should be noted that the information collected on every company is from public sources such as company’s websites, annual reports, sustainability reports, analyst reports and listing documents.
## Healthcare Sector Rankings

<table>
<thead>
<tr>
<th>Short Name</th>
<th>Company</th>
<th>Country</th>
<th>Market Cap in US$M (April 2010)</th>
<th>Environmental</th>
<th>Social</th>
<th>Governance</th>
<th>Total</th>
<th>Rank</th>
<th>Sustainability Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fords</td>
<td>FORRIS HEALTHCARE</td>
<td>IN</td>
<td>1.23</td>
<td>4</td>
<td>7</td>
<td>14</td>
<td>25</td>
<td>1</td>
<td>Leader</td>
</tr>
<tr>
<td>China National</td>
<td>CHINA NATIONAL-A</td>
<td>CH</td>
<td>1.86</td>
<td>5</td>
<td>3</td>
<td>12</td>
<td>20</td>
<td>2</td>
<td>Leader</td>
</tr>
<tr>
<td>Apollo</td>
<td>APOLLO HOSPITALS</td>
<td>IN</td>
<td>1.01</td>
<td>1</td>
<td>6</td>
<td>13</td>
<td>20</td>
<td>2</td>
<td>Leader</td>
</tr>
<tr>
<td>Mindray Medi</td>
<td>MINDRAY MED-ADR</td>
<td>US</td>
<td>4.02</td>
<td>1</td>
<td>4</td>
<td>12</td>
<td>17</td>
<td>4</td>
<td>Leader</td>
</tr>
<tr>
<td>Burnungrad</td>
<td>BURNUNGRAD HOSPITAL</td>
<td>TB</td>
<td>0.69</td>
<td>1</td>
<td>5</td>
<td>11</td>
<td>17</td>
<td>4</td>
<td>Leader</td>
</tr>
<tr>
<td>Top Glove</td>
<td>TOP GLOVE CORP B</td>
<td>MK</td>
<td>1.30</td>
<td>1</td>
<td>3</td>
<td>12</td>
<td>15</td>
<td>6</td>
<td>Follower</td>
</tr>
<tr>
<td>Shenz Accord</td>
<td>SHENZ ACCORD-B</td>
<td>CH</td>
<td>1.22</td>
<td>3</td>
<td>3</td>
<td>10</td>
<td>15</td>
<td>6</td>
<td>Follower</td>
</tr>
<tr>
<td>China Cord</td>
<td>CHINA CORD BLOOD</td>
<td>US</td>
<td>0.40</td>
<td>0</td>
<td>2</td>
<td>12</td>
<td>14</td>
<td>8</td>
<td>Follower</td>
</tr>
<tr>
<td>Bangkok Dust</td>
<td>BANGKOK DUST MD</td>
<td>TB</td>
<td>0.97</td>
<td>0</td>
<td>3</td>
<td>10</td>
<td>13</td>
<td>9</td>
<td>Follower</td>
</tr>
<tr>
<td>Biosensors</td>
<td>BIOSENSORS INTL</td>
<td>SP</td>
<td>0.61</td>
<td>0</td>
<td>1</td>
<td>12</td>
<td>13</td>
<td>9</td>
<td>Follower</td>
</tr>
<tr>
<td>Shandong Weigh</td>
<td>SHANDONG WEIG-H</td>
<td>HK</td>
<td>4.40</td>
<td>0</td>
<td>1</td>
<td>11</td>
<td>12</td>
<td>11</td>
<td>Laggard</td>
</tr>
<tr>
<td>Parkway</td>
<td>PARKWAY HDGS</td>
<td>SP</td>
<td>2.67</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>12</td>
<td>11</td>
<td>Laggard</td>
</tr>
<tr>
<td>Standard Diagnostics</td>
<td>STANDARD DIAGNOS</td>
<td>KS</td>
<td>0.28</td>
<td>0</td>
<td>1</td>
<td>11</td>
<td>12</td>
<td>11</td>
<td>Laggard</td>
</tr>
<tr>
<td>Shang Pharm</td>
<td>SHANG PHARM-A</td>
<td>CH</td>
<td>4.92</td>
<td>0</td>
<td>0</td>
<td>11</td>
<td>11</td>
<td>14</td>
<td>Laggard</td>
</tr>
<tr>
<td>Raffles</td>
<td>RAFFLES MEDICAL</td>
<td>SP</td>
<td>0.65</td>
<td>0</td>
<td>1</td>
<td>10</td>
<td>11</td>
<td>14</td>
<td>Laggard</td>
</tr>
<tr>
<td>Shandong Pharma</td>
<td>SHANDONG PHAR A</td>
<td>CH</td>
<td>0.70</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>Laggard</td>
</tr>
<tr>
<td>Huadong</td>
<td>HUADONG MEDIC-A</td>
<td>CH</td>
<td>1.56</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>8</td>
<td>17</td>
<td>Laggard</td>
</tr>
</tbody>
</table>
TERMS AND CONDITIONS
AND DISCLAIMER

This publication/communication is subject to the following terms and conditions of use. The information provided herein should not be viewed as an offering or solicitation to sell. None of the information contained herein has been approved in any jurisdiction.

Responsible Research Pte Ltd has produced this publication/communication for private circulation to professional clients only. It is not directed to, or intended for distribution to or use by, any person or entity who is a citizen or resident of or located in any jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would subject Responsible Research or its affiliates to any registration or licensing requirement within such jurisdiction.

The content found in this publication/communication is proprietary to Responsible Research Pte Ltd and is provided solely for your personal and non-commercial use. You agree that you will not use this publication/communication for any purpose that is unlawful and that you will not reproduce the publication/communication or redistribute it outside your organisation, or place it on a website for public access without the express written permission of Responsible Research Pte Ltd. Responsible Research Pte Ltd owns the copyright of all original contents of this publication/communication and has endeavoured to credit sources wherever possible.

All information and statistical data herein have been obtained from sources we believe to be reliable. Such information has not been independently verified and we make no representation or warranty as to its accuracy, completeness or correctness. Any opinions or estimates herein reflect the judgment of Responsible Research Pte Ltd at the date of this publication/communication and are subject to change at any time without notice. The material and information contained in this publication/communication has been produced and collated by Responsible Research Pte Ltd with the benefit of information currently available to it. All reasonable efforts have been made to ensure the accuracy of the contents of the pages of the publication/communication at the time of preparation.

The material is for general information only and nothing in it constitutes professional advice, or any binding commitment upon Responsible Research Pte Ltd. Notwithstanding the efforts made by Responsible Research Pte Ltd to ensure the accuracy of the content, Responsible Research Pte Ltd disclaims any responsibility or liability in respect to the content, and Responsible Research Pte Ltd does not warrant or guarantee the adequacy, accuracy or completeness of any information herein or that such information has been delivered in a timely or complete form. Responsible Research Pte Ltd makes no representation or warranty, whether express or implied, of any kind with respect to the publication/communication and its contents, information and materials.

The information in this publication/communication is provided “as is”. Responsible Research Pte Ltd disclaims all warranties express or implied, and any liability for losses or damages that may be directly or indirectly sustained by anyone who obtains access to the material contained in the publication/communication.

This is not a solicitation or any offer to buy or sell. This publication/communication is for information purposes only and is not intended to provide professional, investment or any other type of advice or recommendation and does not take into account the particular investment objectives, financial situation or needs of individual recipients. Before acting on any information in this publication/communication, you should consider whether it is suitable for your particular circumstances and, if appropriate, seek professional advice, including tax advice. Responsible Research Pte Ltd does not accept any responsibility and cannot be held liable for any person’s use of or reliance on the information and opinions contained herein.

To the extent permitted by applicable securities laws and regulations, Responsible Research Pte Ltd accepts no liability whatsoever for any direct or consequential loss arising from the use of this publication/communication or its contents.

By accessing the information contained in this publication/communication you agree that this exclusion of liability is comprehensive and applies to all damages of any kind including without limitation direct, indirect, compensatory, special, multiple, incidental, punitive and consequential.

Past performance is not necessarily indicative of future performance of any company’s performance on Environment, Social and Governance criteria.
Responsible Research is an independent provider of sectoral and thematic Asian environment, social and governance (ESG) research, for global institutional investors.